IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BIAL - PORTELA & CA S.A., BIAL - HOLDING, S.A., and SUNOVION PHARMACEUTICALS INC.,	)	
Plaintiffs,	)	C.A. No. _____
v.	)	
AUROBINDO PHARMA LTD. and AUROBINDO PHARMA USA, INC.	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs BIAL - PORTELA & CA S.A., BIAL - HOLDING, S.A., and Sunovion Pharmaceuticals Inc. (collectively, "Plaintiffs"), by their attorneys, for their Complaint against Defendants Aurobindo Pharma Ltd. and Aurobindo Pharma USA, Inc. (collectively, "Aurobindo"), allege as follows:

THE PARTIES

1. BIAL - PORTELA & CA S.A. is a Portuguese corporation having its principal place of business at Avenida da Siderurgia Nacional, Coronado (São Romão and São Mamede), 4745 455 Trofa, Portugal.

2. BIAL - HOLDING, S.A. is a Portuguese corporation having its principal place of business at Avenida da Siderurgia Nacional, Coronado (São Romão and São Mamede), 4745 365 Trofa, Portugal.

3. BIAL - PORTELA & CA S.A. and BIAL - HOLDING, S.A. (collectively, "Bial") are in the business of developing innovative therapies for epilepsy, partial-onset seizures, and other related neurological conditions. Bial's asserted patent(s) cover APTIOM®, which is marketed and

sold in this judicial district and throughout the United States by Sunovion Pharmaceuticals Inc. for treating partial-onset seizures in patients 4 years of age and older.

4. Sunovion Pharmaceuticals Inc. ("Sunovion") is a corporation operating and existing under the laws of the State of Delaware, with its principal place of business at 84 Waterford Drive, Marlborough, Massachusetts 01752.

5. On information and belief, Aurobindo Pharma Limited is a corporation organized and existing under the laws of India, with its principal place of business at Galaxy, Floors: 22-24, Plot No. 1, Survey No. 83/1, Hyderabad Knowledge City, Raidurg Panmaktha, Ranga Reddy District, Hyderabad - 500032, Telangana, India.

6. On information and belief, Aurobindo Pharma Limited 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.

7. On information and belief, Aurobindo Pharma USA, Inc. is a corporation organized and existing under the laws of Delaware, with its principal place of business at 279 Princeton-Hightstown Road, East Windsor, New Jersey 08520.

8. On information and belief, Aurobindo Pharma USA, Inc. is a wholly owned subsidiary of Aurobindo Pharma Limited.

9. On information and belief, Aurobindo Pharma USA, 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, in concert with Aurobindo Pharma Limited.

10. On information and belief, the acts of Aurobindo Pharma Limited complained of herein were done with the cooperation, participation, and assistance of Aurobindo Pharma USA, Inc.

11. On information and belief, and consistent with their practice with respect to other generic products, following FDA approval of Eslicarbazepine Acetate Tablets 200, 400, 600, and 800 mg Abbreviated New Drug Application ("ANDA") No. 216481, Aurobindo Pharma Limited and Aurobindo Pharma USA, Inc. will act in concert to distribute and sell the generic product described in Eslicarbazepine Acetate Tablets 200, 400, 600, and 800 mg ANDA No. 216481 ("Aurobindo's Generic Product") throughout the United States, including the State of Delaware.

NATURE OF THE ACTION

12. This is a civil action for patent infringement of U.S. Patent No. 11,364,247 ("the '247 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 ANDA No. 216481, which Aurobindo filed or caused to be filed under 21 U.S.C. § 355(j) with the United States Food and Drug Administration ("FDA"), for approval to market in the United States a generic copy of Plaintiffs' APTIOM® product prior to the expiration of the patent-in-suit.

13. Aurobindo has infringed one or more claims of the '247 patent under 35 U.S.C. § 271(e)(2)(A) by virtue of its filing of ANDA No. 216481 seeking FDA approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Aurobindo's Generic Product prior to the expiration of the '247 patent, or any extensions thereof. Aurobindo will infringe one or more claims of the '247 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 Aurobindo's Generic Product prior to the expiration of the '247 patent, or any extensions thereof.

14. Plaintiffs previously filed a separate action in this Court against Aurobindo for patent infringement, which included counts for infringement of U.S. Patent Nos. 8,372,431 ("the '431 patent"), 9,206,135 ("the '135 patent"), 9,566,244 ("the '244 patent"), 9,643,929 ("the '929 patent"), 9,750,747 ("the '747 patent), 9,763,954 ("the '954 patent"), 10,675,287 ("the '287 patent"), 10,695,354 ("the '354 patent"), 10,702,536 ("the '536 patent"), and 10,912,781 ("the '781 patent"). *BIAL - PORTELA & CA S.A., et al. v. Aurobindo Pharma Ltd., et al.*, C.A. No. 21-1682-CFC (the "First Suit") was filed on November 29, 2021. The First Suit was filed in response to a letter from Aurobindo dated October 20, 2021 ("Aurobindo's First Notice Letter"), purporting to be a "Notice of Paragraph IV Certification" for ANDA No. 216481 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 '431 patent, the '135 patent, the '244 patent, the '929 patent, the '747 patent, the '954 patent, the '287 patent, the '354 patent, the '536 patent, and the '781 patent. The First Suit included counts for infringement of the '431 patent, the '135 patent, the '244 patent, the '929 patent, the '747 patent, the '954 patent, the '287 patent, the '354 patent, the '536 patent, and the '781 patent.

15. Based on information and belief, Aurobindo is maintaining its certification as to the '431 patent, the '135 patent, the '244 patent, the '929 patent, the '747 patent, the '954 patent, the '287 patent, the '354 patent, the '536 patent, and the '781 patent set out in Aurobindo's First Notice Letter. Thus, Plaintiffs will continue to prosecute all infringement counts presented in the First Suit.

JURISDICTION AND VENUE

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

17. This is a civil action for patent infringement and declaratory judgment arising under the patent laws of the United States, 35 U.S.C. § 1, *et seq.*, including 35 U.S.C. § 271, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

18. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

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

20. This Court has personal jurisdiction over Aurobindo Pharma Limited, *inter alia*, under Federal Rule of Civil Procedure 4(k)(2), because Aurobindo Pharma Limited is organized under the laws of India.

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

22. Upon information and belief, Aurobindo Pharma USA, Inc. maintains continuous and systematic contacts with Delaware through its authorized U.S. agent, Corporation Service Company, located at 251 Little Falls Dr., Wilmington, DE 19808.

23. This Court also has personal jurisdiction over Aurobindo because at least one provision of the Delaware long-arm statute, 10 Del. C. § 3104(c), is satisfied. On information and belief, Aurobindo 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").

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

25. Upon information and belief, the effort to seek approval for ANDA No. 216481 and to manufacture, import, market, and/or sell Aurobindo's Generic Product upon approval has been a cooperative and joint enterprise and venture between Aurobindo Pharma Limited and Aurobindo Pharma USA, Inc.

26. Upon information and belief, Aurobindo Pharma Limited and Aurobindo Pharma USA, Inc. have an express and/or implied agreement to cooperate in the joint enterprise and venture of preparing, filing, and maintaining ANDA No. 216481 and in commercializing Aurobindo's Generic Product in the United States, including in this judicial district, in accordance with ANDA No. 216481 upon approval.

27. Upon information and belief, Aurobindo Pharma Limited and Aurobindo Pharma USA, Inc. have thus been, and continue to be, joint and prime actors in the drafting, submission, approval, and maintenance of ANDA No. 216481.

28. This Court has personal jurisdiction over Aurobindo by virtue of the fact that, *inter alia*, Aurobindo 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.

29. On information and belief, and consistent with their practice with respect to other generic products, following FDA approval of ANDA No. 216481, Aurobindo will market, distribute, and sell Aurobindo's Generic Product described in ANDA No. 216481 throughout the United States, including in Delaware.

30. This Court also has personal jurisdiction over Aurobindo Pharma USA, Inc. because, *inter alia*, Aurobindo Pharma USA, Inc. has purposefully availed itself of the rights and benefits of Delaware law by engaging in systematic and continuous contacts with Delaware. Upon information and belief, Aurobindo, either directly or through affiliates, currently sells significant quantities of generic drug products in the United States and in the State of Delaware. Aurobindo Pharma USA, Inc.'s website states that their mission is to "add value through superior customer service in the distribution of a broad line of generic pharmaceuticals . . . ." (https://www.aurobindousa.com/company/our-story/, accessed on Sept. 26, 2022). Aurobindo Pharma Limited's 2021-2022 annual report states that the company has "filed 727 Abbreviated New Drug Applications (ANDAs) on a cumulative basis," of which "505 have received final approvals and 33 received tentative approvals." (https://www.aurobindo.com/wp-content/uploads/2022/07/Aurobindo-Pharma-AR-2021-22-4.pdf, at 66, last accessed on Sept. 26, 2022). Aurobindo claims the United States as one of their "key geographies" and the largest market for the company and reports to be the "[l]argest generics company in the US (by Rx dispensed)." (*Id.* at 1, 66, 67, 95). On information and belief, Aurobindo 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.

31. This Court also has personal jurisdiction over Aurobindo because, *inter alia*, it has availed itself of this forum previously for the purpose of litigating a patent dispute. For example,

Aurobindo has previously invoked this Court's jurisdiction by asserting counterclaims in at least 19 other cases. *See, e.g.*, C.A. Nos. 21-cv-1330, 21-cv-843, 21-cv-662, 21-cv-624, 21-cv-003, 20-cv-1589, 20-cv-1528, 20-cv-1426, 20-cv-1099, 20-cv-987, 20-cv-985, 20-cv-949, 20-cv-632, 19-cv-2317, 19-cv-2197, 19-cv-2113, 19-cv-1979, 19-cv-471, and 19-cv-103.

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

FACTUAL BACKGROUND

The NDA

33. Sunovion is the holder of New Drug Application ("NDA") No. 022416 for APTIOM® (eslicarbazepine acetate) Tablets in 200, 400, 600, and 800 mg dosage forms.

34. The FDA approved NDA No. 022416 on November 8, 2013, for use as adjunctive therapy of partial-onset seizures.

35. The FDA approved NDA No. 022416 on August 27, 2015, for use as monotherapy of partial-onset seizures.

36. The FDA approved NDA No. 022416 on September 13, 2017, for pediatric patients 4 years of age and older.

37. APTIOM® Tablets are prescription drugs approved for the treatment of partial-onset seizures in patients 4 years of age and older. Eslicarbazepine acetate is the active ingredient in the APTIOM® Tablets.

The Patent-in-Suit

38. The '247 patent, titled "Methods of Treatment of Partial Onset Seizures Using Eslicarbazepine Acetate" was duly and legally issued by the United States Patent and Trademark Office on June 21, 2022. A true and correct copy of the '247 patent is attached as Exhibit A.

39. BIAL - PORTELA & CA S.A. owns the rights to the '247 patent. Sunovion is the exclusive licensee in the United States of the '247 patent. The '247 patent will expire on May 6, 2025.

40. The '247 patent is listed in the FDA Orange Book in connection with NDA No. 022416 for APTIOM® (Eslicarbazepine Acetate) Tablets.

41. The prescribing information for APTIOM®, instructs physicians to administer APTIOM® Tablets once-daily for the treatment of partial-onset seizures in patients 4 years of age and older.

42. Thus, the once-daily use of APTIOM® (Eslicarbazepine Acetate) Tablets and any generic eslicarbazepine acetate tablets for the treatment of patients with partial-onset seizures is covered by the '247 patent, and Plaintiffs have the right to enforce the '247 patent.

The ANDA

43. On information and belief, Aurobindo filed ANDA No. 216481 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 (eslicarbazepine acetate) Tablets in 200, 400, 600, and 800 mg dosage forms, which are generic versions of Plaintiffs' APTIOM® (eslicarbazepine acetate) Tablets in 200, 400, 600, and 800 mg dosage forms.

44. ANDA No. 216481 contains a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), alleging that the claims of the '247 patent are invalid, unenforceable, and/or would not be infringed by Aurobindo's Generic Product.

45. Sunovion and Bial received a letter sent by Aurobindo, dated August 17, 2022, purporting to be a "Notification of Paragraph IV Certification" for ANDA No. 216481 ("Aurobindo'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. Aurobindo's Second Notice Letter notified Bial that Aurobindo had filed ANDA No. 216481, seeking approval to market Aurobindo's Generic Product prior to the expiration of the '247 patent.

46. Plaintiffs commenced this action within 45 days of receiving Aurobindo's Second Notice Letter.

47. On information and belief, following FDA approval of Aurobindo's ANDA No. 216481, Aurobindo will make, use, sell, or offer to sell Aurobindo's Generic Product throughout the United States, or import such generic products into the United States before the '247 patent expires.

INFRINGEMENT OF THE '247 PATENT UNDER 35 U.S.C. § 271(e)(2)

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

49. On information and belief, Aurobindo filed ANDA No. 216481 in order to obtain approval to manufacture, use, import, offer to sell, and/or sell Aurobindo's Generic Product in the United States before the expiration of the '247 patent.

50. On information and belief, Aurobindo 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 '247 patent are purportedly invalid, unenforceable, and/or not infringed.

51. On information and belief, in its ANDA No. 216481, Aurobindo has represented to the FDA that Aurobindo's Generic Product is pharmaceutically and therapeutically equivalent to Plaintiffs' APTIOM® tablets.

52. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 216481 seeking approval for the commercial manufacture, use, or sale of Aurobindo's Generic Product

before the expiration date of the '247 patent, constitutes infringement, either literally or under the doctrine of equivalents.

53. After FDA approval of ANDA No. 216481, Aurobindo will infringe one or more claims of the '247 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Aurobindo'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 ANDA No. 216481 shall be no earlier than the expiration of the '247 patent and any additional periods of exclusivity.

54. On information and belief, Aurobindo knows, or should know, and intends that physicians will prescribe and patients will take Aurobindo's Generic Product for which approval is sought in ANDA No. 216481, and therefore will infringe at least one claim in the '247 patent.

55. On information and belief, Aurobindo had knowledge of the '247 patent and, by its promotional activities and proposed package insert for Aurobindo's Generic Product, knows or should know that it will induce direct infringement of at least one of the claims of the '247 patent, either literally or under the doctrine of equivalents.

56. On information and belief, Aurobindo 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 Aurobindo's Generic Product according to the instructions in the proposed package insert in a way that directly infringes the '247 patent.

57. The offering to sell, sale, making, and/or importation of Aurobindo's Generic Product would actively induce infringement of at least one of the claims of the '247 patent, either

literally or under the doctrine of equivalents. Aurobindo has knowledge and is aware of Plaintiffs' '247 patent, as evidenced by Aurobindo's Second Notice Letter.

58. On information and belief, if ANDA No. 216481 is approved, Aurobindo intends to and will offer to sell, sell, and/or import in the United States Aurobindo's Generic Product.

59. Aurobindo has had and continues to have knowledge that Aurobindo's Generic Product is especially adapted for a use that infringes the '247 patent.

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

61. On information and belief, Aurobindo's actions relating to Aurobindo's ANDA No. 216481 complained of herein were done by and for the benefit of Aurobindo.

62. Plaintiffs will be irreparably harmed if Aurobindo is not enjoined from infringing or actively inducing infringement of at least one claim of the '247 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:

A. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Aurobindo has infringed at least one claim of the patent-in-suit through Aurobindo's submission of ANDA No. 216481 to the FDA to obtain approval to manufacture, use, import, offer to sell, and/or sell Aurobindo's Generic Product in the United States before the expiration of the patent-in-suit;

B. The entry of judgment under 35 U.S.C. § 271(a), (b), and/or (c) that Aurobindo's making, using, offering to sell, selling, or importing Aurobindo's Generic Product prior to the

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

C. The issuance of an order that the effective date of any FDA approval of Aurobindo's Generic Product shall be no earlier than the expiration date of the patent-in-suit and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(A);

D. The entry of a preliminary and/or permanent injunction, enjoining Aurobindo and all persons acting in concert with Aurobindo from commercially manufacturing, using, offering for sale, or selling Aurobindo's Generic Product within the United States, or importing Aurobindo's Generic Product into the United States, until the expiration of the patent-in-suit, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

E. The entry of a preliminary and/or permanent injunction, enjoining Aurobindo and all persons acting in concert with Aurobindo from seeking, obtaining, or maintaining approval of the ANDA until the expiration of the patent-in-suit, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

F. 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);

G. An award to Plaintiffs of any further appropriate relief under 35 U.S.C. § 271(e)(4); and

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

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