

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.)
TORRENT PHARMACEUTICALS LTD. and)
TORRENT PHARMA 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 Torrent Pharmaceuticals Ltd. ("Torrent Pharmaceuticals") and Torrent Pharma Inc. ("Torrent Pharma") (collectively, "Torrent"), 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 e 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 e 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, Torrent Pharmaceuticals is a corporation organized and existing under the laws of India, with its principal place of business at Torrent House, Off Ashram Road, Navarangpura, Ahmedabad 380009, Gujarat India.

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

7. On information and belief, Torrent Pharma is a corporation organized and existing under the laws of Delaware, with its principal place of business at 150 Allen Road, Suite 102, Basking Ridge, New Jersey 07920-3856.

8. On information and belief, Torrent Pharma is a subsidiary of Torrent Pharmaceuticals.

9. On information and belief, Torrent Pharma 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 Torrent Pharmaceuticals.

10. On information and belief, the acts of Torrent Pharmaceuticals complained of herein were done with the cooperation, participation, and assistance of Torrent Pharma.

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. 211227, Torrent will act in concert to distribute and sell the generic product described in Eslicarbazepine Acetate Tablets 200, 400, 600, and 800 mg ANDA No. 211227 (“Torrent’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. 9,750,747 (“the ’747 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. 211227, which Torrent 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. Plaintiffs filed a separate action in this Court against Torrent for patent infringement, which included counts for infringement of the ’747 patent and 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”), and 9,763,954 (“the ’954 patent), in *Bial - Portela & CA S.A. v. Torrent Pharmaceuticals Ltd.*, No. 1:18-cv-00279-CFC (D. Del. filed February 16, 2018) (“the First Suit”). The First Suit was filed in response to a first letter from Torrent dated January 2, 2018, and a second letter from Torrent dated January 8, 2018 (collectively, “the First Notice Letters”), each purporting to be a “Patent Certification Notice” for ANDA No. 211227 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 ’747 patent, the ’431 patent, the ’135 patent, the ’244 patent, the ’929 patent, the ’954 patent. In addition to the count for infringement of the ’747 patent, the First Suit included counts for

infringement of the '431 patent, the '135 patent, the '244 patent, the '929 patent, and the '954 patent.

14. This complaint is filed in response to a third letter from Torrent dated July 26, 2019 ("the Recertification Notice Letter"), which Sunovion and Bial received on July 29, 2019, purporting to be a "Patent Recertification Notice" for ANDA No. 211227 pursuant to § 505(j)(2)(B)(i)-(iv) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. §§ 314.95 & 314.96(d) as to only the '747 patent.

15. This complaint does not include counts for infringement of the '431 patent, the '135 patent, the '244 patent, the '929 patent, and the '954 patent because the Recertification Notice Letter did not mention those patents. But based on information and belief, Torrent is maintaining its certification as to the '431 patent, the '135 patent, the '244 patent, the '929 patent, and the '954 patent, as well as to the '747 patent, set out in the First Notice Letters. Thus, Plaintiffs will continue to prosecute all infringement counts presented in the First Suit. Further, Plaintiffs will seek to consolidate this new action with 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 Torrent Pharma is incorporated in the State of Delaware, and Torrent Pharmaceuticals 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 Torrent Pharmaceuticals *inter alia*, under Federal Rule of Civil Procedure 4(k)(2), because Torrent Pharmaceuticals is organized under the laws of India.

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

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

23. This Court also has personal jurisdiction over Torrent because at least one provision of the Delaware long-arm statute, 10 Del. C. § 3104(c), is satisfied. On information and belief, Torrent 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 Torrent because, *inter alia*, this action arises from activities of Torrent directed toward Delaware.

25. Upon information and belief, the effort to seek approval for ANDA No. 211227 and to manufacture, import, market, and/or sell Torrent's generic products upon approval has been a cooperative and joint enterprise and venture between Torrent Pharmaceuticals and Torrent Pharma.

26. Upon information and belief, Torrent Pharmaceuticals and Torrent Pharma have an express and/or implied agreement to cooperate in the joint enterprise and venture of

preparing, filing and maintaining ANDA No. 211227 and in commercializing Torrent's generic products in the United States, including in this judicial district, in accordance with ANDA 211227 upon approval.

27. Upon information and belief, Torrent Pharmaceuticals and Torrent Pharma have thus been, and continue to be, joint and prime actors in the drafting, submission, approval and maintenance of ANDA No. 211227.

28. This Court has personal jurisdiction over Torrent by virtue of the fact that, *inter alia*, it 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. 211227, Torrent will market, distribute, and sell Torrent's Generic Product described in ANDA No. 211227 throughout the United States, including in Delaware.

30. This Court also has personal jurisdiction over Torrent Pharma because, *inter alia*, Torrent Pharma 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, Torrent Pharma, either directly or through affiliates, currently sells significant quantities of generic drug products in the United States and in the State of Delaware. Torrent's website, http://www.torrentpharma.com/int_usa.php (accessed January 5, 2018), the contents of which are incorporated herein by reference, states that “[t]he world's largest market for pharmaceuticals, USA, has always been on Torrent Pharma's strategic radar” and provides its goal of “serv[ing] the large and growing need for cost-effective high quality medicines in the USA.” On information and belief, Torrent Pharma 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 Torrent because, *inter alia*, it has

availed itself of this forum previously for the purpose of litigating a patent dispute. For example, Torrent has previously invoked this Court's jurisdiction by asserting counterclaims in the First Suit and at least 9 other cases. *See, e.g.*, 1-07-cv-00332, 1-07-cv-00572, 1-09-cv-00019 1-12-cv-00305, 1-15-cv-00902, 1-17-cv-00112, 1-17-cv-00381, 1-17-cv-00854, and 1-17-cv-01163.

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

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 '747 patent, entitled "Treatments involving eslicarbazepine acetate or eslicarbazepine" was duly and legally issued by the United States Patent and Trademark Office on September 5, 2017. A true and correct copy of the '747 patent is attached as Exhibit A.

39. BIAL - PORTELA & CA. S.A. owns the rights to the '747 patent. Sunovion is the exclusive licensee in the United States of the '747 patent. The '747 patent will expire on August 24, 2032.

40. The '747 patent is listed in the FDA Orange Book in connection with NDA No. 022416 for APTIOM® (Eslicarbazepine Acetate) Tablets.

The ANDA

41. On information and belief, Torrent filed ANDA No. 211227 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 (“Torrent’s Generic Product”), which are generic versions of Bial’s Aptiom® (eslicarbazepine acetate) Tablets in 200, 400, 600, and 800 mg dosage forms.

42. ANDA No. 211227 contains certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (“paragraph IV certifications”), alleging that the claims of the patent-in-suit are invalid, unenforceable, and/or would not be infringed by Torrent’s Generic Product.

43. Plaintiffs commenced this action within 45 days of receiving Torrent’s July 26, 2019 Recertification Notice Letter.

COUNT I

(INFRINGEMENT OF THE '747 PATENT UNDER 35 U.S.C. § 271(e)(2))

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

45. On information and belief, Torrent filed ANDA No. 211227 in order to obtain approval to manufacture, use, import, offer to sell and/or sell Torrent’s Generic Product in the United States before the expiration of the '747 patent.

46. On information and belief, Torrent 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 '747 patent are purportedly invalid, unenforceable, and/or not infringed.

47. On information and belief, in its ANDA No. 211227, Torrent has represented to the FDA that Torrent's Generic Product is pharmaceutically and therapeutically equivalent to Plaintiffs' APTIOM® tablets.

48. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 211227 seeking approval for the commercial manufacture, use, or sale of Torrent's Generic Product before the expiration date of the '747 patent, constitutes infringement, either literally or under the doctrine of equivalents.

49. Upon FDA approval of ANDA No. 211227, Torrent will infringe one or more claims of the '747 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Torrent'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. 211227 shall be no earlier than the expiration of the '747 patent and any additional periods of exclusivity.

50. On information and belief, Torrent knows, or should know, and intends that physicians will prescribe and patients will take Torrent's Generic Product for which approval is sought in ANDA No. 211227, and therefore will infringe at least one claim in the '747 patent.

51. On information and belief, Torrent had knowledge of the '747 patent and, by its promotional activities and proposed package insert for Torrent's Generic Product, knows or

should know that it will induce direct infringement of at least one of the claims of the '747 patent, either literally or under the doctrine of equivalents.

52. On information and belief, Torrent 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 Torrent's Generic Product according to the instructions in the proposed package insert in a way that directly infringes the '747 patent.

53. The offering to sell, sale, making, and/or importation of Torrent's Generic Product would actively induce infringement of at least one of the claims of the '747 patent, either literally or under the doctrine of equivalents. Torrent has knowledge and is aware of Plaintiffs' '747 patent, as evidenced by Torrent's First Notice Letters and Recertification Notice Letter.

54. On information and belief, if ANDA No. 211227 is approved, Torrent intends to and will offer to sell, sell, and/or import in the United States Torrent's Generic Product.

55. Torrent has had and continues to have knowledge that Torrent's Generic Product is especially adapted for a use that infringes the '747 patent.

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

57. On information and belief, Torrent's actions relating to Torrent's ANDA No. 211227 complained of herein were done by and for the benefit of Torrent.

58. Plaintiffs will be irreparably harmed if Torrent is not enjoined from infringing or actively inducing infringement of at least one claim of the '747 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 Torrent has infringed at least one claim of the patent-in-suit through Torrent's submission of ANDA No. 211227 to the FDA to obtain approval to manufacture, use, import, offer to sell, and/or sell Torrent'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 Torrent's making, using, offering to sell, selling or importing Torrent'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 Torrent'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 Torrent and all persons acting in concert with Torrent from commercially manufacturing, using, offering for sale, or selling Torrent's Generic Product within the United States, or importing Torrent'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 Torrent and all persons acting in concert with Torrent 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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