

**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,

v.

TORRENT PHARMACEUTICALS LTD.
and TORRENT PHARMA INC.,

Defendants.

C.A. No. 21-190-CFC

JURY TRIAL DEMANDED

**DEFENDANTS TORRENT PHARMACEUTICALS LTD. AND TORRENT
PHARMA INC.'S ANSWER, AFFIRMATIVE DEFENSES, AND
COUNTERCLAIMS TO PLAINTIFFS' COMPLAINT**

Torrent Pharmaceuticals Ltd. ("Torrent Ltd.") and Torrent Pharma Inc. ("Torrent Inc.") (jointly, "Torrent"), through their undersigned counsel, herein respond to the allegations in the Complaint (C.A. No. 21-190-CFC, D.I. 1) of Bial - Portela & Ca S.A. ("Bial – Portela"), Bial - Holding, S.A. ("Bial – Holding") (together, "Bial"), and Sunovion Pharmaceuticals Inc. ("Sunovion") (collectively, "Plaintiffs"). This response is based on Torrent's current knowledge as to its own activities, and on information and belief as to the activities of others. If not specifically admitted herein, the allegations of the Complaint are denied.

The preamble of the Complaint contains no allegation of fact to which a response is required.

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.

Response: Upon information and belief, admitted.

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.

Response: Upon information and belief, admitted.

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.

Response: Torrent admits that Aptiom® is indicated for the treatment of partial-onset seizures in patients 4 years of age and older. Torrent is without information sufficient to admit or deny the remaining allegations contained in paragraph 3, and therefore denies the allegations.

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.

Response: Upon information and belief, admitted.

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.

Response: Admitted.

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.

Response: Torrent admits that Torrent Ltd. is one of the leading pharmaceutical companies in the world, and a pioneer in initiating the concept of niche marketing. Torrent further admits that Torrent Ltd. ranks amongst the leaders in therapeutic segment of cardiovascular and central nervous system and has achieved significant presence in gastro-intestinal, diabetology, anti-infective, pain management, gynecology, and pediatric segments. Torrent further admits that Torrent Ltd. has recently entered the therapeutic segment of oncology and rheumatology. Torrent denies the remaining allegations in paragraph 6.

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.

Response: Admitted.

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

Response: Admitted.

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.

Response: Torrent admits that Torrent Inc. serves the growing need to make and sell Torrent Ltd.'s products in the U.S. market, including in the State of Delaware. Torrent denies the remaining allegations in paragraph 9.

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

Response: Torrent admits that Torrent Inc. is a wholly-owned U.S. subsidiary of Torrent Ltd. and serves the growing need to make and sell Torrent Ltd.'s products in the U.S. market, including filing ANDA No. 211227 with the FDA. Torrent denies the remaining allegations in paragraph 10.

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 Pharmaceuticals and Torrent Pharma 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.

Response: Torrent admits that it filed ANDA No. 211227 with the FDA seeking regulatory approval to make and sell eslicarbazepine acetate tablets throughout the United States, including Delaware. Torrent is without information sufficient to admit or deny the remaining allegations contained in paragraph 11, and therefore denies the allegations.

NATURE OF THE ACTION

12. This is a civil action for patent infringement of U.S. Patent No. 10,912,781 (“the ’781 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.

Response: Torrent admits that this action purports to arise under the United States Patent Laws, Title 35, United States Code. Torrent further admits that Plaintiffs purport to seek relief from alleged infringement of U.S. Patent No. 10,912,781 (“the ’781 patent” or “the patent-in-suit”). Torrent further admits that, pursuant to 21 U.S.C. § 355(j), it filed or caused to be filed ANDA No. 211227 with the FDA, seeking approval to make and sell the products listed therein. Torrent denies that it has infringed the ’781 patent and denies the remaining allegations in paragraph 12.

13. Torrent has infringed one or more claims of the ’781 patent under 35 U.S.C. § 271(e)(2)(A) by virtue of its filing of ANDA No. 211227 seeking FDA approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Torrent’s Generic Product prior to the expiration of the ’781 patent, or any extensions thereof. Torrent will infringe one or more claims of the ’781 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 Torrent’s Generic Product prior to the expiration of the ’781 patent, or any extensions thereof.

Response: Denied.

14. Plaintiffs previously filed separate actions in this Court against Torrent for patent infringement, which included counts for infringement of U.S. Patent Nos. 9,750,747 (“the ’747 patent”), 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”). *Bial - Portela & CA S.A. v. Torrent Pharmaceuticals Ltd.*, C.A. No. 18-279-CFC (the “First Suit”) was filed on February 16, 2018. *Bial - Portela & CA S.A. v. Torrent Pharmaceuticals Ltd.*, C.A. No. 19-1673-CFC (the “Second Suit”) was filed on September 6, 2019. 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 5, 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, and 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.

Response: Torrent admits that Plaintiffs filed a First Suit alleging infringement of the '747 patent in addition to alleging infringement of U.S. Patents 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"). Torrent further admits that Plaintiff filed a Second Suit on September 6, 2019. Torrent denies that it has infringed the '781 patent, any of the other aforementioned patents that are being asserted in the First Suit and Second Suit, and denies the remaining allegations in paragraph 14.

15. The Second Suit was 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. The Second Suit did 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.

Response: Torrent admits that it sent Plaintiffs a Recertification Notice Letter on or about July 26, 2019 related to ANDA No. 211227. Torrent further admits that the Second Suit did not include counts for infringement of the '431 patent, the '135 patent, the '244 patent, the '929 patent, and the '954 patent. Torrent is without information sufficient to admit or deny the remaining allegations contained in paragraph 15, and therefore denies the allegations.

16. Plaintiff previously filed a third separate action in this Court against Torrent for patent infringement, which included counts for infringement of U.S. Patent Nos. 10,675,287 ("the '287 patent"), 10,695,354 ("the '354 patent"), and 10,702,536 ("the '536 patent"). *Bial – Portela & CA S.A., et al. v. Torrent Pharmaceuticals Ltd., et al.*, C.A. No. 20-781-CFC (the "Third Suit") was filed on June 9, 2020, and an amended complaint was filed on July 7, 2020. Plaintiffs received a letter from Torrent dated August 11, 2020 ("the Once-Daily Patents Notice Letter"), 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 '287 patent, the '354 patent, and the '536 patent. The Third Suit included counts for infringement of the '287 patent, the '354 patent, and the '536 patent.

Response: Torrent admits that Plaintiffs filed a Third Suit alleging infringement of U.S. Patents Nos. 10,675,287 ("the '287 patent"), 10,695,354 ("the '354 patent"), and 10,702,536 ("the '536

patent”). Torrent further admits that it sent Plaintiffs the Once-Daily Patents Notice Letter on or about August 11, 2020 related to ANDA No. 211227. Torrent denies that it has infringed the ’781 patent, any of the other aforementioned patents that are being asserted in the First Suit, Second Suit, and Third Suit, and denies the remaining allegations in paragraph 16.

17. The First Suit, Second Suit, and Third Suit did not include counts for infringement of U.S. Patent No. 5,753,646 (“the ’646 patent”), which will expire on June 27, 2021, because the First Notice Letters, the Recertification Notice Letter, and the Once-Daily Patents Notice Letter (collectively, “Torrent’s Notice Letters”) did not assert noninfringement or invalidity of the ’646 patent. The First Suit and Second Suit have been consolidated for all purposes (D.I. 60 in C.A. No. 18-279-CFC). Based on information and belief, Torrent is maintaining its certification as to the ’431 patent, the ’135 patent, the ’244 patent, the ’929 patent, the ’954 patent, the ’747 patent, the ’287 patent, the ’354 patent, and the ’536 patent set out in Torrent’s Notice Letters. Thus, Plaintiffs will continue to prosecute all infringement counts presented in the First Suit, the Second Suit, and the Third Suit.

Response: Torrent admits that the First Suit, Second Suit, and Third Suit do not include counts for infringement of the ’646 patent. Torrent admits that the First Suit and Second Suit have been consolidated. Torrent admits that it maintains its Paragraph IV certification notice as against the ’431 patent, the ’135 patent, the ’244 patent, the ’929 patent, the ’954 patent, the ’747 patent, the ’287 patent, the ’354 patent, and the ’536 patent. Torrent is without information sufficient to admit or deny the remaining allegations contained in paragraph 17, and therefore denies the allegations.

JURISDICTION AND VENUE

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

Response: Paragraph 18 contains no allegations of fact to which a response is required. If an answer is required, Torrent incorporates its responses to paragraphs 1-17 as if fully set forth herein.

19. 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.

Response: Torrent admits that this action purports to arise 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.

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

Response: Admitted.

21. 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.

Response: Torrent does not contest venue for purposes of this action only. Torrent admits that Torrent Inc. is incorporated in the State of Delaware and that Torrent Ltd. is incorporated in India. All of the remaining allegations in paragraph 21 contain conclusions of law, to which no response is required. To the extent a response is required, Torrent denies the remaining allegations of paragraph 21.

22. 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.

Response: Torrent does not contest personal jurisdiction for purposes of this action only. Torrent admits that Torrent Ltd. is incorporated in India. All of the remaining allegations in paragraph 22 contain conclusions of law, to which no response is required. To the extent a response is required, Torrent denies the remaining allegations of paragraph 22.

23. 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.

Response: Torrent does not contest personal jurisdiction for purposes of this action only. Torrent admits Torrent Inc. is incorporated in the State of Delaware. All of the remaining allegations in paragraph 23 contain conclusions of law, to which no response is required. To the extent a response is required, Torrent denies the remaining allegations of paragraph 23.

24. 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.

Response: Torrent admits that Corporation Service Company, located at 251 Little Falls Drive, Wilmington, DE 19808, is a registered agent of Torrent Inc. All of the remaining allegations in paragraph 24 contain conclusions of law, to which no response is required. To the extent a response is required, Torrent denies the remaining allegations of paragraph 24.

25. 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”).

Response: Torrent does not contest personal jurisdiction for purposes of this action only. All of the allegations in paragraph 25 contain conclusions of law, to which no response is required. To the extent a response is required, Torrent denies the allegations of paragraph 25.

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

Response: Torrent does not contest personal jurisdiction for purposes of this action only. All of the allegations in paragraph 26 contain conclusions of law, to which no response is required. To the extent a response is required, Torrent denies the allegations of paragraph 26.

27. 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.

Response: Torrent admits that Torrent Inc. is a wholly-owned U.S. subsidiary of Torrent Ltd. and serves the growing need to make and sell Torrent Ltd.’s products in the U.S. market,

including filing ANDA No. 211227 with the FDA. Torrent denies all of the remaining allegations of paragraph 27.

28. 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.

Response: Torrent admits that Torrent Inc. is a wholly-owned U.S. subsidiary of Torrent Ltd. and serves the growing need to make and sell Torrent Ltd.'s products in the U.S. market, including filing ANDA No. 211227 with the FDA. Torrent denies all of the remaining allegations of paragraph 28.

29. 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.

Response: Torrent admits that Torrent Inc. is a wholly-owned U.S. subsidiary of Torrent Ltd. and serves the growing need to make and sell Torrent Ltd.'s products in the U.S. market, including filing ANDA No. 211227 with the FDA. Torrent denies all of the remaining allegations of paragraph 29.

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

Response: Torrent does not contest personal jurisdiction for purposes of this action only. Torrent denies all of the allegations of paragraph 30.

31. 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.

Response: Torrent admits that it filed ANDA No. 211227 with the FDA seeking regulatory approval to make and sell eslicarbazepine acetate tablets throughout the United States, including

Delaware. Torrent is without information sufficient to admit or deny the remaining allegations contained in paragraph 31, and therefore denies the allegations.

32. 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/Index.php/site/info/business_usa (accessed February 10, 2021), 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 that Torrent Pharma "serves the growing need of our products in the market and today we are ranked 10th amongst the US generic Indian Companies." 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.

Response: Torrent does not contest personal jurisdiction for purposes of this action only.

Torrent admits that Torrent Inc. sells generic pharmaceutical products in the United States, including in Delaware, and that it derives revenue from such sales. Torrent further admits that its website contains the quoted language from paragraph 32. All of the remaining allegations in paragraph 32 contain conclusions of law, to which no response is required. To the extent a response is required, Torrent denies the remaining allegations of paragraph 32.

33. 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 C.A. Nos. 18-279-CFC, 20-781-CFC, and at least 16 other cases. *See, e.g.*, C.A. Nos. 07-cv-00332, 07-cv-00572, 09-cv-00019, 15-cv-00902, 17-cv-00112, 17-cv-01163, 19-cv-00320, 19-cv-00324, 19-cv-00872, 19-cv-01979.

Response: Torrent does not contest personal jurisdiction for purposes of this action only.

Torrent admits that it previously asserted counterclaims in case C.A. No. 18-279-CFC and in cases C.A. Nos. 20-781, 07-332, 07-572, 09-19, 15-902, 17-112, 17-1163, 19-320, 19-324, 19-872, 19-1979. All of the remaining allegations in paragraph 33 contain conclusions of law, to which no response is required. To the extent a response is required, Torrent denies the remaining allegations of paragraph 33.

34. This Court also has personal jurisdiction over Torrent because Torrent did not contest jurisdiction in the First Suit, the Second Suit, or the Third Suit.

Response: Torrent does not contest personal jurisdiction for purposes of this action only. Torrent admits that it did not contest personal jurisdiction in the First Suit, the Second Suit, or the Third Suit. The allegations in paragraph 34 contain conclusions of law, to which no response is required. To the extent a response is required, Torrent denies the allegations of paragraph 34.

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

Response: Torrent does not contest personal jurisdiction for purposes of this action only. All of the allegations in paragraph 35 contain conclusions of law, to which no response is required. To the extent a response is required, Torrent denies the allegations of paragraph 35.

FACTUAL BACKGROUND

The NDA

36. 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.

Response: Admitted.

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

Response: Torrent admits that in the NDA Approval letter dated November 8, 2013, the FDA stated, “This new drug application provides for the use of Aptiom (eslicarbazepine acetate) 200mg, 400mg, 600mg, and 800mg tablets for adjunctive therapy in the treatment of partial-onset seizures in patients with epilepsy 18 years and older.” Otherwise, the November 8, 2013 NDA Approval letter speaks for itself and Torrent denies any allegations inconsistent therewith.

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

Response: Torrent admits that in the Supplement Approval letter dated August 27, 2015, the FDA stated, “This ‘Prior Approval’ supplemental new drug application provides for the addition of the indication for monotherapy treatment of partial-onset seizures in adults.” Otherwise, the August 27, 2015 Supplement Approval letter speaks for itself and Torrent denies any allegations inconsistent therewith.

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

Response: Torrent admits that in a Supplement Approval letter dated September 13, 2017, the FDA stated, “This Prior Approval supplemental new drug application provides for a change to the indicated patient population for Aptiom used as treatment of partial-onset seizures. Specifically, the indication for Aptiom is being expanded to include pediatric patients 4 years of age and older. In addition, this application provides for a 7 tablet professional sample for the 200 mg strength of Aptiom tablets.” Otherwise, the September 13, 2017 Supplement Approval letter speaks for itself and Torrent denies any allegations inconsistent therewith.

40. 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.

Response: Admitted.

The Patent-in-Suit

41. The ’781 patent, titled “Pharmaceutical Composition Comprising Licarbazepine Acetate,” was duly and legally issued by the United States Patent and Trademark Office on February 9, 2021. A true and correct copy of the ’781 patent is attached as Exhibit A.

Response: Torrent admits that the ’781 patent, titled “Pharmaceutical Composition Comprising Licarbazepine Acetate,” bears on its face an issue date of February 9, 2021. Torrent further admits that a purported true and correct copy of the ’781 patent was attached to the Complaint as

Exhibit A. Torrent is without information sufficient to admit or deny the remaining allegations contained in paragraph 41, and therefore denies the allegations.

42. BIAL - PORTELA & CA S.A. owns the rights to the '781 patent. Sunovion is the exclusive licensee in the United States of the '781 patent. The '781 patent will expire on October 23, 2028.

Response: Torrent admits that the cover page of the '781 patent lists Bial - Portela as an assignee. Torrent is without information sufficient to admit or deny the remaining allegations contained in paragraph 42, and therefore denies the allegations.

43. Information regarding the '781 patent was submitted to the FDA for listing in the Orange Book in connection with NDA No. 022416 for APTIOM® (Eslicarbazepine Acetate) Tablets.

Response: Torrent admits that the '781 patent is listed in the FDA's Orange Book in connection with NDA No. 022416 for Aptiom® (eslicarbazepine acetate) tablets. Torrent is without information sufficient to admit or deny the remaining allegations contained in paragraph 43, and therefore denies the allegations.

44. The '781 patent covers pharmaceutical compositions comprising licarbazepine acetate.

Response: The claims of the '781 patent speak for themselves and Torrent denies any allegations inconsistent therewith. Torrent is without information sufficient to admit or deny the remaining allegations contained in paragraph 44, and therefore denies the allegations.

The ANDA

45. On information and belief, Torrent filed ANDA No. 211227 with the FDA under 21 U.S.C. § 355(j) before January 2, 2018, 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 Plaintiff's APTIOM® (eslicarbazepine acetate) Tablets in 200, 400, 600, and 800 mg dosage forms.

Response: Torrent admits that it 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 further admits that ANDA No. 211227 references listed drug APTIOM® (eslicarbazepine acetate) tablets in 200, 400, 600, and 800 mg dosage forms. Torrent denies the remaining allegations of paragraph 45.

46. Torrent's Notice Letters alleged that the claims of the '747 patent, the '431 patent, the '135 patent, the '244 patent, the '929 patent, the '954 patent, the '287 patent, the '354 patent, and the '536 patent are invalid and/or will not be infringed by the activities described in Torrent's ANDA No. 211227. Torrent's Notice Letters also informed Plaintiffs that Torrent seeks approval to market Torrent's Generic Product before the '747, '431, '135, '244, '929, '954, '287, '354, and '536 patents expire.

Response: Admitted.

47. The '747 patent will expire on August 24, 2032. The '431 patent will expire on April 17, 2030. The '135 and '929 patents expire on April 21, 2026. The '244 patent will expire on October 23, 2028. The '954 patent will expire on September 13, 2028. The '287, '354, and '536 patents will expire on May 6, 2025. The '781 patent will expire on October 23, 2028.

Response: Torrent is without information sufficient to admit or deny the allegations contained in paragraph 47, and therefore denies the allegations

48. Torrent's ANDA No. 211227 has been pending before the FDA since at least January 2, 2018, the date of the first of Torrent's Notice Letters to Plaintiffs.

Response: Admitted.

49. On information and belief, following FDA approval of Torrent's ANDA No. 211227, Torrent will make, use, sell, or offer to sell Torrent's Generic Product throughout the United States, or import such generic products into the United States before the '781 patent expires.

Response: Torrent is without information sufficient to admit or deny the allegations contained in paragraph 49, and therefore denies the allegations.

COUNT I

([ALLEGED] INFRINGEMENT OF THE '781 PATENT UNDER 35 U.S.C. § 271(e)(2))

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

Response: Paragraph 50 contains no allegations of fact to which a response is required. If an answer is required, Torrent incorporates by reference its responses to paragraphs 1-49 as if fully set forth herein.

51. 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 '781 patent.

Response: Torrent admits that it filed ANDA No. 211227 with the FDA seeking regulatory approval to make and sell eslicarbazepine acetate tablets. Torrent denies the remaining allegations in paragraph 51.

52. 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.

Response: Torrent admits that in its ANDA No. 211227, Torrent has represented to the FDA that Torrent's Generic Product is bioequivalent to Plaintiffs' Aptiom® tablets.

53. 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 '781 patent, constitutes infringement, either literally or under the doctrine of equivalents.

Response: All of the allegations in paragraph 53 contain conclusions of law, to which no response is required. To the extent a response is required, Torrent denies the allegations of paragraph 53.

54. After FDA approval of ANDA No. 211227, Torrent will infringe one or more claims of the '781 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 '781 patent and any additional periods of exclusivity.

Response: Denied.

55. 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.

Response: Torrent admits that it filed ANDA No. 211227 with the FDA seeking regulatory approval to make and sell eslicarbazepine acetate tablets. Torrent is without information sufficient to admit or deny the remaining allegations contained in paragraph 55, and therefore denies the allegations.

56. Torrent has had and continues to have knowledge that Torrent's Generic Product is especially adapted for a use that infringes the '781 patent.

Response: Denied.

57. 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.

Response: Torrent is without information sufficient to admit or deny the allegations contained in paragraph 57, and therefore denies the allegations.

58. 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.

Response: Torrent is without information sufficient to admit or deny the allegations contained in paragraph 58, and therefore denies the allegations.

59. Plaintiffs will be irreparably harmed if Torrent is not enjoined from infringing or actively inducing infringement of at least one claim of the '781 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.

Response: Denied.

COUNT II

(DECLARATORY JUDGEMENT OF [APPARENT] INFRINGEMENT OF THE '781 PATENT)

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

Response: Paragraph 60 contains no allegations of fact to which a response is required. If an answer is required, Torrent incorporates by reference its responses to paragraphs 1-59 as if fully set forth herein.

61. This count arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

Response: Admitted.

62. There is an actual and justiciable controversy between Plaintiffs and Torrent concerning infringement of the '781 patent of sufficient immediacy and reality such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

Response: Torrent admits that Plaintiffs are claiming an action for declaratory relief, but deny infringing the '781 patent. The remaining allegations of paragraph 62 are conclusions of law, to which no response is required. To the extent a response is required, Torrent is without information sufficient to admit or deny the remaining allegations contained in paragraph 62, and therefore denies the allegations.

63. Torrent has made, and continues to make, substantial preparation in the United States to manufacture, offer to sell, sell and/or import Torrent's Generic Product prior to expiration of the '781 patent.

Response: Denied.

64. Torrent's actions, including, but not limited to, submitting, or causing to be submitted to the FDA, ANDA No. 211227 seeking approval to manufacture, use, import, offer to sell and sell Torrent's Generic Product before the expiration date of the '781 patent and engaging in litigation, indicate a refusal to change the course of their actions in the face of knowledge of the '781 and acts by Plaintiffs.

Response: Denied.

65. On information and belief, Torrent intends to manufacture, use, import, offer to sell and/or sell Torrent's Generic Product upon FDA approval of ANDA No. 211227.

Response: Torrent admits that it filed ANDA No. 211227 with the FDA seeking regulatory approval to make and sell eslicarbazepine acetate tablets. Torrent is without information sufficient to admit or deny the remaining allegations contained in paragraph 65, and therefore denies the allegations.

66. After FDA approval of ANDA No. 211227, Torrent will infringe one or more claims of the '781 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/or by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c).

Response: Denied.

67. 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.

Response: Torrent admits that it filed ANDA No. 211227 with the FDA seeking regulatory approval to make and sell eslicarbazepine acetate tablets. Torrent is without information sufficient to admit or deny the remaining allegations contained in paragraph 67, and therefore denies the allegations.

68. Torrent has had and continues to have knowledge that Torrent's Generic Product is especially adapted for a use that infringes the '781 patent.

Response: Denied.

69. 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.

Response: Torrent is without information sufficient to admit or deny the allegations contained in paragraph 69, and therefore denies the allegations.

70. 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.

Response: Torrent is without information sufficient to admit or deny the allegations contained in paragraph 70, and therefore denies the allegations.

71. Plaintiffs will be irreparably harmed if Torrent is not enjoined from infringing or actively inducing infringement of at least one claim of the '781 patent.

Response: Denied.

72. Plaintiffs are entitled to a permanent injunction against further infringement. Plaintiffs do not have an adequate remedy at law.

Response: Denied.

73. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale and/or importation of Torrent's Generic Product prior to expiration of the '781 patent by Torrent will constitute direct infringement, contributory infringement and/or active inducement of infringement of the '781 patent.

Response: Denied.

[ANSWER TO] REQUEST FOR RELIEF

Torrent denies that Plaintiffs are entitled to judgment and any relief sought by the Complaint in paragraphs (A) through (I) of its prayer for relief.

AFFIRMATIVE DEFENSES

Torrent, without prejudice to the denials set forth in its Answer above, alleges the following defenses to Plaintiffs' Complaint. Torrent reserves the right to seek leave to assert additional defenses based on the Court's claim construction and as it learns more information through discovery.

**FIRST DEFENSE
(Non-infringement)**

Torrent has not, does not, and will not infringe, contribute[d] to the infringement of, and/or induce[d] the infringement of any valid and enforceable claim of the '781 patent.

**SECOND DEFENSE
(Invalidity)**

Each asserted claim of the '781 patent is invalid for failure to meet the requirements of patentability set forth in 35 U.S.C. §§ 1 *et seq.*, including without limitation §§ 101, 102, 103, and/or 112, and the rules, regulations, and laws pertaining thereto.

THIRD DEFENSE
(Prosecution History Estoppel)

Plaintiffs' claims are barred in whole or in part by the doctrine of prosecution history estoppel. Under the doctrine of prosecution history estoppel, Plaintiffs cannot use the doctrine of equivalents to reclaim claim scope surrendered during prosecution.

FOURTH DEFENSE
(Failure to State a Claim)

The Complaint fails to state a claim upon which relief may be granted and must be dismissed, especially if Torrent has not infringed and will not infringe the '781 patent.

FIFTH DEFENSE
(Not an Exceptional Case)

Plaintiffs are not entitled to a finding that this case is exceptional or to attorneys' fees under 35 U.S.C. § 285, or pursuant to the Court's inherent power.

SIXTH DEFENSE
(No Willful Infringement)

Plaintiffs' claims for enhanced damages, if any, and an award of fees and costs against Torrent have no basis in fact or law and should be denied.

COUNTERCLAIMS

Further responding to the Complaint, Torrent alleges the following counterclaims, without admitting any allegations of the Complaint not otherwise admitted and without assuming the burden when such burden would otherwise be on Plaintiffs.

THE PARTIES

1. Torrent Ltd. is an Indian corporation, having its principal place of business at Torrent House, Off Ashram Road, Navarangpura, Ahmedabad 380009, Gujarat India.

2. Torrent Inc. is a Delaware corporation, having its principal place of business at 150 Allen Road, Suite 102, Basking Ridge, New Jersey 07920-3856.

3. Upon information and belief, based on the allegations in the Complaint, Counterclaim-defendant Bial - Portela 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.

4. Upon information and belief, based on the allegations in the Complaint, Counterclaim-defendant Bial - Holding 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.

5. Upon information and belief, based on the allegations in the Complaint, Counterclaim-defendant 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.

6. Upon information and belief, based on the allegations of the Complaint, Bial – Holding and Bial – Portela (together “Bial”) own U.S. Patent No. 10,912,781 (“the ’781 patent”), and Sunovion is the exclusive licensee of the ’781 patent. Upon information and belief, based on the allegations of the Amended Complaint, Sunovion markets, sells, and distributes APTIOM® throughout the U.S. and holds New Drug Application (“NDA”) No. 022416 for APTIOM® (eslicarbazepine acetate) Tablets in 200 mg, 400 mg, 600 mg, and 800 mg dosage forms.

JURISDICTION AND VENUE

7. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a), in that it involves substantial claims arising under the United States Patent Act, 35 U.S.C. § 1 *et seq.*

8. This Court may declare the rights and other legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because this is a case of actual controversy within the Court's jurisdiction seeking a declaratory judgment that under the broadest reasonable construction the claims of the '781 patent are not and will not be infringed; and if any claim of the '781 patent were to be interpreted more broadly than this broadest reasonable construction, the claims would be invalid.

9. Venue is proper in this District pursuant to 28 U.S.C. § 1391.

THE CONTROVERSY

10. This is an action for declaratory relief seeking a declaration of non-infringement and invalidity of the claims of the '781 patent.

11. Under 21 U.S.C. § 355(b)(1)(G), an NDA holder must provide to FDA the patent number and expiration date of any patent(s) that it believes "claims the drug for which the applicant submitted the application or which claims a method of using such drug." FDA publishes these patent(s) in an electronic, publicly available database called APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, also known as the "Orange Book."

12. Counterclaim-defendants listed the '781 patent in FDA's Orange Book as covering the drug APTIOM®.

13. Torrent filed Abbreviated New Drug Application (“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 ANDA No. 211227 references listed drug APTIOM® (eslicarbazepine acetate) tablets in 200, 400, 600, and 800 mg dosage forms.

14. The present suit by Counterclaim-defendants impairs Torrent’s ability to obtain approval of its ANDA No. 211227 and market the products described therein. Torrent denies that it infringes any valid claim of the ’781 patent.

15. Based on Counterclaim-defendants’ filing of its Complaint against Torrent asserting infringement of the ’781 patent, and Torrent’s denial thereof, an actual controversy now exists between Torrent and Counterclaim-defendants as to whether Torrent will infringe any valid claim of the ’781 patent.

16. Unless enjoined, Counterclaim-defendants will continue to assert that Torrent infringes the ’781 patent and will continue to impair Torrent’s ability to market the products described in Torrent’s ANDA No. 211227, causing irreparable harm to Torrent’s business.

COUNTERCLAIM COUNT I – NON-INFRINGEMENT OF THE ’781 PATENT

17. Torrent repeats and incorporates by reference each of the foregoing paragraphs of its Counterclaims.

18. Torrent’s commercial manufacture, use, offer for sale, sale, or importation of its proposed drug product under ANDA No. 211227—pending approval of ANDA No. 211227—would not directly or indirectly infringe any claim of the ’781 patent.

19. Because Torrent has not infringed and will not infringe any claim of the ’781 patent, Counterclaim-defendants are not entitled to any damages or other relief against Torrent.

20. Accordingly, Torrent is entitled to declaratory judgment that it does not infringe any valid, enforceable claim of the '781 patent.

COUNTERCLAIM COUNT II – INVALIDITY OF THE '781 PATENT

21. Torrent repeats and incorporates by reference each of the foregoing paragraphs of its Counterclaims.

22. Plaintiffs allege that Torrent has infringed or will infringe valid claims of the '781 patent.

23. The claims of the '781 patent are invalid for failure to meet the requirements set forth in 35 U.S.C. §§ 1 *et seq.*, including without limitation §§ 101, 102, 103, and/or 112, and the rules, regulations, and laws pertaining thereto.

24. For at least the reasons stated herein, the claims of the '781 patent are invalid. By way of example and not limitation, the claims of the '781 patent are invalid under 35 U.S.C. §§ 102 and 103 at least in view of, and in combination with, one or more references related to 10-acetoxy-10,11-dihydro-5H-dibenz[b,f]azepine-5-carboxamide and/or eslicarbazepine acetate's use in treating seizures, including P.A. Dekker, "Epilepsy A Manual for Medical and Clinical Officers in Africa," (Revised Edition 2002); Ambrósio et al., "Mechanisms of Action of Carbamazepine and Its Derivatives, Oxcarbazepine, BIA 2-093, and BIA 2-024*," 27 Neurochemical Research, 121-130 (2002); Almeida et al., "Safety Tolerability and Pharmacokinetic Profile of BIA 2-093, a Novel Putative Antiepileptic Agent, during First Administration to Humans," 4(5) Drugs in R&D, 269-284 (2002); Almeida U.S. App. Pub. No. 2006/0252746 A1 (2006); Bialer et al., "Progress report on new antiepileptic drugs: a summary of the Seventh Eilat Conference (EILAT VII)," 61 Epilepsy Research, 1-48 (2004); International Publication Number WO 2004/087168 A1; Dudhara et al., U.S. App. Pub. No. 2003/0175353

(2003); Elger et al., “Eslicarbazepine Acetate: A Double-blind, Add-on, Placebo-controlled Exploratory Trial in Adult Patients with Partial-onset,” 48(3) *Epilepsia*, 497-504 (2007); Franke et al., U.S. App. Pub. No. 2004/0185095 (2004); Almeida et al., “Pharmacokinetic profile of BIA 2-093, a putative new antiepileptic drug, after single and multiple administration in human healthy volunteers,” 43(8) *Epilepsia*, 146-147 (2002); Handbook of Pharmaceutical Excipients (2006); Public Version of “Trileptal (Oxcarbazepine)” NDA 21-014 Approval Labeling (2000); Sharief et al., Double-blind, placebo-controlled study of topiramate in patients with refractory partial epilepsy, 25 *Epilep. Res.* 217 (1996); WO2004087168 *Use Of 10-Hydroxy-10,11-Dihydrocarbamazepine Derivatives For The Treatment Of Affective Disorders* (2004) and Cramer, J et al., *The relationship between poor medication compliance and seizures*, 3(4) *Epilepsy Behav.* 338 (2002). Counterclaim-plaintiffs reserve the right to assert additional prior-art references in the contentions, responses to discovery requests, and/or pleadings filed later in this action.

25. Because Torrent has not infringed and will not infringe any valid claim of the ’781 patent, Counterclaim-defendants are not entitled to damages or other relief against Torrent.

26. Accordingly, Torrent is entitled to declaratory judgment that the ’781 patent is invalid.

27. Pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. § 2202 *et seq.*, Torrent requests a declaration from the court that the asserted claims of the ’781 patent are invalid.

JURY DEMAND

28. Torrent hereby demands a jury trial on all issues so triable.

PRAYER FOR RELIEF

WHEREFORE, Torrent prays this Court:

- A. Enter an Order dismissing the Complaint, with prejudice, for failure to state a claim upon which relief can be granted.
- B. Enter a judgment that Torrent has not infringed the '781 patent by filing its ANDA No. 211227 or any amendments thereto, and that Torrent's commercial manufacture, use, offer for sale, sale or importation of its proposed drug product would not directly or indirectly infringe any claim of the '781 patent.
- C. Enter a judgment that the '781 patent is invalid and/or unenforceable.
- D. Enter an Order requiring Counterclaim-defendants to delete the '781 patent information they submitted to FDA pursuant to 21 U.S.C. § 355(i)(5)(C)(ii)(I).
- E. Enter an Order dismissing the Complaint, with prejudice, and denying Counterclaim-defendants the relief requested in the Complaint and any relief whatsoever.
- F. Find this case to be exceptional under 35 U.S.C. § 285 and award Torrent reasonable attorneys' fees and costs incurred in this litigation.
- G. Award Torrent such other relief as the nature of this case may require and the Court may deem just, proper, and equitable.

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