

**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. 18-279-CFC
CONSOLIDATED

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.") (collectively, "Torrent"), through their undersigned counsel, herein respond to the allegations in the Complaint (C.A. No. 19-1673-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 e 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 e 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 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. 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 patents-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. 9,750,747 (“the ’747 patent”). 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 patent-in-suit and denies all of the remaining allegations in paragraph 12.

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.

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 denies that it has infringed the patent-in-suit or any of the other aforementioned patents that are being asserted in the First Suit.

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.

Response: Torrent admits that it sent Plaintiffs a Recertification Notice Letter on or about July 26, 2019 related to ANDA No. 211227. Torrent is without information sufficient to admit or deny the remaining allegations contained in paragraph 14, and therefore denies the allegations.

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.

Response: Torrent admits that the Complaint only alleges infringement of the ’747 patent. Torrent further admits that it maintains its Paragraph IV certification notice as against the ’747 patent as well as the ’431 patent, the ’135 patent, the ’244 patent, the ’929 patent, and the ’954 patent. Torrent admits that the new action was consolidated with the First Suit on October 10, 2019 (D.I. 61). Torrent is without information sufficient to admit or deny the remaining allegations contained in paragraph 15, and therefore denies the allegations

JURISDICTION AND VENUE

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

Response: Paragraph 16 contains no allegations of fact to which a response is required. If an answer is required, Torrent incorporates its responses to paragraphs 1-15 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.

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.

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

Response: Admitted.

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.

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 19 contain conclusions of law, to which no response is required. To the extent a response is required, Torrent denies the remaining allegations of paragraph 19.

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.

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 20 contain conclusions of law, to which no response is required. To the extent a response is required, Torrent denies the remaining allegations of paragraph 20.

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.

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 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. 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 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 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 23 contain conclusions of law, to which no response is required. To the extent a response is required, Torrent denies the allegations of paragraph 23.

24. 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 24 contain conclusions of law, to which no response is required. To the extent a response is required, Torrent denies the allegations of paragraph 24.

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.

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 25.

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.

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 26.

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.

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. 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.

Response: Torrent does not contest personal jurisdiction for purposes of this action only. Otherwise, Torrent denies all of the allegations of paragraph 28.

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.

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 29, and therefore denies the allegations.

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.

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 30. All of the remaining allegations in paragraph 30 contain conclusions of law, to which no response is required. To the extent a response is required, Torrent denies the remaining allegations of paragraph 30.

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.

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

Torrent admits that it previously asserted counterclaims in the First Suit and in cases 1-07-cv-00332, 1-07-cv-00572, 1-09-cv-00019, 1-12-cv-00305, 1-15-cv-00902, and 1-17-cv-01163. All of the remaining allegations in paragraph 31 contain conclusions of law, to which no response is required. To the extent a response is required, Torrent denies the remaining allegations of paragraph 31.

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.

Response: Torrent does not contest personal jurisdiction for purposes of this action only. All of the allegations in paragraph 32 contain conclusions of law, to which no response is required. To the extent a response is required, Torrent denies the allegations of paragraph 32.

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.

Response: Admitted.

34. 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.

35. 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.

36. 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.

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.

Response: Admitted.

The Patents-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.

Response: Torrent admits that the ‘747 patent, entitled “Treatments involving eslicarbazepine acetate or eslicarbazepine,” bears on its face an issue date of September 5, 2017. Torrent further admits a purported true and correct copy of the ‘747 patent was attached to the Complaint as Exhibit A. Torrent is without information sufficient to admit or deny the remaining allegations contained in paragraph 38, and therefore denies the allegations.

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.

Response: Torrent admits that the cover page of the ‘747 patent lists Bial - Portela as an assignee. Torrent is without information sufficient to admit or deny the remaining allegations contained in paragraph 39, and therefore denies the allegations.

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

Response: Admitted.

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.

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 41.

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.

Response: Admitted.

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

Response: Torrent is without information sufficient to admit or deny the allegations contained in paragraph 43, and therefore denies the allegations.

COUNT I

([ALLEGED] 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.

Response: Paragraph 44 contains no allegations of fact to which a response is required. If an answer is required, Torrent incorporates by reference its responses to paragraphs 1-43 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.

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 45.

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.

Response: Admitted, except as to the "purportedly" qualification, which is denied.

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.

Response: Admitted.

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.

Response: All of the allegations in paragraph 48 contain conclusions of law, to which no response is required. To the extent a response is required, Torrent denies the allegations of paragraph 48.

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.

Response: Denied.

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.

Response: Denied.

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.

Response: Torrent admits that it had knowledge of the '747 patent at least as early as the time of the First Notice Letters. Torrent denies the remaining allegations in paragraph 51.

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.

Response: Denied.

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.

Response: Torrent admits that it had knowledge of the '747 patent at least as early as the time of the First Notice Letters. Torrent denies the remaining allegations in paragraph 53.

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.

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 54, and therefore denies the allegations.

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.

Response: Denied.

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.

Response: Denied.

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.

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

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.

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 (H) 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 to the infringement of, and/or induce the infringement of any valid and enforceable claim of the '747 patent.

SECOND DEFENSE
(Invalidity)

Each claim of the '747 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 '747 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 Inc. is a Delaware corporation, having its principal place of business at 150 Allen Road, Suite 102, Basking Ridge, New Jersey 07920-3856.
2. 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 e São Mamede) 4745-455, Trofa, Portugal.
3. 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 e São Mamede) 4745-365 Trofa, Portugal.
4. 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.
5. Upon information and belief, based on the allegations of the Complaint, Bial – Holding and Bial – Portela (together “Bial”) own the ’747 patent, and Sunovion is the exclusive licensee in the ’747 patent. Upon information and belief, based on the allegations of the 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

6. 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.*

7. 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 ’747 patent are not and will not be infringed; and if any claim of the ’747 patent were to be interpreted more broadly than this broadest reasonable construction, the claims would be invalid.

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

THE CONTROVERSY

9. This is an action for declaratory relief seeking a declaration of non-infringement and invalidity of the claims of the ’747 patent.

10. 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.” The patents-in-suit are all listed in the Orange Book as covering the drug APTIOM®.

11. Plaintiffs and Counterclaim Defendants listed the '747 patent in FDA's Orange Book against their branded eslicarbazepine.

12. Plaintiffs and Counterclaim-defendants listed Use Code **U-2041** TREATMENT OF PARTIAL-ONSET SEIZURES in the Orange Book against the '747 patent. Plaintiffs and Counterclaim Defendants co-listed Use Code **U-2121** TREATMENT OF PARTIAL-ONSET SEIZURES IN A PATIENT SUFFERING FROM OR SUSCEPTIBLE TO ABSENCE SEIZURES in the Orange Book against the '747 patent.

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. On or about January 2, 2018, Torrent provided Plaintiffs and Counterclaim-defendants a detailed statement of the factual and legal bases for Torrent's opinion of non-infringement and invalidity of the then-listed Orange Book patents, including the '747 patent, for APTIOM®. Torrent also provided Plaintiffs an offer of confidential access.

15. On or about January 5, 2018, pursuant to 21 U.S.C. § 355(j)(2)(B)(i)-(iv), Torrent provided written notice to Plaintiffs and Counterclaim-defendants that Torrent certified in ANDA No. 211227 that the claims of the then-listed Orange Book patents, including the '747 patent, for APTIOM® were not infringed by the commercial manufacture, use, or sale of Torrent's proposed drug product: eslicarbazepine acetate tablets in 200 mg, 400 mg, 600 mg, and 800 mg dosage forms.

16. On or about July 26, 2019, pursuant to 21 U.S.C. §355(j)(2)(B)(i)-(iv)) and 21 C.F.R. §§ 314.95 & 314.96(d), Torrent provided Plaintiffs and Counterclaim-defendants notice of recertification of its previously-submitted paragraph IV certification relating to the '747 patent. This recertification notice also included a detailed statement of the factual and legal bases for Torrent's opinion of non-infringement and invalidity of the '747 patent and an offer of confidential access pursuant to 21 U.S.C. § 355(j)(5)(C).

17. Torrent's detailed statements gave comprehensive reasons why its proprietary formulation does not infringe any claims of the '747 patent, and why the proposed labeling indication for Torrent's eslicarbazepine acetate would not induce infringement of any claims of the '747 patent.

18. On February 16, 2018, Plaintiffs filed a Complaint alleging that Torrent's proposed drug product infringes multiple patents-in-suit, including the '747 patent.

19. On September 6, 2019, Plaintiffs filed a Complaint alleging that Torrent's proposed drug product infringes the '747 patent.

20. For at least the reasons detailed in Torrent's detailed statements, the manufacture and sale of Torrent's proposed drug product would not infringe, induce infringement or contribute to infringement of any of the claims of the '747 patent.

COUNTERCLAIM COUNT I – NON-INFRINGEMENT OF THE '747 PATENT

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

22. Torrent's intended commercial manufacture, use, offer for sale, sale, or importation of its proposed drug product under ANDA No. 211227—pending approval of ANDA No. 211227—does not directly or indirectly infringe any claim of the '747 patent.

23. Because Torrent has not infringed and will not infringe any claim of the '747 patent, Plaintiffs and Counterclaim-defendants are not entitled to any damages or other relief against Torrent.

24. Accordingly, Torrent is entitled to declaratory judgment that it does not infringe any valid, enforceable claim of the '747 patent.

COUNTERCLAIM COUNT II – INVALIDITY OF THE '747 PATENT

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

26. Plaintiffs allege that Torrent has infringed or will infringe valid claims of the '747 patent.

27. The claims of the '747 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.

28. For at least the reasons stated in the detailed statements—which are hereby incorporated in their entirety—the claims of the '747 patent are invalid.

29. By way of example and not limitation, the claims of the '747 patent are invalid under 35 U.S.C. §§ 102 and/or 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 Public version EMEA CHMP Assessment Report for Zebinix (eslicarbazepine acetate) EMEA/304525/2009 (Feb. 19, 2009); PCT/GB96/01565 (pub. Jan. 23, 1997); Liu et al., "The Mechanism of Carbamazepine Aggravation of Absence Seizures," 319(2) J. Pharmacol. & Exper. Therapeutics at 790 (2006); Sierra-Paredes et al., "Effect of Eslicarbazepine acetate (BIA 2-093) on latrunculin A-induced

seizures and extracellular amino acid concentrations in the rat hippocampus,” 77 Epil. Res. 36, 39-40 (2007); Zheng et al., “Oxcarbazepine, not its active metabolite, potentiates GABA_A activation and aggravates absence seizures,” 50(1) Epilepsia 83 (2009); Milovan et al., “Effect of eslicarbazepine acetate and oxcarbazepine on cognition and psychomotor function in healthy volunteers,” 18 Epil. & Behav. 366, 373 (Jun. 18, 2010); Maia et al., “BIA 2-093 as add-on therapy for refractory partial epilepsy in adults,” 45 (3) Epilepsia 158 (2004); and Schmitt et al., “Oxcarbazepine for Treatment of Partial Epilepsy: A Review and Recommendations for Clinical Use,” 1(6) Epilepsy. Behav. 396 (2000). 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.

30. Additionally, certain claims of the ’747 patent are invalid under 35 U.S.C. § 101 for failure to claim patent-eligible subject matter and § 112 for lack of written description, lack of enablement, and/or indefiniteness. Counterclaim-plaintiffs reserve the right to provide additional bases for invalidity in their contentions, responses to discovery requests, and/or pleadings filed later in this action.

31. Because Torrent has not infringed and will not infringe any valid claim of the ’747 patent, Plaintiffs and Counterclaim-defendants are not entitled to damages or other relief against Torrent.

32. Accordingly, Torrent is entitled to declaratory judgment that the ’747 patent is invalid.

COUNTERCLAIM COUNT III – IMPROPER USE CODE

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

34. Plaintiffs and Counterclaim-defendants listed the '747 patent in FDA's Orange Book against their branded eslicarbazepine.

35. Plaintiffs and Counterclaim-defendants listed Use Code **U-2041** TREATMENT OF PARTIAL-ONSET SEIZURES in the Orange Book against the '747 patent.

36. The '747 patent, however, instead claims what is in co-listed Use Code **U-2121**: TREATMENT OF PARTIAL-ONSET SEIZURES IN A PATIENT SUFFERING FROM OR SUSCEPTIBLE TO ABSENCE SEIZURES—all claims have absence-seizure limitations.

37. The '747 patent unequivocally distinguishes the two types of epilepsy, stating, “*Partial-onset seizures* are a variety of epileptic seizure which *affect only a part of the brain at onset*. . . . *In contrast, absence seizures*, also known as petit mal seizures, *are a form of generalized seizure, which affects the whole of the brain*, producing abnormal electrical activity throughout both hemispheres and, typically, loss of consciousness” (emphasis added).

38. The '747 patent claims thus require treatment of a patient suffering from or susceptible to absence seizures, and Use Code **U-2041**—directed to treatment of partial-onset seizures, not treatment of patients suffering from or susceptible to absence seizures—should be deleted from the '747 patent's Orange Book listing under NDA No. 211227, thus allowing generic companies, including Torrent, to properly certify against the '747 patent.

39. Under 21 U.S.C. § 355(j)(5)(C)(ii)(I), Torrent is entitled to an order: (1) finding that Plaintiffs and Counterclaim-defendants improperly filed with FDA Use Code **U-2041** for the '747 patent in the Orange Book for NDA No. 211227 for APTIOM; and (2) requiring Plaintiffs and Counterclaim-defendants to immediately request that FDA correct the use code for the '747 patent in the Orange Book listing for NDA No. 211227 for APTIOM by deleting Use Code **U-2041**.

JURY DEMAND

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

PRAAYER 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 '747 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 does not directly or indirectly infringe any claim '747 patent.
- C. Enter a judgment that the '747 patent is invalid and/or unenforceable.
- D. Enter an Order requiring Plaintiffs and Counterclaim-defendants to delete the '747 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 Plaintiffs 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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/s/ Frederick L. Cottrell, III

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