IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BIAL - PORTELA & CA S.A., BIAL - HOLDING, S.A., and SUNOVION PHARMACEUTICALS INC.,	)	**JURY TRIAL DEMANDED**
Plaintiffs,	)	C.A. No. 20-785-CFC
v.	)	
APOTEX INC. and APOTEX CORP.,	)	
Defendants.	)	

DEFENDANTS APOTEX INC. AND APOTEX CORP.'S ANSWER, DEFENSES AND COUNTERCLAIMS TO AMENDED COMPLAINT FOR PATENT INFRINGEMENT

THE PARTIES[1]

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

ANSWER: Defendants Apotex Inc. and Apotex Corp. are without knowledge or information sufficient to form a belief as to the truth or falsity of the averments contained within this Paragraph of the Amended Complaint, and on that basis deny such averments.

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

ANSWER: Defendants Apotex Inc. and Apotex Corp. are without knowledge or information sufficient to form a belief as to the truth or falsity of the averments contained within this Paragraph of the Amended Complaint, and on that basis deny such averments.

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

[1] For convenience, certain section headings used by Plaintiffs in their Amended Complaint are repeated herein. Defendants do not necessarily agree with the characterization of such headings and do not waive any right to object to those characterizations.

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.

ANSWER: Defendants Apotex Inc. and Apotex Corp. are without knowledge or information sufficient to form a belief as to the truth or falsity of the averments contained within this Paragraph of the Amended Complaint, and on that basis deny such averments.

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.

ANSWER: Defendants Apotex Inc. and Apotex Corp. are without knowledge or information sufficient to form a belief as to the truth or falsity of the averments contained within this Paragraph of the Amended Complaint, and on that basis deny such averments.

5. On information and belief, Apotex Inc. is a corporation organized and existing under the laws of Canada, with its principal place of business at 150 Signet Drive, Toronto, Ontario, M9L 1T9, Canada.

ANSWER: Defendants Apotex Inc. and Apotex Corp. admit that Apotex Inc. is incorporated under the laws of Canada with a principal place of business at 150 Signet Drive, Toronto, Ontario, M9L 1T9, Canada.

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

ANSWER: Defendants Apotex Inc. and Apotex Corp. admit only so much of this Paragraph that alleges that Apotex Inc. manufactures and sales pharmaceutical products, some of which may be sold in the State of Delaware. Defendants Apotex Inc. and Apotex Corp. deny the remaining allegations in this Paragraph of the Amended Complaint.

7. On information and belief, Apotex Corp. is a corporation organized and existing under the laws of Delaware, with its principal place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326.

ANSWER: Defendants Apotex Inc. and Apotex Corp. admit that Apotex Corp. is incorporated under the laws of Delaware with a principal place of business at 2400 N. Commerce Parkway, Suite 400, Weston, FL 33326.

8. On information and belief, Apotex Corp. 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 Apotex Inc.

ANSWER: Defendants Apotex Inc. and Apotex Corp. admit only so much of this Paragraph that alleges that Apotex Corp. sells pharmaceutical products in the United States, some of which may be sold in the State of Delaware. Defendants Apotex Inc. and Apotex Corp. deny the remaining allegations of this Paragraph of the Amended Complaint.

9. On information and belief, the acts of Apotex Inc. complained of herein were done with the cooperation, participation, and assistance of Apotex Corp.

ANSWER: Defendants Apotex Inc. and Apotex Corp. admit only that Apotex Inc. appointed Apotex Corp. as the U.S. agent for ANDA No. 211236. Defendants Apotex Inc. and Apotex Corp. deny the remaining allegations of this Paragraph of the Amended Complaint.

10. 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. 211236, Apotex Inc. and Apotex Corp. will act in concert to distribute and sell the generic product described in Eslicarbazepine Acetate Tablets 200, 400, 600, and 800 mg ANDA No. 211236 ("Apotex's Generic Product") throughout the United States, including the State of Delaware.

ANSWER: The allegations in this Paragraph contain legal conclusions to which no Answer is required. To the extent an Answer is required, Defendants Apotex Inc. and Apotex Corp. state that it has not determined when Apotex's ANDA Products, once approved, will be launched, and therefore Defendants Apotex Inc. and Apotex Corp. are without knowledge or information sufficient to form a belief as to the truth or falsity of the

remaining averments of this Paragraph of the Amended Complaint and on that basis deny such averments.

11. On information and belief, Apotex Corp. acts as the United States agent for Apotex Inc. with respect to ANDA No. 211236.

ANSWER: The allegations of this Paragraph contain legal conclusions to which no Answer is required. To the extent an Answer is required, Defendants Apotex Inc. and Apotex Corp. admit only that Apotex Inc. appointed Apotex Corp. as the U.S. agent for ANDA No. 211236. Defendants Apotex Inc. and Apotex Corp. deny the remaining allegations of this Paragraph of the Amended Complaint.

NATURE OF THE ACTION

12. This is a civil action for patent 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") (collectively, "the patents-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. 211236, which Apotex 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.

ANSWER: Defendants Apotex Inc. and Apotex Corp. admit that Plaintiffs' Amended Complaint purports to bring this action for the alleged 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") (collectively, "the patents-in-suit"). Defendants Apotex Inc. and Apotex Corp. admit that Apotex Inc. filed ANDA No. 211236 which included a certification seeking approval from FDA to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of Eslicarbazepine Acetate Tablets 200, 400, 600, and 800 mg prior to the expiration of certain patents listed in the Orange Book, but as of the date of this filing does not include a certification with respect to the patents-in-suit. Apotex Inc. and Apotex Corp. deny the remaining allegations of this Paragraph of the Amended Complaint.

13. Apotex has infringed one or more claims of the patents-in-suit under 35 U.S.C. § 271(e)(2)(A) by virtue of its filing of ANDA No. 211236 seeking FDA approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of generic APTIOM® (eslicarbazepine acetate) Tablets for the treatment of patients with partial-onset seizures prior to the expiration of the patents-in-suit, or any extensions thereof. Apotex will infringe one or more claims of the patents-in-suit 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 generic APTIOM® (eslicarbazepine acetate) Tablets for the treatment of patients with partial-onset seizures prior to the expiration of the patents-in-suit, or any extensions thereof.

ANSWER: Defendants Apotex Inc. and Apotex Corp. deny the allegations of this Paragraph of the Amended Complaint.

14. Plaintiffs previously filed a separate action in this Court against Apotex for patent infringement, which includes counts for infringement of U.S. Patent Nos. 5,753,646 ("the '646 patent"), 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., et al. v. Apotex Inc., et al.,* C.A. No. 18-382-CFC (the "First Suit") was filed on March 9, 2018, and an amended complaint was filed on September 6, 2019. The First Suit was filed in response to a letter from Apotex dated January 23, 2018 ("Apotex's Notice Letter"), purporting to be a "Notification of Paragraph IV Certification" for ANDA No. 211236 pursuant to § 505(j)(2)(B)(i)-(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 '646 patent. The First Suit includes counts for infringement of the '646 patent, the '431 patent, the '135 patent, the '244 patent, the '929 patent, the '747 patent, and the '954 patent.

ANSWER: Defendants Apotex Inc. and Apotex Corp. admit that Plaintiffs filed a separate action in this Court against Apotex Inc. and Apotex Corp. for the alleged infringement of U.S. Patent Nos. 5,753,646 ("the '646 patent"), 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). Defendants Apotex Inc. and Apotex Corp. admit that the action captioned *Bial - Portela & CA S.A., et al. v. Apotex Inc., et al.,* C.A. No. 18-382-CFC (the "First Suit") was filed on March 9, 2018, and an amended complaint was filed on September 6, 2019. Defendants Apotex Inc. and Apotex Corp. further admit that Apotex Inc. provided Sunovion Pharmaceuticals and BIAL - PORTELA & CA, S.A. with notice, dated January 23, 2018, pursuant to 21 U.S.C. §355(j)(2)(B)(iv)

that Apotex Inc. had submitted ANDA No. 211236, seeking approval to engage in the commercial manufacture, use, sale, and/or importation of eslicarbazepine acetate tablets in 200, 400, 600, and 800 mg before the expiration of the '747 patent, the '431 patent, the '135 patent, the '244 patent, the '929 patent, and the '646 patent. Defendants Apotex Inc. and Apotex Corp. admit that the First Suit included alleged counts of infringement with respect to the '646; '431; '135; '244; '929; and '747 patents and the Second Suit included alleged counts of infringement with respect to the '646; '431; '135; '244; '929; '747 patents; and '954 patents. Except as specifically admitted, Defendants Apotex Inc. and Apotex Corp. Defendants Apotex Inc. and Apotex Corp. deny the remaining allegations of this Paragraph of the Amended Complaint.

15. Based on information and belief, Apotex is maintaining its certification as to the '646 patent, the '431 patent, the '135 patent, the '244 patent, the '929 patent, and the '747 patent. Thus, Plaintiffs will continue to prosecute all infringement counts presented in the First Suit.

ANSWER: Defendants Apotex Inc. and Apotex Corp. admit only that ANDA No. 211236 currently includes a certification as to the '646 patent, the '431 patent, the '135 patent, the '244 patent, the '929 patent, and the '747 patent. Defendants Apotex Inc. and Apotex Corp. are without knowledge or information sufficient to form a belief as to the truth or falsity of the averments contained within this Paragraph of the Amended Complaint, and on that basis deny such averments

JURISDICTION AND VENUE

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

ANSWER: Defendants Apotex Inc. and Apotex Corp. incorporate by reference and reallege each of the responses in the foregoing Paragraphs 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.

ANSWER: This Paragraph of the Amended Complaint states Plaintiffs' alleged statutory basis for asserting jurisdiction in this action, which dos not require an answer.

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

ANSWER: This Paragraph of the Amended Complaint states a legal conclusion with respect to Plaintiffs' alleged statutory basis for asserting jurisdiction in this action, which does not require an answer.

19. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c), and 1400(b), because Apotex Corp. is incorporated in the State of Delaware, and Apotex Inc. is incorporated in Canada and may be sued in any judicial district in the United States in which it is subject to the court's personal jurisdiction.

ANSWER: This Paragraph of the Amended Complaint is a legal conclusion and does not require an answer. To the extent an answer is required, Apotex admits that Apotex Corp. is incorporated in the State of Delaware and Apotex Inc. is incorporated in Canada. Solely for purposes of this action, Defendants Apotex Inc. and Apotex Corp. do not contest venue in this District.

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

ANSWER: This Paragraph of the Amended Complaint is a legal conclusion and does not require an answer. To the extent an answer is required, Apotex admits that Apotex Inc. is incorporated in Canada and solely for purposes of this action, Defendants Apotex Inc. and Apotex Corp. do not contest venue in this District, but deny that Plaintiffs have alleged sufficient basis for personal jurisdiction in this Paragraph.

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

ANSWER: This Paragraph of the Amended Complaint is a legal conclusion and does not require an answer. To the extent an answer is required, Apotex admits that Apotex Corp.

is organized and existing under the laws of the State of Delaware. Solely for purposes of this action, Defendants Apotex Inc. and Apotex Corp. are not contesting venue in this District, but deny that the Plaintiffs have alleged sufficient basis for personal jurisdiction in this Paragraph.

22. Upon information and belief, Apotex Corp. maintains continuous and systematic contacts with Delaware through its authorized U.S. agent, Corporate Creations Network Inc. located at 3411 Silverside Road, Tatnall Building, Suite 104, Wilmington, DE 19810.

ANSWER: This Paragraph of the Amended Complaint is a legal conclusion and does not require an answer. To the extent an answer is required, Apotex admits that Apotex Corp. has an authorized agent in Delaware named Corporate Creations Network Inc, but deny that the Plaintiffs have alleged sufficient basis for personal jurisdiction in this Paragraph.

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

ANSWER: This Paragraph of the Amended Complaint is a legal conclusion and does not require an answer. To the extent an answer is required, solely for purposes of this action, Defendants Apotex Inc. and Apotex Corp. are not contesting venue in this District, but deny the alleged bases for personal jurisdiction and all remaining allegations in this Paragraph of the Amended Complaint.

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

ANSWER: This Paragraph of the Amended Complaint is a legal conclusion and does not require an answer. To the extent an answer is required, solely for purposes of this action,

Defendants Apotex Inc. and Apotex Corp. are not contesting venue in this District, but deny the alleged bases for personal jurisdiction and all remaining allegations in this Paragraph of the Amended Complaint.

25. Upon information and belief, the effort to seek approval for ANDA No. 211236 and to manufacture, import, market, and/or sell Apotex's Generic Product upon approval has been a cooperative and joint enterprise and venture between Apotex Inc. and Apotex Corp.

ANSWER: This Paragraph of the Amended Complaint contains conclusions of law, to which no response is required. To the extent a response is required, Defendants Apotex Inc. and Apotex Corp. admit only that Apotex Inc. filed ANDA No. 211236 with FDA seeking approval to engage in the commercial manufacture, use, sale, and/or importation of tablets containing 200, 400, 600, and 800 mg of Eslicarbazepine acetate. Defendants Apotex Inc. and Apotex Corp. deny the remaining allegations of this Paragraph of the Amended Complaint.

26. Upon information and belief, Apotex Inc. and Apotex Corp. have an express and/or implied agreement to cooperate in the joint enterprise and venture of preparing, filing and maintaining ANDA No. 211236 and in commercializing Apotex's Generic Product in the United States, including in this judicial district, in accordance with ANDA 211236 upon approval.

ANSWER: This Paragraph of the Amended Complaint contains conclusions of law, to which no response is required. To the extent a response is required, Defendants Apotex Inc. and Apotex Corp. deny the allegations of this Paragraph of the Amended Complaint.

27. Upon information and belief, Apotex Inc. and Apotex Corp. have thus been, and continue to be, joint and prime actors in the drafting, submission, approval and maintenance of ANDA No. 211236.

ANSWER: This Paragraph of the Amended Complaint contains conclusions of law, to which no response is required. To the extent a response is required, Defendants Apotex Inc. and Apotex Corp. deny the allegations of this Paragraph of the Amended Complaint.

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

ANSWER: This Paragraph of the Amended Complaint contains conclusions of law, to which no response is required. To the extent a response is required, Defendants Apotex Inc. and Apotex Corp. are not contesting personal jurisdiction in this District but deny the alleged bases for personal jurisdiction and all remaining allegations of this Paragraph of the Amended Complaint.

29. On information and belief, and consistent with their practice with respect to other generic products, following FDA approval of ANDA No. 211236, Apotex will market, distribute, and sell Apotex's Generic Product described in ANDA No. 211236 throughout the United States, including in Delaware.

ANSWER: Defendants Apotex Inc. and Apotex Corp. have not determined when Apotex's ANDA Products once approved will be launched, and therefore Defendants Apotex Inc. and Apotex Corp. are without knowledge or information sufficient to form a belief as to the truth or falsity of the remaining averments of this Paragraph of the Amended Complaint and on that basis deny the averments of this Paragraph.

30. This Court also has personal jurisdiction over Apotex because, *inter alia*, Apotex 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, Apotex, either directly or through affiliates, currently sells significant quantities of generic drug products in the United States and in the State of Delaware. Apotex's website states that Apotex is "a global pharmaceutical company, headquartered in Canada, that produces high-quality, affordable medicines (both generic and innovative pharmaceuticals) for patients around the world" and that Apotex "operate[s] in more than 45 countries, including a significant presence in the US." *See* https://www1.apotex.com/us/about-us (accessed June 8, 2020). On information and belief, Apotex 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.

ANSWER: This Paragraph of the Amended Complaint contains conclusions of law, to which no response it required. To the extent a response is required, Defendants Apotex

Inc. and Apotex Corp. admit that the alleged website speaks for itself. Further, solely for purposes of this action, Defendants Apotex Inc. and Apotex Corp. are not contesting personal jurisdiction in this District but deny the alleged bases for personal jurisdiction and all remaining averment s of this Paragraph of the Amended Complaint.

31. This Court also has personal jurisdiction over Apotex because, *inter alia*, it has availed itself of this forum previously for the purpose of litigating a patent dispute. For example, Apotex has previously invoked this Court's jurisdiction by asserting counterclaims in at least 7 cases in the last few years. *See, e.g.,* 17-cv-01553, 17-cv-01554, 17-cv-01164, 17-cv-00399; 16-cv-01267, 16-cv-00926, and 16-cv-00269.

ANSWER: Defendants Apotex Inc. and Apotex Corp. admit only that Apotex Inc. and Apotex Corp. have previously been sued and asserted counterclaims in this Judicial District. However, solely for purposes of this action, Defendants Apotex Inc. and Apotex Corp. are not contesting personal jurisdiction in this District but deny the alleged bases for personal jurisdiction and all remaining averment s of this Paragraph of the Amended Complaint.

32. This Court also has personal jurisdiction over Apotex because Apotex did not contest jurisdiction in the First Suit.

ANSWER: Defendants Apotex Inc. and Apotex Corp. admit only that Apotex Inc. and Apotex Corp. did not contest personal jurisdiction in the First Suit solely for purposes of that action. However, solely for purposes of this action, Defendants Apotex Inc. and Apotex Corp. are not contesting personal jurisdiction in this District but deny the alleged bases for personal jurisdiction and all remaining averment s of this Paragraph of the Amended Complaint.

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

ANSWER: This Paragraph of the Amended Complaint is a legal conclusion and does not require an answer. However, solely for purposes of this action, Defendants Apotex Inc. and Apotex Corp. are not contesting personal jurisdiction in this District.

FACTUAL BACKGROUND

The NDA

34. 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.

ANSWER: Defendants Apotex Inc. and Apotex Corp. admit only the Sunovion Pharmaceuticals is listed as the applicant on the FDA website for NDA No. 022416. Defendants Apotex Inc. and Apotex Corp. lack knowledge or information sufficient to admit or deny the remaining averments of this Paragraph of the Amended Complaint and therefore deny such averments.

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

ANSWER: Defendants Apotex Inc. and Apotex Corp. admit only that the FDA website lists the approval date for NDA No. 022416 as November 8, 2013, and the Aptiom 2013 label includes an Indications and Usage section that states that "APTIOM is indicated as adjunctive treatment of partial-onset seizures." Defendants Apotex Inc. and Apotex Corp. lack knowledge or information sufficient to admit or deny the remaining averments of this Paragraph of the Amended Complaint and therefore deny such averments.

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

ANSWER: Defendants Apotex Inc. and Apotex Corp. admit only that the FDA website lists the approval date for NDA No. 022416 as November 8, 2013 and the Aptiom 2015 label includes an Indications and Usage section that states that "APTIOM is indicated for the treatment of partial-onset seizures as monotherapy or adjunctive therapy.". Defendants

Apotex Inc. and Apotex Corp. lack knowledge or information sufficient to admit or deny the remaining averments of this Paragraph of the Amended Complaint and therefore deny such averments.

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

ANSWER: Defendants Apotex Inc. and Apotex Corp. admit only that the FDA website lists the approval date for NDA No. 022416 as November 8, 2013 and the Aptiom 2017 label includes an Indications and Usage section that states that "APTIOM is indicated for treatment of partial-onset seizures in patients 4 years of age and older." Defendants Apotex Inc. and Apotex Corp. lack knowledge or information sufficient to admit or deny the remaining averments of this Paragraph of the Amended Complaint and therefore deny such averments.

38. 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.

ANSWER: Defendants Apotex Inc. and Apotex Corp. admit only that the FDA website (www.accessdata.fda.gov/scripts/cder/daf) identifies eslicarbazepine acetate as the active ingredient in Aptiom®. Defendants Apotex Inc. and Apotex Corp. further admit that the label, dated September 2017, provided on the FDA website indicates that "APTIOM is indicated for the treatment of partial-onset seizures in patients 4 years of age and older." Defendants Apotex Inc. and Apotex Corp. deny any remaining averments of this Paragraph of the Amended Complaint.

The Patents-in-Suit

39. The '287 patent, titled "Methods of Treatment of Partial Onset Seizures Using Eslicarbazepine Acetate," was duly and legally issued by the United States Patent and Trademark Office on June 9, 2020. A true and correct copy of the '287 patent is attached as Exhibit A.

ANSWER: Defendants Apotex Inc. and Apotex Corp. admit that the '287 patent, entitled "Methods of Treatment of Partial Onset Seizures Using Eslicarbazepine Acetate," was issued by the USPTO on June 9, 2020 but deny that the '287 patent was duly and legally issued. Defendants Apotex Inc. and Apotex Corp. admit that the '287 patent appears to be attached to the Amended Complaint as Exhibit A. Defendants Apotex Inc. and Apotex Corp. deny the remaining allegations in this Paragraph of the Amended Complaint.

40. BIAL - PORTELA & CA S.A. owns the rights to the '287 patent. Sunovion is the exclusive licensee in the United States of the '287 patent. The '287 patent will expire on May 6, 2025.

ANSWER: Defendants Apotex Inc. and Apotex Corp. admit that Bial-Portela & CA S.A. is identified as the assignee on the face of the '287 patent. Defendants Apotex Inc. and Apotex Corp. are without knowledge or information sufficient to form a belief as to the truth or falsity of the remaining averments within this Paragraph of the Amended Complaint and on that basis denies such averments.

41. The '287 patent is listed in the FDA Orange Book in connection with NDA No. 022416 for APTIOM® (Eslicarbazepine Acetate) Tablets.

ANSWER: Defendants Apotex Inc. and Apotex Corp. admit that the '287 patent is listed in the FDA Orange Book in connection with APTIOM® but deny that it is properly listed. Defendants Apotex Inc. and Apotex Corp. deny the remaining allegations of this Paragraph of the Amended Complaint.

42. The '287 patent covers methods for treating a patient with partial-onset seizures by administering once-daily about 1200 mg of eslicarbazepine acetate.

ANSWER: This Paragraph of the Amended Complaint purports to characterize the scope of the claims of the '287 patent but does not include all of the limitations of those claims and contains conclusions of law, to which no response is required. To the extent a

response is required, Defendants Apotex Inc. and Apotex Corp. deny the allegations of this Paragraph of the Amended Complaint.

43. The prescribing information for APTIOM®, instructs physicians to administer APTIOM® Tablets once-daily for the treatment of partial-onset seizures in patients 4 years of age and older in a dosage of about 1200 mg of eslicarbazepine acetate.

ANSWER: Defendants Apotex Inc. and Apotex Corp. admit only that the label, dated September 2017, provided on the FDA website indicates that "APTIOM is indicated for the treatment of partial-onset seizures in patients 4 years of age and older." Defendants Apotex Inc. and Apotex Corp. deny any remaining averments of this Paragraph of the Amended Complaint.

44. Thus, the once-daily use of APTIOM® (Eslicarbazepine Acetate) Tablets in a dosage of about 1200 mg and any generic eslicarbazepine acetate tablets in a dosage of about 1200 mg for the treatment of patients with partial-onset seizures is covered by the '287 patent, and Plaintiffs have the right to enforce the '287 patent.

ANSWER: This Paragraph of the Amended Complaint contains conclusions of law, to which no response is required. To the extent a response is required, Defendants Apotex Inc. and Apotex Corp. deny the allegations of this Paragraph of the Amended Complaint.

45. The '354 patent, titled "Methods of Treatment of Partial Onset Seizures Using Eslicarbazepine Acetate," was duly and legally issued by the United States Patent and Trademark Office on June 30, 2020. A true and correct copy of the '354 patent is attached as Exhibit B.

ANSWER: Defendants Apotex Inc. and Apotex Corp. admit that the '354 patent, entitled "Methods of Treatment of Partial Onset Seizures Using Eslicarbazepine Acetate," was issued by the USPTO on June 30, 2020 but deny that the '354 patent was duly and legally issued. Defendants Apotex Inc. and Apotex Corp. admit that the '354 patent appears to be attached to the Amended Complaint as Exhibit B. Defendants Apotex Inc. and Apotex Corp. deny the remaining allegations in this Paragraph of the Amended Complaint.

46. BIAL - PORTELA & CA S.A. owns the rights to the '354 patent. Sunovion is the exclusive licensee in the United States of the '354 patent. The '354 patent will expire on May 6, 2025.

ANSWER: Defendants Apotex Inc. and Apotex Corp. admit that Bial-Portela & CA S.A. is identified as the assignee on the face of the '354 patent. Defendants Apotex Inc. and Apotex Corp. are without knowledge or information sufficient to form a belief as to the truth or falsity of the remaining averments within this Paragraph of the Amended Complaint and on that basis denies such averments.

47. The '354 patent is listed in the FDA Orange Book in connection with NDA No. 022416 for APTIOM® (Eslicarbazepine Acetate) Tablets.

ANSWER: Defendants Apotex Inc. and Apotex Corp. admit that the '354 patent is listed in the FDA Orange Book in connection with APTIOM® but deny that it is properly listed. Defendants Apotex Inc. and Apotex Corp. deny the remaining allegations of this Paragraph of the Amended Complaint.

48. The '354 patent covers methods for treating a patient with partial-onset seizures by administering eslicarbazepine acetate once-daily.

ANSWER: This Paragraph of the Amended Complaint purports to characterize the scope of the claims of the '354 patent but does not include all of the limitations of those claims and contains conclusions of law, to which no response is required. To the extent a response is required, Defendants Apotex Inc. and Apotex Corp. deny the allegations of this Paragraph of the Amended Complaint.

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

ANSWER: Defendants Apotex Inc. and Apotex Corp. admit only that the label, dated September 2017, provided on the FDA website indicates that "APTIOM is indicated for the treatment of partial-onset seizures in patients 4 years of age and older." Defendants Apotex Inc. and Apotex Corp. deny any remaining averments of this Paragraph of the Amended Complaint.

50. Thus, the once-daily use of APTIOM® (Eslicarbazepine Acetate) Tablets and any generic eslicarbazepine acetate tablets for the treatment of patients with partial-onset seizures is covered by the '354 patent, and Plaintiffs have the right to enforce the '354 patent.

ANSWER: This Paragraph of the Amended Complaint contains conclusions of law, to which no response is required. To the extent a response is required, Defendants Apotex Inc. and Apotex Corp. deny the allegations of this Paragraph of the Amended Complaint.

51. The '536 patent, titled "Methods of Treatment of Partial Onset Seizures Using Eslicarbazepine Acetate," was duly and legally issued by the United States Patent and Trademark Office on July 7, 2020. A true and correct copy of the '536 patent is attached as Exhibit C.

ANSWER: Defendants Apotex Inc. and Apotex Corp. admit that the '536 patent, entitled "Methods of Treatment of Partial Onset Seizures Using Eslicarbazepine Acetate," was issued by the USPTO on July 7, 2020 but deny that the '536 patent was duly and legally issued. Defendants Apotex Inc. and Apotex Corp. admit that the '536 patent appears to be attached to the Amended Complaint as Exhibit C. Defendants Apotex Inc. and Apotex Corp. deny the remaining allegations in this Paragraph of the Amended Complaint.

52. BIAL - PORTELA & CA S.A. owns the rights to the '536 patent. Sunovion is the exclusive licensee in the United States of the '536 patent. The '536 patent will expire on May 6, 2025.

ANSWER: Defendants Apotex Inc. and Apotex Corp. admit that Bial-Portela & CA S.A. is identified as the assignee on the face of the '536 patent. Defendants Apotex Inc. and Apotex Corp. are without knowledge or information sufficient to form a belief as to the truth or falsity of the remaining averments within this Paragraph of the Amended Complaint and on that basis denies such averments.

53. Information regarding the '536 patent was submitted to the FDA for listing in the Orange Book in connection with NDA No. 022416 for APTIOM® (Eslicarbazepine Acetate) Tablets.

ANSWER: Defendants Apotex Inc. and Apotex Corp. admit that the '536 patent is listed in the FDA Orange Book in connection with APTIOM® but deny that it is properly listed. Defendants Apotex Inc. and Apotex Corp. deny the remaining allegations of this Paragraph of the Amended Complaint.

54. The '536 patent covers methods for treating a patient with partial-onset seizures by administering eslicarbazepine acetate once-daily.

ANSWER: This Paragraph of the Amended Complaint purports to characterize the scope of the claims of the '536 patent but does not contain all of the limitations of those claims and contains conclusions of law, to which no response is required. To the extent a response is required, Defendants Apotex Inc. and Apotex Corp. deny the allegations of this Paragraph of the Amended Complaint.

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

ANSWER: Defendants Apotex Inc. and Apotex Corp. admit only that the label, dated September 2017, provided on the FDA website indicates that "APTIOM is indicated for the treatment of partial-onset seizures in patients 4 years of age and older." Defendants Apotex Inc. and Apotex Corp. deny any remaining averments of this Paragraph of the Amended Complaint.

56. Thus, the once-daily use of APTIOM® (Eslicarbazepine Acetate) Tablets and any generic eslicarbazepine acetate tablets for the treatment of patients with partial-onset seizures is covered by the '536 patent, and Plaintiffs have the right to enforce the '536 patent.

ANSWER: This Paragraph of the Amended Complaint contains conclusions of law, to which no response is required. To the extent a response is required, Defendants Apotex Inc. and Apotex Corp. deny the allegations of this Paragraph of the Amended Complaint.

The ANDA

57. On information and belief, Apotex filed ANDA No. 211236 with the FDA under 21 U.S.C. § 355(j) before January 23, 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 Plaintiffs' APTIOM® (eslicarbazepine acetate) Tablets in 200, 400, 600, and 800 mg dosage forms.

ANSWER: Defendants Apotex Inc. and Apotex Corp. admit that Apotex Inc. provided BIAL-PORTELA & CA, S.A. and Sunovion Pharmaceutical Inc. with notice pursuant to 21 U.S.C. §355(j)(2)(B)(iv) that Apotex Inc. had submitted to the FDA ANDA No. 211236, seeking approval to engage in the commercial manufacture, use, sale, and/or importation of eslicarbazepine acetate tablets in 200, 400, 600, and 800 mg dosage forms before the expiration of the '747; '431; '135; '244; '929; and '646 patents and that Aptiom is the reference listed drug for the recited dosages. Defendants Apotex Inc. and Apotex Corp. deny the remaining averments of this Paragraph of the Amended Complaint.

58. Apotex's Notice Letter alleged that the claims of the '747 patent, the '431 patent, the '135 patent, the '244 patent, the '929 patent, and the '646 patent are invalid and/or will not be infringed by the activities described in Apotex's ANDA No. 211236. Apotex's Notice Letter also informed Plaintiffs that Apotex seeks approval to market Apotex's Generic Product before the '747, '431, '135, '244, '929, and '646 patents expire.

ANSWER: Defendants Apotex Inc. and Apotex Corp. admit that ANDA No. 211236 includes a certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV) that the '646 patent, the '431 patent, the '135 patent, the '244 patent, the '929 patent, and the '747 patent are invalid, unenforceable, and/or would not be infringed by the manufacture, use, sale and/or importation of the new drug for which the application is submitted. Defendants Apotex Inc. and Apotex Corp. deny the remaining averments of this Paragraph of the Amended Complaint.

59. The '646 patent expires on June 27, 2021. The patents-in-suit will expire on May 6, 2025.

ANSWER: Defendants Apotex Inc. and Apotex Corp. admit only that the Orange Book lists the expiration date for the '646 patent as June 27, 2021 and the expiration for the

patents-in-suit as May 6, 2025. Defendants Apotex Inc. and Apotex Corp. deny the remaining averments of this Paragraph of the Amended Complaint.

60. Apotex's ANDA No. 211236 has been pending before the FDA since at least January 23, 2018, the date of Apotex's Notice Letter to Plaintiffs.

ANSWER: Defendants Apotex Inc. and Apotex Corp. admit that Apotex Inc. provided BIAL-PORTELA & CA, S.A. and Sunovion Pharmaceutical Inc. with notice, dated January 23, 2018, pursuant to 21 U.S.C. §355(j)(2)(B)(iv) that Apotex Inc. had submitted to the FDA ANDA No. 211236, and that this ANDA remains pending. Defendants Apotex Inc. and Apotex Corp. deny any remaining averments of this Paragraph of the Amended Complaint.

61. On information and belief, following FDA approval of Apotex's ANDA No. 211236, Apotex will make, use, sell, or offer to sell Apotex's Generic Product throughout the United States, or import such generic products into the United States before the patents-in-suit expire.

ANSWER: Defendants Apotex Inc. and Apotex Corp. state that it has not determined when Apotex's ANDA Products, once approved, will be launched, and therefore Defendants Apotex Inc. and Apotex Corp. are without knowledge or information sufficient to form a belief as to the truth or falsity of the remaining averments of this Paragraph of the Amended Complaint and on that basis deny such averments.

COUNT I

([ALLEGED] INFRINGEMENT OF THE '287 PATENT UNDER 35 U.S.C. § 271(e)(2))

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

ANSWER: Defendants Apotex Inc. and Apotex Corp. incorporate by reference and reallege each of the responses in the foregoing paragraphs as if set forth specifically here.

63. On information and belief, Apotex filed ANDA No. 211236 in order to obtain approval to manufacture, use, import, offer to sell and/or sell Apotex's Generic Product in the United States before the expiration of the '287 patent.

ANSWER: Defendants Apotex Inc. and Apotex Corp. admit that Apotex Inc. provided BIAL-PORTELA & CA, S.A. and Sunovion Pharmaceutical Inc. with notice, dated January 23, 2018, pursuant to 21 U.S.C. §355(j)(2)(B)(iv) that Apotex Inc. had submitted to the FDA ANDA No. 211236, seeking approval to engage in the commercial manufacture, use, sale, and/or importation of eslicarbazepine acetate tablets in 200, 400, 600, and 800 mg dosage forms before the expiration of the '747; '431; '135; '244; '929; and '646 patents. Defendants Apotex Inc. and Apotex Corp. deny the remaining averments of this Paragraph of the Amended Complaint.

64. On information and belief, in its ANDA No. 211236, Apotex has represented to the FDA that Apotex's Generic Product is pharmaceutically and therapeutically equivalent to Plaintiffs' APTIOM® tablets.

ANSWER: Defendants Apotex Inc. and Apotex Corp. admit that Defendant Apotex Inc. filed ANDA No. 211236 with FDA for approval of the subject matter therein and that said ANDA is a document that speaks for itself. Defendants Apotex Inc. and Apotex Corp. deny any remaining averments in this Paragraph of the Amended Complaint.

65. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 211236 seeking approval for the commercial manufacture, use, or sale of Apotex's Generic Product before the expiration date of the '287 patent, constitutes infringement, either literally or under the doctrine of equivalents.

ANSWER: Defendants Apotex Inc. and Apotex Corp. deny the allegations of this Paragraph of the Amended Complaint.

66. Upon FDA approval of ANDA No. 211236, Apotex will infringe one or more claims of the '287 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Apotex'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. 211236 shall be no earlier than the expiration of the '287 patent and any additional periods of exclusivity.

ANSWER: Defendants Apotex Inc. and Apotex Corp. deny the allegations of this Paragraph of the Amended Complaint.

67. On information and belief, Apotex knows, or should know, and intends that physicians will prescribe and patients will take Apotex's Generic Product for which approval is sought in ANDA No. 211236, and therefore will infringe at least one claim in the '287 patent.

ANSWER: Defendants Apotex Inc. and Apotex Corp. deny the allegations of this Paragraph of the Amended Complaint.

68. On information and belief, Apotex had knowledge of the '287 patent and, by its promotional activities and proposed package insert for Apotex's Generic Product, knows or should know that it will induce direct infringement of at least one of the claims of the '287 patent, either literally or under the doctrine of equivalents.

ANSWER: Defendants Apotex Inc. and Apotex Corp. deny the allegations of this Paragraph of the Amended Complaint.

69. On information and belief, Apotex 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 Apotex's Generic Product according to the instructions in the proposed package insert in a way that directly infringes the '287 patent.

ANSWER: Defendants Apotex Inc. and Apotex Corp. deny the allegations of this Paragraph of the Amended Complaint.

70. The offering to sell, sale, making, and/or importation of Apotex's Generic Product would actively induce infringement of at least one of the claims of the '287 patent, either literally or under the doctrine of equivalents. Apotex has knowledge and is aware of Plaintiffs' '287 patent.

ANSWER: Defendants Apotex Inc. and Apotex Corp. are aware that Plaintiffs have filed this action alleging infringement of the '287 patent. Defendants Apotex Inc. and Apotex Corp. deny the allegations of this Paragraph of the Amended Complaint.

71. On information and belief, if ANDA No. 211236 is approved, Apotex intends to and will offer to sell, sell, and/or import in the United States Apotex's Generic Product.

ANSWER: Defendants Apotex Inc. and Apotex Corp. are without knowledge or information sufficient to form a belief as to the truth or falsity of the averments contained within this Paragraph of the Amended Complaint and on that basis deny such averments.

72. Apotex has had and continues to have knowledge that Apotex's Generic Product is especially adapted for a use that infringes the '287 patent.

ANSWER: Defendants Apotex Inc. and Apotex Corp. deny the allegations of this Paragraph of the Amended Complaint.

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

ANSWER: Defendants Apotex Inc. and Apotex Corp. deny the allegations of this Paragraph of the Amended Complaint.

74. On information and belief, Apotex's actions relating to Apotex's ANDA No. 211236 complained of herein were done by and for the benefit of Apotex.

ANSWER: Defendants Apotex Inc. and Apotex Corp. deny the allegations of this Paragraph of the Amended Complaint.

75. Plaintiffs will be irreparably harmed if Apotex is not enjoined from infringing or actively inducing infringement of at least one claim of the '287 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.

ANSWER: Defendants Apotex Inc. and Apotex Corp. deny the allegations of this Paragraph of the Amended Complaint.

COUNT II
(DECLARATORY JUDGEMENT OF [ALLEGED] INFRINGEMENT OF THE '287 PATENT)

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

ANSWER: Defendants Apotex Inc. and Apotex Corp. incorporate by reference and reallege each of the responses in the foregoing paragraphs as if set forth specifically here.

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

ANSWER: This Paragraph of the Amended Complaint states Plaintiffs' alleged statutory basis for asserting jurisdiction in this action, which does not require an answer. .

78. There is an actual and justiciable controversy between Plaintiffs and Apotex concerning infringement of the '287 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.

ANSWER: This Paragraph of the Amended Complaint is a legal conclusion and does not require any answer.

79. Apotex has made, and continues to make, substantial preparation in the United States to manufacture, offer to sell, sell and/or import Apotex's Generic Product prior to expiration of the '287 patent.

ANSWER: Defendants Apotex Inc. and Apotex Corp. deny the allegations of this Paragraph of the Amended Complaint.

80. Apotex's actions, including, but not limited to, submitting, or causing to be submitted to the FDA, ANDA No. 211236 seeking approval to manufacture, use, import, offer to sell and sell Apotex's Generic Product before the expiration date of the '287 patent and engaging in litigation, indicate a refusal to change the course of their actions in the face of knowledge of the '287 patent and acts by Plaintiffs.

ANSWER: Defendants Apotex Inc. and Apotex Corp. deny the allegations of this Paragraph of the Amended Complaint.

81. On information and belief, the FDA could approve Apotex's ANDA No. 211236 prior to expiration of the '287 patent and as early as the conclusion of the First Suit, which is currently scheduled for trial in January 2021.

ANSWER: Defendants Apotex Inc. and Apotex Corp. deny that they First Suit is scheduled for trial in January 2021. Defendants Apotex Inc. and Apotex Corp. are without knowledge or information sufficient to form a belief as to the truth or falsity of the

remaining averments contained within this Paragraph of the Amended Complaint and on that basis deny such averments.

82. On information and belief, Apotex intends to manufacture, use, import, offer to sell and/or sell Apotex's Generic Product upon FDA approval of ANDA No. 211236.

ANSWER: Defendants Apotex Inc. and Apotex Corp. are without knowledge or information sufficient to form a belief as to the truth or falsity of the averments contained within this Paragraph of the Amended Complaint and on that basis deny such averments.

83. Upon FDA approval of ANDA No. 211236, Apotex will infringe one or more claims of the '287 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Apotex's Generic Product, and/or by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c).

ANSWER: Defendants Apotex Inc. and Apotex Corp. deny the allegations of this Paragraph of the Amended Complaint.

84. On information and belief, Apotex knows, or should know, and intends that physicians will prescribe and patients will take Apotex's Generic Product for which approval is sought in ANDA No. 211236, and therefore will infringe at least one claim in the '287 patent.

ANSWER: Defendants Apotex Inc. and Apotex Corp. deny the allegations of this Paragraph of the Amended Complaint.

85. On information and belief, Apotex had knowledge of the '287 patent and, by its promotional activities and proposed package insert for Apotex's Generic Product, knows or should know that it will induce direct infringement of at least one of the claims of the '287 patent, either literally or under the doctrine of equivalents.

ANSWER: Defendants Apotex Inc. and Apotex Corp. deny the allegations of this Paragraph of the Amended Complaint.

86. On information and belief, Apotex 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 Apotex's Generic Product according to the instructions in the proposed package insert in a way that directly infringes the '287 patent.

ANSWER: Defendants Apotex Inc. and Apotex Corp. deny the allegations of this Paragraph of the Amended Complaint.

87. The offering to sell, sale, making, and/or importation of Apotex's Generic Product would actively induce infringement of at least one of the claims of the '287 patent, either literally or under the doctrine of equivalents. Apotex has knowledge and is aware of Plaintiffs' '287 patent.

ANSWER: Defendants Apotex Inc. and Apotex Corp. are aware that Plaintiffs have filed this action alleging infringement of the '287 patent Defendants Apotex Inc. and Apotex Corp. deny the allegations of this Paragraph of the Amended Complaint.

88. On information and belief, if ANDA No. 211236 is approved, Apotex intends to and will offer to sell, sell, and/or import in the United States Apotex's Generic Product.

ANSWER: Defendants Apotex Inc. and Apotex Corp. are without knowledge or information sufficient to form a belief as to the truth or falsity of the averments contained within this Paragraph of the Amended Complaint and on that basis deny such averments.

89. Apotex has had and continues to have knowledge that Apotex's Generic Product is especially adapted for a use that infringes the '287 patent.

ANSWER: Defendants Apotex Inc. and Apotex Corp. deny the allegations of this Paragraph of the Amended Complaint.

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

ANSWER: Defendants Apotex Inc. and Apotex Corp. deny the allegations of this Paragraph of the Amended Complaint.

91. On information and belief, Apotex's actions relating to Apotex's ANDA No. 211236 complained of herein were done by and for the benefit of Apotex.

ANSWER: Defendants Apotex Inc. and Apotex Corp. deny the allegations of this Paragraph of the Amended Complaint.

92. Plaintiffs will be irreparably harmed if Apotex is not enjoined from infringing or actively inducing infringement of at least one claim of the '287 patent.

ANSWER: Defendants Apotex Inc. and Apotex Corp. deny the allegations of this Paragraph of the Amended Complaint.

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

ANSWER: Defendants Apotex Inc. and Apotex Corp. deny the allegations of this Paragraph of the Amended Complaint.

94. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale and/or importation of Apotex's Generic Product prior to expiration of the '287 patent by Apotex will constitute direct infringement, contributory infringement and/or active inducement of infringement of the '287 patent.

ANSWER: Defendants Apotex Inc. and Apotex Corp. deny the allegations of this Paragraph of the Amended Complaint.

COUNT III
([ALLEGED] INFRINGEMENT OF THE '354 PATENT UNDER 35 U.S.C. § 271(e)(2))

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

ANSWER: Defendants Apotex Inc. and Apotex Corp. incorporate by reference and reallege each of the responses in the foregoing paragraphs as if set forth specifically here.

96. On information and belief, Apotex filed ANDA No. 211236 in order to obtain approval to manufacture, use, import, offer to sell and/or sell Apotex's Generic Product in the United States before the expiration of the '354 patent.

ANSWER: Defendants Apotex Inc. and Apotex Corp. admit that Apotex Inc. provided BIAL-PORTELA & CA, S.A. and Sunovion Pharmaceutical Inc. with notice, dated January 23, 2018, pursuant to 21 U.S.C. §355(j)(2)(B)(iv) that Apotex Inc. had submitted to the FDA ANDA No. 211236, seeking approval to engage in the commercial manufacture, use, sale, and/or importation of eslicarbazepine acetate tablets in 200, 400, 600, and 800 mg dosage forms before the expiration of the '747; '431; '135; '244; '929; and '646 patents.

Defendants Apotex Inc. and Apotex Corp. deny the remaining averments of this Paragraph of the Amended Complaint.

97. On information and belief, in its ANDA No. 211236, Apotex has represented to the FDA that Apotex's Generic Product is pharmaceutically and therapeutically equivalent to Plaintiffs' APTIOM® tablets.

ANSWER: Defendants Apotex Inc. and Apotex Corp. admit that Defendant Apotex Inc. filed ANDA No. 211236 with FDA for approval of the subject matter therein and that said ANDA is a document that speaks for itself. Defendants Apotex Inc. and Apotex Corp. deny any remaining averments in this Paragraph of the Amended Complaint.

98. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 211236 seeking approval for the commercial manufacture, use, or sale of Apotex's Generic Product before the expiration date of the '354 patent, constitutes infringement, either literally or under the doctrine of equivalents.

ANSWER: Defendants Apotex Inc. and Apotex Corp. deny the allegations of this Paragraph of the Amended Complaint.

99. Upon FDA approval of ANDA No. 211236, Apotex will infringe one or more claims of the '354 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Apotex'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. 211236 shall be no earlier than the expiration of the '354 patent and any additional periods of exclusivity.

ANSWER: Defendants Apotex Inc. and Apotex Corp. deny the allegations of this Paragraph of the Amended Complaint.

100. On information and belief, Apotex knows, or should know, and intends that physicians will prescribe and patients will take Apotex's Generic Product for which approval is sought in ANDA No. 211236, and therefore will infringe at least one claim in the '354 patent.

ANSWER: Defendants Apotex Inc. and Apotex Corp. deny the allegations of this Paragraph of the Amended Complaint.

101. On information and belief, Apotex had knowledge of the '354 patent and, by its promotional activities and proposed package insert for Apotex's Generic Product, knows or

should know that it will induce direct infringement of at least one of the claims of the '354 patent, either literally or under the doctrine of equivalents.

ANSWER: Defendants Apotex Inc. and Apotex Corp. deny the allegations of this Paragraph of the Amended Complaint.

102. On information and belief, Apotex 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 Apotex's Generic Product according to the instructions in the proposed package insert in a way that directly infringes the '354 patent.

ANSWER: Defendants Apotex Inc. and Apotex Corp. deny the allegations of this Paragraph of the Amended Complaint.

103. The offering to sell, sale, making, and/or importation of Apotex's Generic Product would actively induce infringement of at least one of the claims of the '354 patent, either literally or under the doctrine of equivalents. Apotex has knowledge and is aware of Plaintiffs' '354 patent.

ANSWER: Defendants Apotex Inc. and Apotex Corp. are aware that Plaintiffs have filed this action alleging infringement of the '354 patent. Defendants Apotex Inc. and Apotex Corp. deny the allegations of this Paragraph of the Amended Complaint.

104. On information and belief, if ANDA No. 211236 is approved, Apotex intends to and will offer to sell, sell, and/or import in the United States Apotex's Generic Product.

ANSWER: Defendants Apotex Inc. and Apotex Corp. are without knowledge or information sufficient to form a belief as to the truth or falsity of the averments contained within this Paragraph of the Amended Complaint and on that basis deny such averments.

105. Apotex has had and continues to have knowledge that Apotex's Generic Product is especially adapted for a use that infringes the '354 patent.

ANSWER: **Defendants Apotex Inc. and Apotex Corp. deny the allegations of this Paragraph of the Amended Complaint.**

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

ANSWER: **Defendants Apotex Inc. and Apotex Corp. deny the allegations of this Paragraph of the Amended Complaint.**

107. On information and belief, Apotex's actions relating to Apotex's ANDA No. 211236 complained of herein were done by and for the benefit of Apotex.

ANSWER: **Defendants Apotex Inc. and Apotex Corp. deny the allegations of this Paragraph of the Amended Complaint.**

108. Plaintiffs will be irreparably harmed if Apotex is not enjoined from infringing or actively inducing infringement of at least one claim of the '354 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.

ANSWER: **Defendants Apotex Inc. and Apotex Corp. deny the allegations of this Paragraph of the Amended Complaint.**

COUNT IV
(DECLARATORY JUDGEMENT OF [ALLEGED] INFRINGEMENT OF THE '354 PATENT)

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

ANSWER: Defendants Apotex Inc. and Apotex Corp. incorporate by reference and reallege each of the responses in the foregoing paragraphs as if set forth specifically here.

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

ANSWER: This Paragraph of the Amended Complaint states Plaintiffs' alleged statutory basis for asserting jurisdiction in this action, which does not require an answer. .

111. There is an actual and justiciable controversy between Plaintiffs and Apotex concerning infringement of the '354 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.

ANSWER: This Paragraph of the Amended Complaint is a legal conclusion and does not require any answer. To the extent an answer is required, Apotex Inc. and Apotex Corp. deny the averments in this Paragraph of the Amended Complaint.

112. Apotex has made, and continues to make, substantial preparation in the United States to manufacture, offer to sell, sell and/or import Apotex's Generic Product prior to expiration of the '354 patent.

ANSWER: Defendants Apotex Inc. and Apotex Corp. deny the allegations of this Paragraph of the Amended Complaint.

113. Apotex's actions, including, but not limited to, submitting, or causing to be submitted to the FDA, ANDA No. 211236 seeking approval to manufacture, use, import, offer to sell and sell Apotex's Generic Product before the expiration date of the '354 patent and engaging in litigation, indicate a refusal to change the course of their actions in the face of knowledge of the '354 patent and acts by Plaintiffs.

ANSWER: Defendants Apotex Inc. and Apotex Corp. deny the allegations of this Paragraph of the Amended Complaint.

114. On information and belief, the FDA could approve Apotex's ANDA No. 211236 prior to expiration of the '354 patent and as early as the conclusion of the First Suit, which is currently scheduled for trial in January 2021.

ANSWER: Defendants Apotex Inc. and Apotex Corp. deny that they First Suit is scheduled for trial in January 2021. Defendants Apotex Inc. and Apotex Corp. are without knowledge or information sufficient to form a belief as to the truth or falsity of the remaining averments contained within this Paragraph of the Amended Complaint and on that basis deny such averments.

115. On information and belief, Apotex intends to manufacture, use, import, offer to sell and/or sell Apotex's Generic Product upon FDA approval of ANDA No. 211236.

ANSWER: Defendants Apotex Inc. and Apotex Corp. are without knowledge or information sufficient to form a belief as to the truth or falsity of the averments contained within this Paragraph of the Amended Complaint and on that basis deny such averments.

116. Upon FDA approval of ANDA No. 211236, Apotex will infringe one or more claims of the '354 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Apotex's Generic Product, and/or by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c).

ANSWER: Defendants Apotex Inc. and Apotex Corp. deny the allegations of this Paragraph of the Amended Complaint.

117. On information and belief, Apotex knows, or should know, and intends that physicians will prescribe and patients will take Apotex's Generic Product for which approval is sought in ANDA No. 211236, and therefore will infringe at least one claim in the '354 patent.

ANSWER: Defendants Apotex Inc. and Apotex Corp. deny the allegations of this Paragraph of the Amended Complaint.

118. On information and belief, Apotex had knowledge of the '354 patent and, by its promotional activities and proposed package insert for Apotex's Generic Product, knows or should know that it will induce direct infringement of at least one of the claims of the '354 patent, either literally or under the doctrine of equivalents.

ANSWER: Defendants Apotex Inc. and Apotex Corp. deny the allegations of this Paragraph of the Amended Complaint.

119. On information and belief, Apotex 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 Apotex's Generic Product according to the instructions in the proposed package insert in a way that directly infringes the '354 patent.

ANSWER: Defendants Apotex Inc. and Apotex Corp. deny the allegations of this Paragraph of the Amended Complaint.

120. The offering to sell, sale, making, and/or importation of Apotex's Generic Product would actively induce infringement of at least one of the claims of the '354 patent, either literally or under the doctrine of equivalents. Apotex has knowledge and is aware of Plaintiffs' '354 patent.

ANSWER: Defendants Apotex Inc. and Apotex Corp. deny the allegations of this Paragraph of the Amended Complaint.

121. On information and belief, if ANDA No. 211236 is approved, Apotex intends to and will offer to sell, sell, and/or import in the United States Apotex's Generic Product.

ANSWER: Defendants Apotex Inc. and Apotex Corp. are without knowledge or information sufficient to form a belief as to the truth or falsity of the averments contained within this Paragraph of the Amended Complaint and on that basis deny such averments.

122. Apotex has had and continues to have knowledge that Apotex's Generic Product is especially adapted for a use that infringes the '354 patent.

ANSWER: Defendants Apotex Inc. and Apotex Corp. deny the allegations of this Paragraph of the Amended Complaint.

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

ANSWER: Defendants Apotex Inc. and Apotex Corp. deny the allegations of this Paragraph of the Amended Complaint.

124. On information and belief, Apotex's actions relating to Apotex's ANDA No. 211236 complained of herein were done by and for the benefit of Apotex.

ANSWER: Defendants Apotex Inc. and Apotex Corp. deny the allegations of this Paragraph of the Amended Complaint.

125. Plaintiffs will be irreparably harmed if Apotex is not enjoined from infringing or actively inducing infringement of at least one claim of the '354 patent.

ANSWER: Defendants Apotex Inc. and Apotex Corp. deny the allegations of this Paragraph of the Amended Complaint.

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

ANSWER: Defendants Apotex Inc. and Apotex Corp. deny the allegations of this Paragraph of the Amended Complaint.

127. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale and/or importation of Apotex's Generic Product prior to expiration of the '354 patent by Apotex will constitute direct infringement, contributory infringement and/or active inducement of infringement of the '354 patent.

ANSWER: Defendants Apotex Inc. and Apotex Corp. deny the allegations of this Paragraph of the Amended Complaint.

COUNT V
([ALLEGED] INFRINGEMENT OF THE '536 PATENT UNDER 35 U.S.C. § 271(e)(2))

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

ANSWER: Defendants Apotex Inc. and Apotex Corp. incorporate by reference and reallege each of the responses in the foregoing paragraphs as if set forth specifically here.

129. On information and belief, Apotex filed ANDA No. 211236 in order to obtain approval to manufacture, use, import, offer to sell and/or sell Apotex's Generic Product in the United States before the expiration of the '536 patent.

ANSWER: Defendants Apotex Inc. and Apotex Corp. admit that Apotex Inc. provided BIAL-PORTELA & CA, S.A. and Sunovion Pharmaceutical Inc. with notice, dated January 23, 2018, pursuant to 21 U.S.C. §355(j)(2)(B)(iv) that Apotex Inc. had submitted to the FDA ANDA No. 211236, seeking approval to engage in the commercial manufacture, use, sale, and/or importation of eslicarbazepine acetate tablets in 200, 400, 600, and 800 mg dosage forms before the expiration of the '747; '431; '135; '244; '929; and '646 patents. Defendants Apotex Inc. and Apotex Corp. deny the remaining averments of this Paragraph of the Amended Complaint.

130. On information and belief, in its ANDA No. 211236, Apotex has represented to the FDA that Apotex's Generic Product is pharmaceutically and therapeutically equivalent to Plaintiffs' APTIOM® tablets.

ANSWER: Defendants Apotex Inc. and Apotex Corp. admit that Defendant Apotex Inc. filed ANDA No. 211236 with FDA for approval of the subject matter therein and that said ANDA is a document that speaks for itself. Defendants Apotex Inc. and Apotex Corp. deny any remaining averments in this Paragraph of the Amended Complaint.

131. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 211236 seeking approval for the commercial manufacture, use, or sale of Apotex's Generic Product before the expiration date of the '536 patent, constitutes infringement, either literally or under the doctrine of equivalents.

ANSWER: Defendants Apotex Inc. and Apotex Corp. deny the allegations of this Paragraph of the Amended Complaint.

132. Upon FDA approval of ANDA No. 211236, Apotex will infringe one or more claims of the '536 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Apotex'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. 211236 shall be no earlier than the expiration of the '536 patent and any additional periods of exclusivity.

ANSWER: Defendants Apotex Inc. and Apotex Corp. deny the allegations of this Paragraph of the Amended Complaint.

133. On information and belief, Apotex knows, or should know, and intends that physicians will prescribe and patients will take Apotex's Generic Product for which approval is sought in ANDA No. 211236, and therefore will infringe at least one claim in the '536 patent.

ANSWER: Defendants Apotex Inc. and Apotex Corp. deny the allegations of this Paragraph of the Amended Complaint.

134. On information and belief, Apotex had knowledge of the '536 patent and, by its promotional activities and proposed package insert for Apotex's Generic Product, knows or should know that it will induce direct infringement of at least one of the claims of the '536 patent, either literally or under the doctrine of equivalents.

ANSWER: Defendants Apotex Inc. and Apotex Corp. deny the allegations of this Paragraph of the Amended Complaint.

135. On information and belief, Apotex 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 Apotex's Generic Product according to the instructions in the proposed package insert in a way that directly infringes the '536 patent.

ANSWER: Defendants Apotex Inc. and Apotex Corp. deny the allegations of this Paragraph of the Amended Complaint.

136. The offering to sell, sale, making, and/or importation of Apotex's Generic Product would actively induce infringement of at least one of the claims of the '536 patent, either literally or under the doctrine of equivalents. Apotex has knowledge and is aware of Plaintiffs' '536 patent.

ANSWER: Defendants Apotex Inc. and Apotex Corp. are aware that Plaintiffs have filed this action alleging infringement of the '536 patent. Defendants Apotex Inc. and Apotex Corp. deny the allegations of this Paragraph of the Amended Complaint.

137. On information and belief, if ANDA No. 211236 is approved, Apotex intends to and will offer to sell, sell, and/or import in the United States Apotex's Generic Product.

ANSWER: Defendants Apotex Inc. and Apotex Corp. are without knowledge or information sufficient to form a belief as to the truth or falsity of the averments contained within this Paragraph of the Amended Complaint and on that basis deny such averments.

138. Apotex has had and continues to have knowledge that Apotex's Generic Product is especially adapted for a use that infringes the '536 patent.

ANSWER: Defendants Apotex Inc. and Apotex Corp. deny the allegations of this Paragraph of the Amended Complaint.

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

ANSWER: Defendants Apotex Inc. and Apotex Corp. deny the allegations of this Paragraph of the Amended Complaint.

140. On information and belief, Apotex's actions relating to Apotex's ANDA No. 211236 complained of herein were done by and for the benefit of Apotex.

ANSWER: Defendants Apotex Inc. and Apotex Corp. deny the allegations of this Paragraph of the Amended Complaint.

141. Plaintiffs will be irreparably harmed if Apotex is not enjoined from infringing or actively inducing infringement of at least one claim of the '536 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.

ANSWER: Defendants Apotex Inc. and Apotex Corp. deny the allegations of this Paragraph of the Amended Complaint.

COUNT VI
(DECLARATORY JUDGEMENT OF [ALLEGED] INFRINGEMENT OF THE '536 PATENT)

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

ANSWER: Defendants Apotex Inc. and Apotex Corp. incorporate by reference and reallege each of the responses in the foregoing paragraphs as if set forth specifically here.

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

ANSWER: This Paragraph of the Amended Complaint states Plaintiffs' alleged statutory basis for asserting jurisdiction in this action, which does not require an answer.

144. There is an actual and justiciable controversy between Plaintiffs and Apotex concerning infringement of the '536 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.

ANSWER: This Paragraph of the Amended Complaint is a legal conclusion and does not require any answer.

145. Apotex has made, and continues to make, substantial preparation in the United States to manufacture, offer to sell, sell and/or import Apotex's Generic Product prior to expiration of the '536 patent.

ANSWER: Defendants Apotex Inc. and Apotex Corp. deny the allegations of this Paragraph of the Amended Complaint.

146. Apotex's actions, including, but not limited to, submitting, or causing to be submitted to the FDA, ANDA No. 211236 seeking approval to manufacture, use, import, offer to sell and sell Apotex's Generic Product before the expiration date of the '536 patent and engaging in litigation, indicate a refusal to change the course of their actions in the face of knowledge of the '536 patent and acts by Plaintiffs.

ANSWER: Defendants Apotex Inc. and Apotex Corp. deny the allegations of this Paragraph of the Amended Complaint.

147. On information and belief, the FDA could approve Apotex's ANDA No. 211236 prior to expiration of the '536 patent and as early as the conclusion of the First Suit, which is currently scheduled for trial in January 2021.

ANSWER: Defendants Apotex Inc. and Apotex Corp. deny that they First Suit is scheduled for trial in January 2021. Defendants Apotex Inc. and Apotex Corp. are without knowledge or information sufficient to form a belief as to the truth or falsity of the remaining averments contained within this Paragraph of the Amended Complaint and on that basis deny such averments.

148. On information and belief, Apotex intends to manufacture, use, import, offer to sell and/or sell Apotex's Generic Product upon FDA approval of ANDA No. 211236.

ANSWER: Defendants Apotex Inc. and Apotex Corp. are without knowledge or information sufficient to form a belief as to the truth or falsity of the averments contained within this Paragraph of the Amended Complaint and on that basis deny such averments.

149. Upon FDA approval of ANDA No. 211236, Apotex will infringe one or more claims of the '536 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Apotex's Generic Product, and/or by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c).

ANSWER: Defendants Apotex Inc. and Apotex Corp. deny the allegations of this Paragraph of the Amended Complaint.

150. On information and belief, Apotex knows, or should know, and intends that physicians will prescribe and patients will take Apotex's Generic Product for which approval is sought in ANDA No. 211236, and therefore will infringe at least one claim in the '536 patent.

ANSWER: Defendants Apotex Inc. and Apotex Corp. deny the allegations of this Paragraph of the Amended Complaint.

151. On information and belief, Apotex had knowledge of the '536 patent and, by its promotional activities and proposed package insert for Apotex's Generic Product, knows or should know that it will induce direct infringement of at least one of the claims of the '536 patent, either literally or under the doctrine of equivalents.

ANSWER: Defendants Apotex Inc. and Apotex Corp. deny the allegations of this Paragraph of the Amended Complaint.

152. On information and belief, Apotex 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 Apotex's Generic Product according to the instructions in the proposed package insert in a way that directly infringes the '536 patent.

ANSWER: Defendants Apotex Inc. and Apotex Corp. deny the allegations of this Paragraph of the Amended Complaint.

153. The offering to sell, sale, making, and/or importation of Apotex's Generic Product would actively induce infringement of at least one of the claims of the '536 patent, either literally or under the doctrine of equivalents. Apotex has knowledge and is aware of Plaintiffs' '536 patent.

ANSWER: Defendants Apotex Inc. and Apotex Corp. deny the allegations of this Paragraph of the Amended Complaint.

154. On information and belief, if ANDA No. 211236 is approved, Apotex intends to and will offer to sell, sell, and/or import in the United States Apotex's Generic Product.

ANSWER: Defendants Apotex Inc. and Apotex Corp. are without knowledge or information sufficient to form a belief as to the truth or falsity of the averments contained within this Paragraph of the Amended Complaint and on that basis deny such averments.

155. Apotex has had and continues to have knowledge that Apotex's Generic Product is especially adapted for a use that infringes the '536 patent.

ANSWER: Defendants Apotex Inc. and Apotex Corp. deny the allegations of this Paragraph of the Amended Complaint.

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

ANSWER: Defendants Apotex Inc. and Apotex Corp. deny the allegations of this Paragraph of the Amended Complaint.

157. On information and belief, Apotex's actions relating to Apotex's ANDA No. 211236 complained of herein were done by and for the benefit of Apotex.

ANSWER: Defendants Apotex Inc. and Apotex Corp. deny the allegations of this Paragraph of the Amended Complaint.

158. Plaintiffs will be irreparably harmed if Apotex is not enjoined from infringing or actively inducing infringement of at least one claim of the '536 patent.

ANSWER: Defendants Apotex Inc. and Apotex Corp. deny the allegations of this Paragraph of the Amended Complaint.

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

ANSWER: Defendants Apotex Inc. and Apotex Corp. deny the allegations of this Paragraph of the Amended Complaint.

160. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale and/or importation of Apotex's Generic Product prior to expiration of the '536 patent by Apotex will constitute direct infringement, contributory infringement and/or active inducement of infringement of the '536 patent.

ANSWER: Defendants Apotex Inc. and Apotex Corp. deny the allegations of this Paragraph of the Amended Complaint.

GENERAL DENIAL

Any allegations in Plaintiffs' Amended Complaint not expressly admitted by Defendants Apotex Inc. and Apotex Corp. are hereby denied. Having answered Plaintiffs' Amended Complaint, Defendants Apotex Inc. and Apotex Corp. deny that Plaintiffs are entitled to the relief requested in Plaintiffs' Request for Relief or any relief whatsoever.

ADDITIONAL DEFENSES

Without prejudice to denials set forth in its Answer, and without admitting any allegations of the Complaint not otherwise admitted, Defendants Apotex Inc. and Apotex Corp. assert the following additional defenses to the Complaint without assuming the burden of proof on any such defense that would otherwise rest on the Plaintiffs.

FIRST ADDITIONAL DEFENSE: FAILURE TO STATE A CLAIM

Plaintiffs have failed to state a claim upon which relief can be granted.

SECOND ADDITIONAL DEFENSE: INVALIDITY OF THE '287 PATENT

The claims of the '287 patent are invalid for failure to satisfy one or more of the conditions for patentability contained in 35 U.S.C. §§ 101, 102, 103 and/or 112, double patenting or other judicially created bases for invalidation.

THIRD ADDITIONAL DEFENSE: NON-INFRINGEMENT OF THE '287 PATENT

The manufacture, use, sale, offer for sale or importation into the United States of the product that is the subject of ANDA No. 211236 has not infringed, does not infringe, and would not, if marketed, infringe one or more of the claims of the '287 patent, either literally or under the doctrine of equivalents. Nor would such actions make Defendants liable for inducing infringement or contributorily infringing the identified patent.

FOURTH ADDITIONAL DEFENSE: INVALIDITY OF THE '354 PATENT

The claims of the '354 patent are invalid for failure to satisfy one or more of the conditions for patentability contained in 35 U.S.C. §§ 101, 102, 103 and/or 112, double patenting or other judicially created bases for invalidation.

FIFTH ADDITIONAL DEFENSE: NON-INFRINGEMENT OF THE '354 PATENT

The manufacture, use, sale, offer for sale or importation into the United States of the product that is the subject of ANDA No. 211236 has not infringed, does not infringe, and would not, if marketed, infringe one or more of the claims of the '354 patent, either literally or under

the doctrine of equivalents. Nor would such actions make Defendants liable for inducing infringement or contributorily infringing the identified patent.

SIXTH ADDITIONAL DEFENSE: INVALIDITY OF THE '536 PATENT

The claims of the '536 patent are invalid for failure to satisfy one or more of the conditions for patentability contained in 35 U.S.C. §§ 101, 102, 103 and/or 112, double patenting or other judicially created bases for invalidation.

SEVENTH ADDITIONAL DEFENSE: NON-INFRINGEMENT OF THE '536 PATENT

The manufacture, use, sale, offer for sale or importation into the United States of the product that is the subject of ANDA No. 211236 has not infringed, does not infringe, and would not, if marketed, infringe one or more of the claims of the '536 patent, either literally or under the doctrine of equivalents. Nor would such actions make Defendants liable for inducing infringement or contributorily infringing the identified patent.

EIGHTH ADDITIONAL DEFENSE: 35 U.S.C. § 288

Plaintiffs are barred by 35 U.S.C. § 288 from recovering any costs associated with this Action.

RESERVATION OF DEFENSES

Defendants Apotex Inc. and Apotex Corp. reserve all affirmative defenses under the Federal Rules of Civil Procedure, defenses under the Patent Laws of the United States, and any other defenses at law or in equity, that may now exist or in the future be available.

COUNTERCLAIMS

Counter-plaintiffs Apotex Inc. and Apotex Corp., for its Counterclaims against Counter-defendants BIAL-PORTELA & CA S.A., BIAL-HOLDING, S.A., and Sunovion Pharmaceuticals Inc. (collectively, "Counter-defendants"), allege as follows:

PARTIES

1. Counter-defendants have alleged that BIAL-PORTELA & CA S.A. is a Portuguese corporation having its principal place of business at Av da Siderurgia Nacional, Coronado (São Romão e São Mamede), 4745 455 São Mamede do Coronado, Portugal. *See* Amended Complaint (D.I. 6), ¶ 1.

2. Counter-defendants have alleged that 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. *See* Amended Complaint (D.I. 6), ¶ 2.

3. Counter-defendants have alleged that 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. *See* Amended Complaint (D.I. 6), ¶ 4.

4. Apotex Inc. is a corporation organized and existing under the laws of Canada with a principal place of business at 150 Signet Drive, Toronto, Ontario, M9L 1T9, Canada.

5. Apotex Corp. is a corporation organized and existing under the laws of the State of Delaware, with a place of business at 2400 Commerce Parkway, Suite 400, Weston, Florida 33326.

JURISDICTION AND VENUE

6. These Counterclaims arise under the Patent Laws of the United States, 35 U.S.C. § 100 et seq., the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301 et seq., as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355) (hereinafter "Hatch-Waxman Amendments"), and the Medicare Prescription Drug, Improvement and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat.

2066 (2003) ("hereinafter "MMA").

7. This Court has original jurisdiction over the subject matter of these Counterclaims pursuant to 28 U.S.C. §§ 1331 and 1338(a).

8. This Court has personal jurisdiction over BIAL - PORTELA & CA S.A. in this district because BIAL - PORTELA & CA S.A. has availed itself to the rights and privileges of this forum by suing Apotex Inc. and Apotex Corp. in this District.

9. This Court has personal jurisdiction over BIAL - HOLDING, S.A. in this district because BIAL - HOLDING, S.A. has availed itself to the rights and privileges of this forum by suing Apotex Inc. and Apotex Corp. in this District.

10. This Court has personal jurisdiction over Sunovion Pharmaceuticals Inc. in this district because Sunovion Pharmaceuticals Inc. has availed itself to the rights and privileges of this forum by suing Apotex Inc. and Apotex Corp. in this District.

11. Venue is proper in this District under 28 U.S.C. §§ 1391(b), (c) and 1400 (b).

FACTUAL BACKGROUND

12. On or about June 9, 2020 the United States Patent and Trademark Office ("USPTO") issued United States Patent No. 10,675,287 ("the '287 Patent"), attached to the Amended Complaint (D.I. 6) as Exhibit A, entitled "Methods of Treatment of Partial Onset Seizures Using Eslicarbazepine Acetate."

13. Counter-defendants have alleged that BIAL - PORTELA & CA S.A. owns the rights to the '287 patent and that Sunovion Pharmaceuticals Inc. is the exclusive licensee in the United States of the '287 patent. *See* Amended Complaint (D.I. 6), ¶ 40.

14. On or about June 30, 2020, the USPTO issued United States Patent No. 10,695,354 ("the '354 Patent"), attached to the Amended Complaint (D.I. 6) as Exhibit B, entitled "Methods of Treatment of Partial Onset Seizures Using Eslicarbazepine Acetate."

15. Counter-defendants have alleged that BIAL - PORTELA & CA S.A. owns the rights to the '354 patent and that Sunovion Pharmaceuticals Inc. is the exclusive licensee in the United States of the '354 patent. *See* Amended Complaint (D.I. 6), ¶ 46.

16. On or about July 7, 2020, the USPTO issued United States Patent No. 10,702,536 ("the '536 patent"), attached to the Amended Complaint (D.I. 6) as Exhibit C, entitled "Methods of Treatment of Partial Onset Seizures Using Eslicarbazepine Acetate."

17. Counter-defendants have alleged that BIAL - PORTELA & CA S.A. owns the rights to the '536 patent and that Sunovion Pharmaceuticals Inc. is the exclusive licensee in the United States of the '536 patent. *See* Amended Complaint (D.I. 6), ¶ 52.

18. Each of the '287 patent, the '354 patent; and the '536 patent have been listed in connection with APTIOM® in the FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations,* commonly referred to as the "Orange Book".

19. Apotex Inc. is the current owner of FDA Abbreviated New Drug Application ("ANDA") No. 211236 seeking approval for the commercial manufacture, use, sale, offer for sale, and/or importation of Eslicarbazepine Acetate tablets, 200 mg, 400 mg, 600 mg, and 800 mg.

20. Apotex Inc. as the owner of ANDA No. 211236 has designated Apotex Corp. as its U.S. agent regarding all activities involving ANDA No. 211236.

21. As a result of BIAL - PORTELA & CA S.A., BIAL - HOLDING, S.A., and Sunovion Pharmaceuticals Inc.'s actions in listing of the '287 patent, the '354 patent; and the

'536 patent in the Orange Book and in suing Apotex for alleged infringement of the '287 patent, the '354 patent; and the '536 patent, Apotex is presently prevented from selling Eslicarbazepine Acetate tablets, 200 mg, 400 mg, 600 mg, and 800 mg and is being injured as a result. Apotex seeks patent certainty with respect to the '287 patent, the '354 patent; and the '536 patent regarding the legal rights relating to ANDA No. 211236 through a judicial declaration that the '287 patent, the '354 patent; and the '536 patent are invalid and/or not infringed by selling Eslicarbazepine Acetate tablets, 200 mg, 400 mg, 600 mg, and 800 mg. described in ANDA No. 211236.

22. A real, actual, and justiciable controversy exists between counter-plaintiffs Apotex Inc. and Apotex Corp. and counter-defendants regarding the invalidity and noninfringement of the '287 patent, the '354 patent; and the '536 patent constituting a case or actual controversy within the jurisdiction of this Court under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202.

COUNT I
(Declaration of Non-Infringement of the '287 Patent)

23. Apotex realleges and incorporates by reference paragraphs 1-22 of these Counterclaims.

24. The manufacture, use, sale, offer for sale, or importation into the United States of the Eslicarbazepine Acetate tablets, 200 mg, 400 mg, 600 mg, and 800 mg that are the subject of ANDA No. 211236 have not infringed, do not infringe, and would not, if marketed, infringe any valid or enforceable claim of the '287 patent. The Eslicarbazepine Acetate tablets, 200 mg, 400 mg, 600 mg, and 800 mg described in ANDA No. 211236 do not meet each and every limitation of any valid or enforceable claim of the '287 patent and therefore do not infringe the '287 patent.

25. Apotex is entitled to a declaration that the manufacture, use, sale, offer for sale, or importation into the United States of the Eslicarbazepine Acetate tablets, 200 mg, 400 mg, 600 mg, and 800 mg that are the subject of ANDA No. 211236 have not infringed, do not infringe, and would not, if marketed, infringe any valid or enforceable claim of the '287 patent.

COUNT II
(Declaration of Non-Infringement of the '354 Patent)

26. Apotex realleges and incorporates by reference paragraphs 1-25 of these Counterclaims.

27. The manufacture, use, sale, offer for sale, or importation into the United States of the Eslicarbazepine Acetate tablets, 200 mg, 400 mg, 600 mg, and 800 mg that are the subject of ANDA No. 211236 have not infringed, do not infringe, and would not, if marketed, infringe any valid or enforceable claim of the '354 patent. The Eslicarbazepine Acetate tablets, 200 mg, 400 mg, 600 mg, and 800 mg described in ANDA No. 211236 do not meet each and every limitation of any valid or enforceable claim of the '354 patent and therefore do not infringe the '354 patent.

28. Apotex is entitled to a declaration that the manufacture, use, sale, offer for sale, or importation into the United States of the Eslicarbazepine Acetate tablets, 200 mg, 400 mg, 600 mg, and 800 mg that are the subject of ANDA No. 211236 have not infringed, do not infringe, and would not, if marketed, infringe any valid or enforceable claim of the '354 patent.

COUNT III
(Declaration of Non-Infringement of the '536 Patent)

29. Apotex realleges and incorporates by reference paragraphs 1-28 of these Counterclaims.

30. The manufacture, use, sale, offer for sale, or importation into the United States of the Eslicarbazepine Acetate tablets, 200 mg, 400 mg, 600 mg, and 800 mg that are the subject

of ANDA No. 211236 have not infringed, do not infringe, and would not, if marketed, infringe any valid or enforceable claim of the '536 patent. The Eslicarbazepine Acetate tablets, 200 mg, 400 mg, 600 mg, and 800 mg described in ANDA No. 211236 do not meet each and every limitation of any valid or enforceable claim of the '536 patent and therefore do not infringe the '536 patent.

31. Apotex is entitled to a declaration that the manufacture, use, sale, offer for sale, or importation into the United States of the Eslicarbazepine Acetate tablets, 200 mg, 400 mg, 600 mg, and 800 mg that are the subject of ANDA No. 211236 have not infringed, do not infringe, and would not, if marketed, infringe any valid or enforceable claim of the '536 patent.

COUNT IV
(Declaration of Invalidity of the '287 Patent)

32. Apotex realleges and incorporates by reference paragraphs 1-31 of these Counterclaims.

33. The claims of the '287 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103 and/or 112, double patenting or other judicially created bases for invalidation.

34. Apotex is entitled to a declaration that the claims of the '287 patent are invalid.

COUNT V
(Declaration of Invalidity of the '354 Patent)

35. Apotex realleges and incorporates by reference paragraphs 1-34 of these Counterclaims.

36. The claims of the '354 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103 and/or 112, double patenting or other judicially created bases for invalidation.

37. Apotex is entitled to a declaration that the claims of the '354 patent are invalid.

COUNT VI
(Declaration of Invalidity of the '536 Patent)

38. Apotex realleges and incorporates by reference paragraphs 1-37 of these Counterclaims.

39. The claims of the '536 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103 and/or 112, double patenting or other judicially created bases for invalidation.

40. Apotex is entitled to a declaration that the claims of the '536 patent are invalid.

PRAYER FOR RELIEF

WHEREFORE, Apotex respectfully requests that this Court enter a Judgment and Order in their favor and against Counter-Defendants as follows:

a. Declaring that the manufacture, use, sale, offer for sale, or importation into the United States of Eslicarbazepine Acetate tablets, 200 mg, 400 mg, 600 mg, and 800 mg that are the subject of ANDA No. 211236 have not infringed, do not infringe, and would not, if marketed, infringe any valid or enforceable claim of the '287 patent.

b. Declaring that the manufacture, use, sale, offer for sale, or importation into the United States of Eslicarbazepine Acetate tablets, 200 mg, 400 mg, 600 mg, and 800 mg that are the subject of ANDA No. 211236 have not infringed, do not infringe, and would not, if marketed, infringe any valid or enforceable claim of the '354 patent.

c. Declaring that the manufacture, use, sale, offer for sale, or importation into the United States of Eslicarbazepine Acetate tablets, 200 mg, 400 mg, 600 mg, and 800 mg that are

the subject of ANDA No. 211236 have not infringed, do not infringe, and would not, if marketed, infringe any valid or enforceable claim of the '536 patent.

d. Declaring the claims of the '287 patent invalid.

e. Declaring the claims of the '354 patent invalid.

f. Declaring the claims of the '536 patent invalid.

g. Declaring that the Food & Drug Administration may approve Abbreviated New Drug Application (No. 211236) concerning Eslicarbazepine Acetate tablets, 200 mg, 400 mg, 600 mg, and 800 mg whenever that application is otherwise in condition for approval, without awaiting any further order, judgment, or decree of this Court; that the judgment entered in this case is a judgment reflecting a decision that the patents in suit are invalid or not infringed pursuant to 21 U.S.C. § 355(j)(5)(B)(iii)(I)(aa); and that the thirty-month period referred to in 21 U.S.C. § 355(j)(5)(B)(iii) and any other marketing exclusivity periods to which Counter-Defendants might otherwise be entitled (including any pediatric exclusivity) are shortened to expire upon the date of entry of judgment in this case.

h. Awarding Apotex costs, expenses, and reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

i. Awarding such other relief that the Court deems just and proper under the circumstances.

JURY DEMAND

Apotex Inc. and Apotex Corp. demand a trial by jury with respect to all issues that are triable as a matter of right.

Dated: August 11, 2020

Respectfully Submitted,

/s/ Damien Nicholas Tancredi

FLASTER/GREENBERG P.C.
Damien Nicholas Tancredi
1007 North Orange Street
Suite 400
Wilmington, DE 19801
(302) 351-1910
damien.tancredi@flastergreenberg.com

and

HAHN LOESER & PARKS, LLP
Steven E. Feldman (*pro hac vice*)
Sherry L. Rollo (*pro hac vice*)
Herve Jacquiau (*pro hac vice*)
200 West Madison Street, Suite 2700
Chicago, IL 60606
(312) 637-3000

Attorneys for Defendants, Apotex Inc. and Apotex Corp.

CERTIFICATE OF SERVICE

I hereby certify that on August 11, 2020, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF which will send electronic notification of such filing to all registered participants.

Dated: August 11, 2020

FLASTER/GREENBERG P.C.

/s/ Damien Nicholas Tancredi

Damien Nicholas Tancredi (DE No. 5395)
1007 N. Orange Street, Suite 400
Wilmington, DE 19801
Tel: (302) 351-1910
damien.tancredi@flastergreenberg.com