IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BIAL - PORTELA & CA S.A., BIAL - HOLDING, S.A., AND SUNOVION PHARMACEUTICALS INC., Plaintiffs, v. SPH SHANGHAI ZHONGXI PHARMACEUTICAL CO., LTD., Defendant.	)	C.A. No. 18-775-CFC

ANSWER TO COMPLAINT FOR PATENT INFRINGEMENT

Defendant SPH Shanghai Zhongxi Pharmaceutical Co., Ltd. ("Defendant" or "SPH"), by its attorneys, hereby responds to Plaintiffs', BIAL - PORTELA & CA S.A., BIAL - HOLDING, S.A., and Sunovion Pharmaceuticals Inc. (collectively, "Plaintiffs"), Complaint against Defendant SPH Shanghai Zhongxi Pharmaceutical Co., Ltd. ("SPH Shanghai Zhongxi"). This response is based on SPH's current knowledge as to its own activities, and on information and belief as to the activities of others, including Plaintiffs. If not specifically admitted herein, the allegations of the Complaint are denied.

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

THE PARTIES

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

Response: Upon information and belief, admitted.

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

Response: Upon information and belief, admitted.

3. BIAL - PORTELA & CA S.A. and BIAL - HOLDING, S.A. (collectively, "Bial") are in the business of developing innovative therapies for epilepsy, partial-onset seizures, and other related neurological conditions. Bial's asserted patent(s) cover APTIOM®, which is marketed and sold in this judicial district and throughout the United States by Sunovion Pharmaceuticals Inc. for treating partial-onset seizures in patients 4 years of age and older.

Response: Upon information and belief, admitted.

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

Response: Upon information and belief, admitted.

5. On information and belief, SPH Shanghai Zhongxi is a corporation organized and existing under the laws of the People's Republic of China, with its principal place of business at No. 446 Waiqingsong Road, Jiading District, Shanghai, 201806 China.

Response: Admitted.

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

Response: SPH admits that it submitted Abbreviated New Drug Application No.

("ANDA No. 211247") seeking FDA approval to market and sell a generic version of Aptiom® in the United States prior to the expiration of the patents-in-suit identified in paragraph 7 of the Complaint. SPH denies the remaining allegations.

NATURE OF THE ACTION

7. This is a civil action for patent infringement of U.S. Patent Nos. 5,753,646 ("the '646 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"), 9,750,747 ("the '747 patent), and 9,763,954 ("the '954 patent) (collectively, "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 Eslicarbazepine Acetate Tablets 200, 400, 600, and 800 mg Abbreviated New Drug Application No. 211247 ("ANDA No. 211247"), which SPH Shanghai Zhongxi filed or caused to be filed under 21 U.S.C. § 355(j) with the United States Food and Drug Administration ("FDA"), for approval to market in the United States a generic copy of Plaintiffs' APTIOM® product prior to the expiration of the patents-in-suit.

Response: SPH admits that the Complaint alleges infringement of the patents-in-suit under 35 U.S.C. § 271 and that the action relates to Eslicarbazepine Acetate Tablets 200, 400, 600, and 800 mg and ANDA No. 211247 filed by SPH seeking to market a generic version of Aptiom®. To the extent any additional allegations are contained in this paragraph, SPH denies same.

JURISDICTION AND VENUE

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

Response: SPH incorporates its responses to the prior paragraphs of this Answer that

correspond to the prior paragraphs referenced in paragraph 8 of Plaintiffs' Complaint as if fully set forth herein.

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

Response: SPH admits that the Complaint alleges infringement 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.

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

Response: Admitted.

11. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c), and 1400(b), because SPH Shanghai Zhongxi is incorporated in the People's Republic of China and may be sued in any judicial district in the United States in which it is subject to the court's personal jurisdiction. *See In re: HTC Corp.*, -- F.3d --, 2018 WL 2123357 (Fed. Cir. 2018).

Response: Paragraph 11 contains legal conclusions to which no answer is required. To the extent an answer is required, SPH, for purposes of this action only, does not contest that venue in Delaware is proper. SPH denies any remaining allegations.

12. This Court has personal jurisdiction over SPH Shanghai Zhongxi *inter alia*, under Federal Rule of Civil Procedure 4(k)(2), because SPH Shanghai Zhongxi is organized under the laws of the People's Republic of China.

Response: Paragraph 12 contains legal conclusions to which no answer is required. To the extent an answer is required, SPH, for purposes of this action only, does not dispute personal jurisdiction. SPH denies any remaining allegations.

13. Alternatively, this Court has personal jurisdiction over SPH Shanghai Zhongxi because at least one provision of the Delaware long-arm statute, 10 Del. C. § 3104(c), is satisfied. On information and belief, SPH Shanghai Zhongxi satisfies at least § 3104(c)(1) ("[t]ransacts any business or performs any character of work or service in the State), § 3104(c)(2) ("[c]ontracts to supply services or things in this State"), § 3104(c)(3) ("[c]auses tortious injury in the State by an act or omission in this State), § 3104(c)(4) ("[c]auses tortious injury in the State or outside of the State by an act or omission outside the State if the person regularly does or solicits business, engages in any other persistent course of conduct in the State or derives substantial revenue from services, or things used or consumed in the State"), and § 3104(c)(5) ("[h]as an interest in, uses or possesses real property in the State").

Response: Paragraph 13 contains legal conclusions to which no answer is required. To the extent an answer is required, SPH, for purposes of this action only, does not dispute personal jurisdiction. SPH denies any remaining allegations.

14. SPH Shanghai Zhongxi "has taken the costly, significant step of applying to the FDA for approval to engage in future activities—including the marketing of its generic drugs that will be purposefully directed at," on information and belief, Delaware and elsewhere. *Acorda Therapeutics Inc. v. Mylan Pharm. Inc.*, 817 F.3d 755, 759 (Fed. Cir. 2016), *cert. denied sub nom. Mylan Pharm. v. Acorda Therapeutics*, 137 S. Ct. 625, 196 L. Ed. 2d 580 (2017). SPH Shanghai Zhongxi's "ANDA filing[] constitute[s] formal acts that reliably indicate plans to engage in marketing of the proposed generic drugs." *Id.* at 760. On information and belief, SPH Shanghai Zhongxi "intends to direct sales of its drugs into Delaware, among other places, once it has the requested FDA approval to market them." *Id.* at 758. On information and belief, SPH Shanghai Zhongxi will engage in marketing of its proposed ANDA products in Delaware upon

approval of its ANDA.

Response: Paragraph 14 contains legal conclusions to which no answer is required. To the extent an answer is required, SPH, for purposes of this action only, does not dispute personal jurisdiction. SPH further admits it filed ANDA No. 211247. SPH denies any remaining allegations.

15. This Court also has personal jurisdiction over SPH Shanghai Zhongxi because, *inter alia*, this action arises from activities of SPH Shanghai Zhongxi directed toward Delaware.

Response: Paragraph 15 contains legal conclusions to which no answer is required. To the extent an answer is required, SPH, for purposes of this action only, does not dispute personal jurisdiction. SPH denies any remaining allegations.

16. This Court has personal jurisdiction over SPH Shanghai Zhongxi by virtue of the fact that, *inter alia*, it has committed—or aided, abetted, induced, contributed to, or participated in the commission of—the tortious act of patent infringement that has led and/or will lead to foreseeable harm and injury to Plaintiffs.

Response: Paragraph 16 contains legal conclusions to which no answer is required. To the extent an answer is required, SPH, for purposes of this action only, does not dispute personal jurisdiction. SPH denies any remaining allegations.

17. On information and belief, following FDA approval of ANDA No. 211247, SPH Shanghai Zhongxi will distribute and sell the generic product described in ANDA No. 211247 ("SPH Shanghai Zhongxi's Generic Product") throughout the United States, including in the State of Delaware.

Response: SPH denies the allegations of paragraph 17 as premature because SPH has not received approval of ANDA No. 211247 and no definitive decision has been made as to where

SPH intends to sell any approved generic version of Aptiom®.

18. For these reasons and other reasons that will be presented to the Court if jurisdiction is challenged, the Court has personal jurisdiction over SPH Shanghai Zhongxi.

Response: Paragraph 18 contains legal conclusions to which no answer is required. To the extent an answer is required, SPH, for purposes of this action only, does not dispute personal jurisdiction. SPH denies any remaining allegations.

FACTUAL BACKGROUND
The NDA

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

Response: SPH admits that the Orange Book lists Sunovion as the Application holder of NDA No. 022416 for Aptiom® (eslicarbazepine acetate) tablets in 200, 400, 600, and 800 mg strengths. SPH lacks knowledge or information sufficient to admit or deny the remaining allegations in paragraph 19 of the Complaint and therefore denies those allegations.

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

Response: SPH admits that, according to FDA electronic records, FDA approved NDA No. 022416 on November 8, 2013. SPH admits that on approval FDA stated: "This new drug application provides for the use of Aptiom (eslicarbazepine acetate) 200 mg, 400 mg, 600 mg, and 800 mg, tablets for adjunctive therapy in the treatment of partial-onset seizures in patients with epilepsy 18 years or older." SPH denies any remaining allegations.

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

Response: SPH admits that, according to FDA electronic records, FDA approved NDA

No. 022416/S-01 on August 27, 2015. SPH admits that the prescribing information for Aptiom® dated in the Supplemental Approval letter dated August 2015, recites in part "APTIOM (eslicarbazepine acetate) is indicated for the treatment of partial-onset seizures as monotherapy or adjunctive therapy." SPH denies any remaining allegations.

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

Response: SPH admits that, according to FDA electronic records, FDA approved NDA No. 022416/S-09 on September 13, 2017. SPH admits that the prescribing information for Aptiom® dated in the Supplemental Approval letter dated September 2017, recites in part "APTIOM is indicated for the treatment of partial-onset seizures in patients 4 years of age and older." SPH denies any remaining allegations.

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

Response: SPH admits that the prescribing information for Aptiom® dated in the Supplemental Approval letter dated September 2017, recites in part "APTIOM is indicated for the treatment of partial-onset seizures in patients 4 years of age and older." SPH admits that eslicarbazepine acetate is the active ingredient in Aptiom®.

The Patents-in-Suit

24. United States Patent No. 5,753,646 ("the '646 patent"), entitled "Substituted dihydrodibenzodiazazepines, method of their preparation, their use in the treatment of some central nervous system disorders, and pharmaceutical compositions containing them" was duly and legally issued by the United States Patent and Trademark Office on May 19, 1998. A true

and correct copy of the ’646 patent is attached as Exhibit A.

Response: SPH admits that the ’646 patent, entitled “Substituted dihydrodi-benzodiazazepines, method of their preparation, their use in the treatment of some central nervous system disorders, and pharmaceutical compositions containing them,” bears on its face an issue date of May 19, 1998. SPH further admits a purported true and correct copy of the ’431 patent was attached to the Complaint as Exhibit A. SPH is without information sufficient to admit or deny the remaining allegations contained in paragraph 24, and therefore denies the allegations.

25. BIAL - PORTELA & CA S.A. owns the rights to the ’646 patent. Sunovion is the exclusive licensee in the United States of the ’646 patent. The ’646 patent will expire on June 27, 2021.

Response: SPH admits that the cover page of the ’646 patent lists Bial - Portela as an assignee. SPG is without information sufficient to admit or deny the remaining allegations contained in paragraph 25, and therefore denies the allegations.

26. The ’646 patent is listed in the FDA Orange Book in connection with NDA No. 022416 for APTIOM® (Eslicarbazepine Acetate) Tablets.

Response: Admitted.

27. United States Patent No. 8,372,431 (“the ’431 patent”), entitled “Pharmaceutical composition comprising licarbazepine acetate” was duly and legally issued by the United States Patent and Trademark Office on February 12, 2013. A true and correct copy of the ’431 patent is attached as Exhibit B.

Response: SPH admits that the ’431 patent, entitled “Pharmaceutical composition comprising licarbazepine acetate,” bears on its face an issue date of February 12, 2013. SPH further admits a purported true and correct copy of the ’431 patent was attached to the Complaint

as Exhibit B. Torrent is without information sufficient to admit or deny the remaining allegations contained in paragraph 27, and therefore denies the allegations.

28. BIAL - PORTELA & CA S.A. owns the rights to the ’431 patent. Sunovion is the exclusive licensee in the United States of the ’431 patent. The ’431 patent will expire on April 17, 2030.

Response: SPH admits that the cover page of the ’431 patent lists Bial - Portela as an assignee. SPH is without information sufficient to admit or deny the remaining allegations contained in paragraph 28, and therefore denies the allegations.

29. The ’431 patent is listed in the FDA Orange Book in connection with NDA No. 022416 for APTIOM® (Eslicarbazepine Acetate) Tablets.

Response: Admitted.

30. United States Patent No. 9,206,135 (“the ’135 patent”), entitled “Asymmetric catalytic reduction of oxcarbazepine” was duly and legally issued by the United States Patent and Trademark Office on December 8, 2015. A true and correct copy of the ’135 patent is attached as Exhibit C.

Response: SPH admits that the ’135 patent, entitled “Asymmetric catalytic reduction of oxcarbazepine,” bears on its face an issue date of December 8, 2015. SPH further admits a purported true and correct copy of the ’135 patent was attached to the Complaint as Exhibit C. SPH is without information sufficient to admit or deny the remaining allegations contained in paragraph 30, and therefore denies the allegations.

31. BIAL - PORTELA & CA S.A. owns the rights to the ’135 patent. Sunovion is the exclusive licensee in the United States of the ’135 patent. The ’135 patent will expire on April 21, 2026.

Response: SPH admits that the cover page of the ’135 patent lists Bial - Portela as an assignee. SPH is without information sufficient to admit or deny the remaining allegations contained in paragraph 31, and therefore denies the allegations

32. The ’135 patent is listed in the FDA Orange Book in connection with NDA No. 022416 for APTIOM® (Eslicarbazepine Acetate) Tablets.

Response: Admitted.

33. United States Patent No. 9,566,244 (“the ’244 patent”), entitled “Pharmaceutical composition comprising licarbazepine acetate” was duly and legally issued by the United States Patent and Trademark Office on February 14, 2017. A true and correct copy of the ’244 patent is attached as Exhibit D.

Response: SPH admits that the ’244 patent, entitled “Pharmaceutical composition comprising licarbazepine acetate,” bears on its face an issue date of February 14, 2017. SPH further admits a purported true and correct copy of the ’244 patent was attached to the Complaint as Exhibit D. SPH is without information sufficient to admit or deny the remaining allegations contained in paragraph 33, and therefore denies the allegations.

34. BIAL - PORTELA & CA S.A. owns the rights to the ’244 patent. Sunovion is the exclusive licensee in the United States of the ’244 patent. The ’244 patent will expire on October 23, 2028.

Response: SPH admits that the cover page of the ’244 patent lists Bial - Portela as an assignee. SPH is without information sufficient to admit or deny the remaining allegations contained in paragraph 34, and therefore denies the allegations.

35. The ’244 patent is listed in the FDA Orange Book in connection with NDA No. 022416 for APTIOM® (Eslicarbazepine Acetate) Tablets.

Response: Admitted.

36. United States Patent No. 9,643,929 ("the '929 patent"), entitled "Asymmetric catalytic reduction of oxcarbazepine" was duly and legally issued by the United States Patent and Trademark Office on May 9, 2017. A true and correct copy of the '929 patent is attached as Exhibit E.

Response: SPH admits that the '929 patent, entitled "Asymmetric catalytic reduction of oxcarbazepine," bears on its face an issue date of May 9, 2017. SPH further admits a purported true and correct copy of the '929 patent was attached to the Complaint as Exhibit E. SPH is without information sufficient to admit or deny the remaining allegations contained in paragraph 36, and therefore denies the allegations.

37. BIAL - PORTELA & CA S.A. owns the rights to the '929 patent. Sunovion is the exclusive licensee in the United States of the '929 patent. The '929 patent will expire on April 21, 2026.

Response: SPH admits that the cover page of the '929 patent lists Bial - Portela as an assignee. SPH is without information sufficient to admit or deny the remaining allegations contained in paragraph 37, and therefore denies the allegations.

38. The '929 patent is listed in the FDA Orange Book in connection with NDA No. 022416 for APTIOM® (Eslicarbazepine Acetate) Tablets.

Response: Admitted.

39. United States Patent No. 9,750,747 ("the '747 patent"), entitled "Treatments involving eslicarbazepine acetate or eslicarbazepine" was duly and legally issued by the United States Patent and Trademark Office on September 5, 2017. A true and correct copy of the '747 patent is attached as Exhibit F.

Response: SPH admits that the '747 patent, entitled "Treatments involving eslicarbazepine acetate or eslicarbazepine," bears on its face an issue date of September 5, 2017. SPH further admits a purported true and correct copy of the '747 patent was attached to the Complaint as Exhibit F. SPH is without information sufficient to admit or deny the remaining allegations contained in paragraph 39, and therefore denies the allegations.

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

Response: SPH admits that the cover page of the '747 patent lists Bial - Portela as an assignee. SPH is without information sufficient to admit or deny the remaining allegations contained in paragraph 40, and therefore denies the allegations.

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

Response: Admitted.

42. United States Patent No. 9,763,954 ("the '954 patent"), entitled "Therapeutical uses of eslicarbazepine" was duly and legally issued by the United States Patent and Trademark Office on September 19, 2017. A true and correct copy of the '954 patent is attached as Exhibit G.

Response: SPH admits that the '954 patent, entitled "Therapeutical uses of eslicarbazepine," bears on its face an issue date of September 19, 2017. SPH further admits a purported true and correct copy of the '954 patent was attached to the Complaint as Exhibit G. SPH is without information sufficient to admit or deny the remaining allegations contained in paragraph 42, and therefore denies the allegations.

43. BIAL - PORTELA & CA S.A. owns the rights to the '954 patent. Sunovion is the exclusive licensee in the United States of the '954 patent. The '954 patent will expire on September 13, 2028.

Response: SPH admits that the cover page of the '954 patent lists Bial - Portela as an assignee. SPH is without information sufficient to admit or deny the remaining allegations contained in paragraph 43, and therefore denies the allegations.

44. The '954 patent is listed in the FDA Orange Book in connection with NDA No. 022416 for APTIOM® (Eslicarbazepine Acetate) Tablets.

Response: Admitted.

The ANDA

45. On information and belief, SPH Shanghai Zhongxi filed ANDA No. 211247 with the FDA under 21 U.S.C. § 355(j) to obtain FDA approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of (eslicarbazepine acetate) Tablets in 200, 400, 600, and 800 mg dosage forms, which are generic versions of Bial's APTIOM® (eslicarbazepine acetate) Tablets in 200, 400, 600, and 800 mg dosage forms.

Response: SPH admits that it filed ANDA No. 211247 with the FDA under 21 U.S.C. § 355(j) to obtain FDA approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of eslicarbazepine acetate tablets in 200, 400, 600, and 800 mg dosage forms. SPH further admits that ANDA No. 211247 references listed drug APTIOM® (eslicarbazepine acetate) tablets in 200, 400, 600, and 800 mg dosage forms. Torrent denies the remaining allegations of paragraph 45.

46. ANDA No. 211247 contains certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("paragraph IV certifications"), alleging that the claims of the patents-in-

suit are invalid, unenforceable, and/or would not be infringed by SPH Shanghai Zhongxi's Generic Product.

Response: Admitted.

47. On April 6, 2018 and April 9, 2018, Sunovion and Bial, respectively, received a letter sent by SPH Shanghai Zhongxi, dated April 6, 2018, purporting to be a "Notice of Certification" for ANDA No. 211247 ("SPH Shanghai Zhongxi's Notice Letter") pursuant to § 505(j)(2)(b)(iv) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. § 314.95. SPH Shanghai Zhongxi's Notice Letter notified Plaintiffs that SPH Shanghai Zhongxi had filed ANDA No. 211247, seeking approval to market SPH Shanghai Zhongxi's Generic Product prior to the expiration of the patents-in-suit.

Response: SPH admits that its Notice Letters to Plaintiffs notified Plaintiffs that ANDA No. 211247 had been filed and that SPH was seeking marketing approval from the FDA regarding its eslicarbazepine acetate ANDA products. SPH is without information sufficient to admit or deny the remaining allegations contained in paragraph 47, and therefore denies the allegations.

48. Plaintiffs commenced this action within 45 days of receiving SPH Shanghai Zhongxi's April 6, 2018 Notice Letter.

Response: SPH is without information sufficient to admit or deny the allegations contained in paragraph 48, and therefore denies the allegations.

COUNT I

(INFRINGEMENT OF THE '646 PATENT UNDER 35 U.S.C. § 271(e)(2))

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

Response: Paragraph 49 contains no allegations of fact to which a response is required.

If an answer is required, SPH incorporates by reference its responses to paragraphs 1-48 as if fully set forth herein.

50. On information and belief, SPH Shanghai Zhongxi filed ANDA No. 211247 in order to obtain approval to manufacture, use, import, offer to sell and/or sell SPH Shanghai Zhongxi's Generic Product in the United States before the expiration of the '646 patent.

Response: SPH admits that it filed ANDA No. 211247 with the FDA seeking regulatory approval to make and sell eslicarbazepine acetate tablets. SPH denies the remaining allegations in paragraph 50.

51. On information and belief, SPH Shanghai Zhongxi filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the '646 patent are purportedly invalid, unenforceable, and/or not infringed.

Response: Admitted.

52. On information and belief, in its ANDA No. 211247, SPH Shanghai Zhongxi has represented to the FDA that SPH Shanghai Zhongxi's Generic Product is pharmaceutically and therapeutically equivalent to Plaintiffs' APTIOM® tablets.

Response: Admitted.

53. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 211247 seeking approval for the commercial manufacture, use, or sale of SPH Shanghai Zhongxi's Generic Product before the expiration date of the '646 patent, constitutes infringement, either literally or under the doctrine of equivalents.

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

54. Upon FDA approval of ANDA No. 211247, SPH Shanghai Zhongxi will infringe one or more claims of the '646 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing SPH Shanghai Zhongxi'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. 211247 shall be no earlier than the expiration of the '646 patent and any additional periods of exclusivity.

Response: Denied; SPH's generic eslicarbazepine acetate tablets will not infringe any valid claim of the '646 patent.

55. On information and belief, SPH Shanghai Zhongxi knows, or should know, and intends that physicians will prescribe and patients will take SPH Shanghai Zhongxi's Generic Product for which approval is sought in ANDA No. 211247, and therefore will infringe at least one claim in the '646 patent.

Response: Denied; SPH's generic eslicarbazepine acetate tablets will not infringe any valid claim of the '646 patent.

56. On information and belief, SPH Shanghai Zhongxi had knowledge of the '646 patent and, by its promotional activities and proposed package insert for SPH Shanghai Zhongxi's Generic Product, knows or should know that it will induce direct infringement of at least one of the claims of the '646 patent, either literally or under the doctrine of equivalents.

Response: Denied; SPH's generic eslicarbazepine acetate tablets will not infringe any valid claim of the '646 patent. SPH further denies the allegations of paragraph 56 because SPH is not promoting its eslicarbazepine acetate products.

57. On information and belief, SPH Shanghai Zhongxi 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 SPH Shanghai Zhongxi's Generic Product according to the instructions in the proposed package insert in a way that directly infringes the '646 patent.

Response: Denied; SPH's generic eslicarbazepine acetate tablets will not infringe any valid claim of the '646 patent. SPH further denies the allegations of paragraph 57 because SPH is not advertising its eslicarbazepine acetate products.

58. The offering to sell, sale, making, and/or importation of SPH Shanghai Zhongxi's Generic Product would actively induce infringement of at least one of the claims of the '646 patent, either literally or under the doctrine of equivalents. SPH Shanghai Zhongxi has knowledge and is aware of Plaintiffs' '646 patent, as evidenced by SPH Shanghai Zhongxi's April 6, 2018 Notice Letter.

Response: Denied; SPH's generic eslicarbazepine acetate tablets will not infringe any valid claim of the '646 patent. SPH further denies the allegations of paragraph 58 because SPH is not advertising its eslicarbazepine acetate products.

59. On information and belief, if ANDA No. 211247 is approved, SPH Shanghai Zhongxi intends to and will offer to sell, sell, and/or import in the United States SPH Shanghai Zhongxi's Generic Product.

Response: SPH admits it filed ANDA No. 211247 seeking approval to market and sell eslicarbazepine acetate tablets in the United States. Currently, SPH is without information sufficient to admit or deny the remaining allegations contained in paragraph 59 and therefore denies the allegations.

60. SPH Shanghai Zhongxi has had and continues to have knowledge that SPH

Shanghai Zhongxi's Generic Product is especially adapted for a use that infringes the '646 patent.

Response: Denied.

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

Response: Denied.

62. On information and belief, SPH Shanghai Zhongxi's actions relating to SPH Shanghai Zhongxi's ANDA No. 211247 complained of herein were done by and for the benefit of SPH Shanghai Zhongxi.

Response: SPH is without information sufficient to admit or deny the allegations contained in paragraph 62 and therefore denies the allegations.

63. Plaintiffs will be irreparably harmed if SPH Shanghai Zhongxi is not enjoined from infringing or actively inducing infringement of at least one claim of the '646 patent. Pursuant to 35 U.S.C. § 283, Plaintiffs are entitled to a permanent injunction against further infringement. Plaintiffs do not have an adequate remedy at law.

Response: Denied.

COUNT II

(INFRINGEMENT OF THE '431 PATENT UNDER 35 U.S.C. § 271(e)(2))

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

Response: Paragraph 64 contains no allegations of fact to which a response is required. If an answer is required, SPH incorporates by reference its responses to paragraphs 1-63 as if fully set forth herein.

65. On information and belief, SPH Shanghai Zhongxi filed ANDA No. 211247 in order to obtain approval to manufacture, use, import, offer to sell and/or sell SPH Shanghai Zhongxi's Generic Product in the United States before the expiration of the '431 patent.

Response: SPH admits that it filed ANDA No. 211247 with the FDA seeking regulatory approval to make and sell eslicarbazepine acetate tablets. SPH denies the remaining allegations in paragraph 65.

66. On information and belief, SPH Shanghai Zhongxi filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the '431 patent are purportedly invalid, unenforceable, and/or not infringed.

Response: Admitted.

67. On information and belief, in its ANDA No. 211247, SPH Shanghai Zhongxi has represented to the FDA that SPH Shanghai Zhongxi's Generic Product is pharmaceutically and therapeutically equivalent to Plaintiffs' APTIOM® tablets.

Response: Admitted.

68. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 211247 seeking approval for the commercial manufacture, use, or sale of SPH Shanghai Zhongxi's Generic Product before the expiration date of the '431 patent, constitutes infringement, either literally or under the doctrine of equivalents.

Response: All of the allegations in paragraph 68 contain conclusions of law, to which no response is required. To the extent a response is required, SPH denies the allegations of paragraph 68.

69. Upon FDA approval of ANDA No. 211247, SPH Shanghai Zhongxi will infringe one or more claims of the '431 patent, either literally or under the doctrine of equivalents under

§ 271(a) by making, using, offering to sell, selling, and/or importing SPH Shanghai Zhongxi's Generic Product, and/or 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. 211247 shall be no earlier than the expiration of the '431 patent and any additional periods of exclusivity.

Response: Denied.

70. On information and belief, if ANDA No. 211247 is approved, SPH Shanghai Zhongxi intends to and will offer to sell, sell, and/or import in the United States SPH Shanghai Zhongxi's Generic Product.

Response: SPH admits it filed ANDA No. 211247 seeking approval to market and sell eslicarbazepine acetate tablets in the United States. Currently, SPH is without information sufficient to admit or deny the remaining allegations contained in paragraph 70 and therefore denies the allegations.

71. SPH Shanghai Zhongxi has had and continues to have knowledge that SPH Shanghai Zhongxi's Generic Product is especially adapted for a use that infringes the '431 patent.

Response: Denied.

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

Response: Denied.

73. On information and belief, SPH Shanghai Zhongxi's actions relating to SPH Shanghai Zhongxi's ANDA No. 211247 complained of herein were done by and for the benefit of SPH Shanghai Zhongxi.

Response: SPH is without information sufficient to admit or deny the allegations contained in paragraph 73 and therefore denies the allegations.

74. Plaintiffs will be irreparably harmed if SPH Shanghai Zhongxi is not enjoined from infringing and/or actively inducing infringement of at least one claim of the '431 patent. Pursuant to 35 U.S.C. § 283, Plaintiffs are entitled to a permanent injunction against further infringement. Plaintiffs do not have an adequate remedy at law.

Response: Denied.

COUNT III

(INFRINGEMENT OF THE '135 PATENT UNDER 35 U.S.C. § 271(e)(2))

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

Response: Paragraph 75 contains no allegations of fact to which a response is required. If an answer is required, SPH incorporates by reference its responses to paragraphs 1-74 as if fully set forth herein.

76. On information and belief, SPH Shanghai Zhongxi filed ANDA No. 211247 in order to obtain approval to manufacture, use, import, offer to sell and/or sell SPH Shanghai Zhongxi's Generic Product in the United States before the expiration of the '135 patent.

Response: SPH admits that it filed ANDA No. 211247 with the FDA seeking regulatory approval to make and sell eslicarbazepine acetate tablets. SPH denies the remaining allegations in paragraph 76.

77. On information and belief, SPH Shanghai Zhongxi filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the '135 patent are purportedly invalid, unenforceable, and/or not infringed.

Response: Admitted.

78. On information and belief, in its ANDA No. 211247, SPH Shanghai Zhongxi has represented to the FDA that SPH Shanghai Zhongxi's Generic Product is pharmaceutically and therapeutically equivalent to Plaintiffs' APTIOM® tablets.

Response: Admitted.

79. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 211247 seeking approval for the commercial manufacture, use, or sale of SPH Shanghai Zhongxi's Generic Product before the expiration date of the '135 patent, constitutes infringement, either literally or under the doctrine of equivalents.

Response: All of the allegations in paragraph 79 contain conclusions of law, to which no response is required. To the extent a response is required, SPH denies the allegations of paragraph 79.

80. Upon FDA approval of ANDA No. 211247, SPH Shanghai Zhongxi will infringe one or more claims of the '135 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing SPH Shanghai Zhongxi'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. 211247 shall be no earlier than the expiration of the '135 patent and any additional periods of exclusivity.

Response: Denied.

81. On information and belief, SPH Shanghai Zhongxi knows, or should know, and intends that physicians will prescribe and patients will take SPH Shanghai Zhongxi's Generic Product for which approval is sought in ANDA No. 211247, and therefore will infringe at least

one claim in the ’135 patent.

Response: Denied.

82. On information and belief, SPH Shanghai Zhongxi had knowledge of the ’135 patent and, by its promotional activities and proposed package insert for SPH Shanghai Zhongxi’s Generic Product, knows or should know that it will induce direct infringement of at least one of the claims of the ’135 patent, either literally or under the doctrine of equivalents.

Response: Denied.

83. On information and belief, SPH Shanghai Zhongxi 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 SPH Shanghai Zhongxi’s Generic Product according to the instructions in the proposed package insert in a way that directly infringes the ’135 patent.

Response: Denied.

84. The offering to sell, sale, making, and/or importation of SPH Shanghai Zhongxi’s Generic Product would actively induce infringement of at least one of the claims of the ’135 patent, either literally or under the doctrine of equivalents. SPH Shanghai Zhongxi has knowledge and is aware of Plaintiffs’ ’135 patent, as evidenced by SPH Shanghai Zhongxi’s April 6, 2018 Notice Letter.

Response: Denied.

85. On information and belief, if ANDA No. 211247 is approved, SPH Shanghai Zhongxi intends to and will offer to sell, sell, and/or import in the United States SPH Shanghai Zhongxi’s Generic Product.

Response: SPH admits it filed ANDA No. 211247 seeking approval to market and sell

eslicarbazepine acetate tablets in the United States. Currently, SPH is without information sufficient to admit or deny the remaining allegations contained in paragraph 85 and therefore denies the allegations.

86. SPH Shanghai Zhongxi has had and continues to have knowledge that SPH Shanghai Zhongxi's Generic Product is especially adapted for a use that infringes the '135 patent.

Response: Denied.

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

Response: Denied.

88. On information and belief, SPH Shanghai Zhongxi's actions relating to SPH Shanghai Zhongxi's ANDA No. 211247 complained of herein were done by and for the benefit of SPH Shanghai Zhongxi.

Response: SPH is without information sufficient to admit or deny the allegations contained in paragraph 88 and therefore denies the allegations.

89. Plaintiffs will be irreparably harmed if SPH Shanghai Zhongxi is not enjoined from infringing or actively inducing infringement of at least one claim of the '135 patent. Pursuant to 35 U.S.C. § 283, Plaintiffs are entitled to a permanent injunction against further infringement. Plaintiffs do not have an adequate remedy at law.

Response: Denied.

COUNT IV

(INFRINGEMENT OF THE '244 PATENT UNDER 35 U.S.C. § 271(e)(2))

90. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if

fully set forth herein.

Response: Paragraph 90 contains no allegations of fact to which a response is required. If an answer is required, SPH incorporates by reference its responses to paragraphs 1-89 as if fully set forth herein.

91. On information and belief, SPH Shanghai Zhongxi filed ANDA No. 211247 in order to obtain approval to manufacture, use, import, offer to sell and/or sell SPH Shanghai Zhongxi's Generic Product in the United States before the expiration of the '244 patent.

Response: SPH admits that it filed ANDA No. 211247 with the FDA seeking regulatory approval to make and sell eslicarbazepine acetate tablets. SPH denies the remaining allegations in paragraph 91.

92. On information and belief, SPH Shanghai Zhongxi filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the '244 patent are purportedly invalid, unenforceable, and/or not infringed.

Response: Admitted.

93. On information and belief, in its ANDA No. 211247, SPH Shanghai Zhongxi has represented to the FDA that SPH Shanghai Zhongxi's Generic Product is pharmaceutically and therapeutically equivalent to Plaintiffs' APTIOM® tablets.

Response: Admitted.

94. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 211247 seeking approval for the commercial manufacture, use, or sale of SPH Shanghai Zhongxi's Generic Product before the expiration date of the '244 patent, constitutes infringement, either literally or under the doctrine of equivalents.

Response: All of the allegations in paragraph 94 contain conclusions of law, to which no

response is required. To the extent a response is required, SPH denies the allegations of paragraph 94.

95. Upon FDA approval of ANDA No. 211247, SPH Shanghai Zhongxi will infringe one or more claims of the '244 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing SPH Shanghai Zhongxi's Generic Product, and/or 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. 211247 shall be no earlier than the expiration of the '244 patent and any additional periods of exclusivity.

Response: Denied.

96. On information and belief, if ANDA No. 211247 is approved, SPH Shanghai Zhongxi intends to and will offer to sell, sell, and/or import in the United States SPH Shanghai Zhongxi's Generic Product.

Response: SPH admits it filed ANDA No. 211247 seeking approval to market and sell eslicarbazepine acetate tablets in the United States. Currently, SPH is without information sufficient to admit or deny the remaining allegations contained in paragraph 96 and therefore denies the allegations.

97. SPH Shanghai Zhongxi has had and continues to have knowledge that SPH Shanghai Zhongxi's Generic Product is especially adapted for a use that infringes the '244 patent.

Response: Denied.

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

Response: Denied.

99. On information and belief, SPH Shanghai Zhongxi's actions relating to SPH Shanghai Zhongxi's ANDA No. 211247 complained of herein were done by and for the benefit of SPH Shanghai Zhongxi.

Response: SPH is without information sufficient to admit or deny the allegations contained in paragraph 99 and therefore denies the allegations.

100. Plaintiffs will be irreparably harmed if SPH Shanghai Zhongxi is not enjoined from infringing and/or actively inducing infringement of at least one claim of the '244 patent. Pursuant to 35 U.S.C. § 283, Plaintiffs are entitled to a permanent injunction against further infringement. Plaintiffs do not have an adequate remedy at law.

Response: Denied.

COUNT V

(INFRINGEMENT OF THE '929 PATENT UNDER 35 U.S.C. § 271(e)(2))

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

Response: Paragraph 101 contains no allegations of fact to which a response is required. If an answer is required, SPH incorporates by reference its responses to paragraphs 1-100 as if fully set forth herein.

102. On information and belief, SPH Shanghai Zhongxi filed ANDA No. 211247 in order to obtain approval to manufacture, use, import, offer to sell and/or sell SPH Shanghai Zhongxi's Generic Product in the United States before the expiration of the '929 patent.

Response: SPH admits that it filed ANDA No. 211247 with the FDA seeking regulatory approval to make and sell eslicarbazepine acetate tablets. SPH denies the remaining allegations

in paragraph 102.

103. On information and belief, SPH Shanghai Zhongxi filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the '929 patent are purportedly invalid, unenforceable, and/or not infringed.

Response: Admitted.

104. On information and belief, in its ANDA No. 211247, SPH Shanghai Zhongxi has represented to the FDA that SPH Shanghai Zhongxi's Generic Product is pharmaceutically and therapeutically equivalent to Plaintiffs' APTIOM® tablets.

Response: Admitted.

105. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 211247 seeking approval for the commercial manufacture, use, or sale of SPH Shanghai Zhongxi's Generic Product before the expiration date of the '929 patent, constitutes infringement, either literally or under the doctrine of equivalents.

Response: All of the allegations in paragraph 105 contain conclusions of law, to which no response is required. To the extent a response is required, SPH denies the allegations of paragraph 105.

106. Upon FDA approval of ANDA No. 211247, SPH Shanghai Zhongxi will infringe one or more claims of the '929 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing SPH Shanghai Zhongxi's Generic Product, and/or 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. 211247 shall be no earlier than the expiration of the '929 patent and any additional periods of exclusivity.

Response: Denied; SPH's generic eslicarbazepine acetate tablets will not infringe any valid claim of the '929 patent.

107. On information and belief, if ANDA No. 211247 is approved, SPH Shanghai Zhongxi intends to and will offer to sell, sell, and/or import in the United States SPH Shanghai Zhongxi's Generic Product.

Response: SPH admits it filed ANDA No. 211247 seeking approval to market and sell eslicarbazepine acetate tablets in the United States. Currently, SPH is without information sufficient to admit or deny the remaining allegations contained in paragraph 107 and therefore denies the allegations.

108. SPH Shanghai Zhongxi has had and continues to have knowledge that SPH Shanghai Zhongxi's Generic Product is especially adapted for a use that infringes the '929 patent.

Response: Denied.

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

Response: Denied.

110. On information and belief, SPH Shanghai Zhongxi's actions relating to SPH Shanghai Zhongxi's ANDA No. 211247 complained of herein were done by and for the benefit of SPH Shanghai Zhongxi.

Response: SPH is without information sufficient to admit or deny the allegations contained in paragraph 110 and therefore denies the allegations.

111. Plaintiffs will be irreparably harmed if SPH Shanghai Zhongxi is not enjoined from infringing and/or actively inducing infringement of at least one claim of the '929 patent.

Pursuant to 35 U.S.C. § 283, Plaintiffs are entitled to a permanent injunction against further infringement. Plaintiffs do not have an adequate remedy at law.

Response: Denied.

COUNT VI

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

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

Response: Paragraph 112 contains no allegations of fact to which a response is required. If an answer is required, SPH incorporates by reference its responses to paragraphs 1-111 as if fully set forth herein.

113. On information and belief, SPH Shanghai Zhongxi filed ANDA No. 211247 in order to obtain approval to manufacture, use, import, offer to sell and/or sell SPH Shanghai Zhongxi's Generic Product in the United States before the expiration of the '747 patent.

Response: SPH admits that it filed ANDA No. 211247 with the FDA seeking regulatory approval to make and sell eslicarbazepine acetate tablets. SPH denies the remaining allegations in paragraph 113.

114. On information and belief, SPH Shanghai Zhongxi filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the '747 patent are purportedly invalid, unenforceable, and/or not infringed.

Response: Admitted.

115. On information and belief, in its ANDA No. 211247, SPH Shanghai Zhongxi has represented to the FDA that SPH Shanghai Zhongxi's Generic Product is pharmaceutically and therapeutically equivalent to Plaintiffs' APTIOM® tablets.

Response: Admitted.

116. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 211247 seeking approval for the commercial manufacture, use, or sale of SPH Shanghai Zhongxi's Generic Product before the expiration date of the '747 patent, constitutes infringement, either literally or under the doctrine of equivalents.

Response: All of the allegations in paragraph 116 contain conclusions of law, to which no response is required. To the extent a response is required, SPH denies the allegations of paragraph 116.

117. Upon FDA approval of ANDA No. 211247, SPH Shanghai Zhongxi will infringe one or more claims of the '747 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing SPH Shanghai Zhongxi'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. 211247 shall be no earlier than the expiration of the '747 patent and any additional periods of exclusivity.

Response: Denied.

118. On information and belief, SPH Shanghai Zhongxi knows, or should know, and intends that physicians will prescribe and patients will take SPH Shanghai Zhongxi's Generic Product for which approval is sought in ANDA No. 211247, and therefore will infringe at least one claim in the '747 patent.

Response: Denied.

119. On information and belief, SPH Shanghai Zhongxi had knowledge of the '747 patent and, by its promotional activities and proposed package insert for SPH Shanghai Zhongxi's

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

Response: Denied.

120. On information and belief, SPH Shanghai Zhongxi 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 SPH Shanghai Zhongxi’s Generic Product according to the instructions in the proposed package insert in a way that directly infringes the ’747 patent.

Response: Denied.

121. The offering to sell, sale, making, and/or importation of SPH Shanghai Zhongxi’s Generic Product would actively induce infringement of at least one of the claims of the ’747 patent, either literally or under the doctrine of equivalents. SPH Shanghai Zhongxi has knowledge and is aware of Plaintiffs’ ’747 patent, as evidenced by SPH Shanghai Zhongxi’s April 6, 2018 Notice Letter.

Response: Denied.

122. On information and belief, if ANDA No. 211247 is approved, SPH Shanghai Zhongxi intends to and will offer to sell, sell, and/or import in the United States SPH Shanghai Zhongxi’s Generic Product.

Response: SPH admits it filed ANDA No. 211247 seeking approval to market and sell eslicarbazepine acetate tablets in the United States. Currently, SPH is without information sufficient to admit or deny the remaining allegations contained in paragraph 122 and therefore denies the allegations.

123. SPH Shanghai Zhongxi has had and continues to have knowledge that SPH

Shanghai Zhongxi's Generic Product is especially adapted for a use that infringes the '747 patent.

Response: Denied.

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

Response: Denied.

125. On information and belief, SPH Shanghai Zhongxi's actions relating to SPH Shanghai Zhongxi's ANDA No. 211247 complained of herein were done by and for the benefit of SPH Shanghai Zhongxi.

Response: SPH is without information sufficient to admit or deny the allegations contained in paragraph 125 and therefore denies the allegations.

126. Plaintiffs will be irreparably harmed if SPH Shanghai Zhongxi is not enjoined from infringing or actively inducing infringement of at least one claim of the '747 patent. Pursuant to 35 U.S.C. § 283, Plaintiffs are entitled to a permanent injunction against further infringement. Plaintiffs do not have an adequate remedy at law.

Response: Denied.

COUNT VII

(INFRINGEMENT OF THE '954 PATENT UNDER 35 U.S.C. § 271(e)(2))

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

Response: Paragraph 127 contains no allegations of fact to which a response is required. If an answer is required, SPH incorporates by reference its responses to paragraphs 1-126 as if fully set forth herein.

128. On information and belief, SPH Shanghai Zhongxi filed ANDA No. 211227 in order to obtain approval to manufacture, use, import, offer to sell and/or sell SPH Shanghai Zhongxi's Generic Product in the United States before the expiration of the '954 patent.

Response: SPH admits that it filed ANDA No. 211247[1] with the FDA seeking regulatory approval to make and sell eslicarbazepine acetate tablets. SPH denies the remaining allegations in paragraph 128.

129. On information and belief, SPH Shanghai Zhongxi filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the '954 patent are purportedly invalid, unenforceable, and/or not infringed.

Response: Admitted.

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

Response: Admitted.

131. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 211227 seeking approval for the commercial manufacture, use, or sale of SPH Shanghai Zhongxi's Generic Product before the expiration date of the '954 patent, constitutes infringement, either literally or under the doctrine of equivalents.

Response: All of the allegations in paragraph 131 contain conclusions of law, to which no response is required. To the extent a response is required, SPH denies the allegations of paragraph 131.

132. Upon FDA approval of ANDA No. 211227, SPH Shanghai Zhongxi will infringe

[1] SPH presumes Plaintiffs intended to reference ANDA No. 211247 as opposed to 211227 and answers based on that presumption at all points where such a typo in the Complaint occurred.

one or more claims of the '954 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing SPH Shanghai Zhongxi's Generic Product, and by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 211227 shall be no earlier than the expiration of the '954 patent and any additional periods of exclusivity.

Response: Denied.

133. On information and belief, SPH Shanghai Zhongxi knows, or should know, and intends that physicians will prescribe and patients will take SPH Shanghai Zhongxi's Generic Product for which approval is sought in ANDA No. 211227, and therefore will infringe at least one claim in the '954 patent.

Response: Denied.

134. On information and belief, SPH Shanghai Zhongxi had knowledge of the '954 patent and, by its promotional activities and proposed package insert for SPH Shanghai Zhongxi's Generic Product, knows or should know that it will induce direct infringement of at least one of the claims of the '954 patent, either literally or under the doctrine of equivalents.

Response: Denied.

135. On information and belief, SPH Shanghai Zhongxi 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 SPH Shanghai Zhongxi's Generic Product according to the instructions in the proposed package insert in a way that directly infringes the '954 patent.

Response: Denied

136. The offering to sell, sale, making, and/or importation of SPH Shanghai Zhongxi's Generic Product would actively induce infringement of at least one of the claims of the '954 patent, either literally or under the doctrine of equivalents. SPH Shanghai Zhongxi has knowledge and is aware of Plaintiffs' '954 patent, as evidenced by SPH Shanghai Zhongxi's April 6, 2018 Notice Letter.

Response: Denied.

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

Response: SPH admits it filed ANDA No. 211247 seeking approval to market and sell eslicarbazepine acetate tablets in the United States. Currently, SPH is without information sufficient to admit or deny the remaining allegations contained in paragraph 137 and therefore denies the allegations.

138. SPH Shanghai Zhongxi has had and continues to have knowledge that SPH Shanghai Zhongxi's Generic Product is especially adapted for a use that infringes the '954 patent.

Response: Denied.

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

Response: Denied.

140. On information and belief, SPH Shanghai Zhongxi's actions relating to SPH Shanghai Zhongxi's ANDA No. 211227 complained of herein were done by and for the benefit of SPH Shanghai Zhongxi.

Response: SPH is without information sufficient to admit or deny the allegations contained in paragraph 140 and therefore denies the allegations.

141. Plaintiffs will be irreparably harmed if SPH Shanghai Zhongxi is not enjoined from infringing or actively inducing infringement of at least one claim of the '954 patent. Pursuant to 35 U.S.C. § 283, Plaintiffs are entitled to a permanent injunction against further infringement. Plaintiffs do not have an adequate remedy at law.

Response: Denied.

[ANSWER TO] REQUEST FOR RELIEF

SPH denies that Plaintiffs are entitled do judgment and any relief sought by the Complaint in paragraphs (A) – (H) of its Request for Relief.

AFFIRMATIVE DEFENSES

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

FIRST DEFENSE
(Non-infringement)

SPH has not, does not, and will not infringe, contribute to the infringement of, and/or induce the infringement of any valid and enforceable claim of the patents-in-suit.

SECOND DEFENSE
(Invalidity)

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

THIRD DEFENSE
(Prosecution History Estoppel)

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

FOURTH DEFENSE
(Failure to State a Claim)

The Complaint fails to state a claim upon which relief may be granted and must be dismissed, especially since SPH has not infringed and will not infringe the patents-in-suit.

FIFTH DEFENSE
(Not an Exceptional Case/No Willful Infringement)

Plaintiffs are not entitled to a finding that this case is exceptional or to attorneys' fees under 35 U.S.C. § 285, or pursuant to the Court's inherent power. Plaintiffs' claims for enhanced damages based on a claim of willful infringement have no basis in law or fact.

JURY DEMAND

SPH hereby demands a jury on all issues so triable.

PRAYER FOR RELIEF

WHEREFORE, SPH prays this Court:

A. Enter an Order dismissing the Complaint, with prejudice, for failure to state a claim upon which relief can be granted.

B. Enter a judgment that SPH has not infringed the patents-in-suit by filing its ANDA No. 211247 or any amendments thereto, and that SPH's commercial manufacture, use, offer for sale, sale or importation of its proposed drug product does not directly or indirectly infringe any valid claim of the patents-in-suit.

C. Enter a judgment that the patents-in-suit are invalid and/or unenforceable.

D. Enter an Order dismissing the Complaint, with prejudice, and denying Plaintiffs the relief requested in the Complaint and any relief whatsoever.

E. Find this case to be exceptional under 35 U.S.C. § 285 and award SPH reasonable attorneys' fees and costs incurred in this litigation.

F. Enter an Order stating that the effective date of any FDA approval of SPH's eslicarbazepine acetate ANDA tablets shall not be stayed thirty months from the date of the Notice Letter, in accordance with 21 U.S.C. § 355(j)(5)(B)(iii);

G. Award SPH such other relief as the nature of this case may require and the Court may deem just, proper, and equitable.

Respectfully submitted,

GREENBERG TRAURIG, LLP

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Dated: September 24, 2018

CERTIFICATE OF SERVICE

I, Benjamin J. Schladweiler, hereby certify that on September 24, 2018, a true copy of the foregoing ***Answer to Complaint for Patent Infringement*** was served via electronic mail or via electronic service through the United States District Court for the District of Delaware's CM/ECF system upon the following counsel of record:

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