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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

AXSOME MALTA LTD. and AXSOME THERAPEUTICS, INC., **Plaintiffs,** **v.** **ALKEM LABORATORIES LTD.,** **Defendant.**	**Civil Action No. 2:25-cv-14694** **ANSWER TO THE COMPLAINT, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS**

Defendant Alkem Laboratories Ltd. ("Alkem" or "Defendant"), by their undersigned attorneys, for their Answer to the Complaint for Patent Infringement filed by Plaintiffs Axsome Malta Ltd. and Axsome Therapeutics, Inc. (collectively, "Plaintiffs"), state as follows. Pursuant to Fed R. Civ. P. 8(b)(3), Alkem denies all allegations in Plaintiffs' Complaint except those expressly admitted below.

Nature of the Action

1. This complaint is an action for patent infringement under the patent laws of the United States, 35 U.S.C. §100, *et seq.*, arising from Alkem's submission of Abbreviated New Drug Application ("ANDA") Nos. 218722 ("Alkem's ANDA"), with the United States Food and Drug Administration ("FDA") seeking approval to commercially market generic versions of Axsome's solriamfetol oral tablets drug products prior to the expiration of United States Patent Nos. 12,102,609 ("the '609 patent"), 12,194,016 ("the '016 patent"), 12,263,145 ("the '145 patent"),

and 12,318,362 ("the '362 patent") (collectively, "the patents-in-suit"). Axsome is the owner of the patents-in-suit.

ANSWER: Paragraph 1 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Alkem admits that Plaintiffs' Complaint purports to assert an action for patent infringement based on Alkem's filing of Abbreviated New Drug Application ("ANDA") No. 218722 seeking approval from the U.S. Food and Drug Administration ("FDA") to commercially market a generic solriamfetol product prior to the expiration of the patents-in-suit. Alkem is without sufficient information with which to form a belief as to the truth or accuracy of the remaining allegations of Paragraph 1 of the Complaint and therefore denies them.

The Parties

2. Plaintiff Axsome is a biopharmaceutical company focused on developing novel therapies for central nervous system ("CNS") conditions that have limited treatment options. One such therapy, Sunosi® (solriamfetol) oral tablets, is a dopamine and norepinephrine reuptake inhibitor ("DNRI") indicated to improve wakefulness in adult patients with excessive daytime sleepiness associated with narcolepsy or obstructive sleep apnea.

ANSWER: Alkem is without sufficient information with which to form a belief as to the truth or accuracy of the allegations in Paragraph 2 of the Complaint and, therefore, denies all allegations.

3. Axsome Malta Ltd. is a corporation organized and existing under the laws of the Republic of Malta, having its principal place of business at Pinto Business Centre, Level 4, Office 4, Mill Street, Qormi, Triq il-Mithna Hal, Malta, QRM 3104.

ANSWER: Alkem is without sufficient information with which to form a belief as to the truth or accuracy of the allegations in Paragraph 3 of the Complaint and, therefore, denies all allegations.

4. Axsome Therapeutics, Inc. is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at One World Trade Center, 29th Floor, New York, New York 10007.

ANSWER: Alkem is without sufficient information with which to form a belief as to the truth or accuracy of the allegations in Paragraph 4 of the Complaint and, therefore, denies all allegations.

5. On information and belief, Alkem is a corporation organized and existing under the laws of India, having a principal place of business at Devashish Building, Alkem House, Senapati Bapat Road, Lower Parel, Mumbai, 400 013, Maharashtra, India.

ANSWER: Admitted.

6. On information and belief, Alkem is a pharmaceutical company that formulates, manufactures, packages, and markets generic drug products for distribution in the District of New Jersey and throughout the United States.

ANSWER: Alkem admits that it is a pharmaceutical company that, among other things, develops and markets drug products for the United States market. Alkem denies the remaining allegations in Paragraph 6 of the Complaint.

The Patents-in-Suit

7. On October 1, 2024, the USPTO duly and lawfully issued the '609 patent, entitled, "Methods of Administering Solriamfetol to Lactating Women." The face of the '609 patent

identifies Herriot Tabuteau as the inventor. A copy of the '609 patent is attached hereto as Exhibit A.

ANSWER: Paragraph 7 contains legal conclusions to which no answer is required. To the extent an answer is required, Alkem admits that the '609 patent is entitled "Methods of Administering Solriamfetol to Lactating Women," that, on its face, the '609 patent identifies Herriot Tabuteau as the inventor, and that a purported copy of the '609 patent is attached as Exhibit A. Alkem denies that the '609 patent was "duly and lawfully issued," and further denies any remaining allegations of Paragraph 7.

8. On January 14, 2025, the USPTO duly and lawfully issued the '016 patent, entitled, "Methods of Providing Solriamfetol Therapy to Subjects with Impaired Renal Function." The face of the '016 patent identifies Katayoun Zomorodi as the inventor. A copy of the '016 patent is attached hereto as Exhibit B.

ANSWER: Paragraph 8 contains legal conclusions to which no answer is required. To the extent an answer is required, Alkem admits that the '016 patent is entitled "Methods of Providing Solriamfetol Therapy to Subjects with Impaired Renal Function," that, on its face, the '016 patent identifies Katayoun Zomorodi as the inventor, and that a purported copy of the '016 patent is attached as Exhibit B. Alkem denies that the '016 patent was "duly and lawfully issued," and further denies any remaining allegations of Paragraph 8.

9. On April 1, 2025, the USPTO duly and lawfully issued the '145 patent, entitled, "Methods of Administering Solriamfetol to Lactating Women." The face of the '145 patent identifies Herriot Tabuteau as the inventor. A copy of the '145 patent is attached hereto as Exhibit C.

ANSWER: Paragraph 9 contains legal conclusions to which no answer is required. To the extent an answer is required, Alkem admits that the '145 patent is entitled "Methods of Administering Solriamfetol to Lactating Women," that, on its face, the '145 patent identifies Herriot Tabuteau as the inventor, and that a purported copy of the '145 patent is attached as Exhibit C. Alkem denies that the '145 patent was "duly and lawfully issued," and further denies any remaining allegations of Paragraph 9.

10. On June 3, 2025, the USPTO duly and lawfully issued the '362 patent, entitled, "Methods of Providing Solriamfetol Therapy to Subjects with Impaired Renal Function." The face of the '362 patent identifies Katayoun Zomorodi as the inventor. A copy of the '362 patent is attached hereto as Exhibit D.

ANSWER: Paragraph 10 contains legal conclusions to which no answer is required. To the extent an answer is required, Alkem admits that the '362 patent is entitled "Methods of Providing Solriamfetol Therapy to Subjects with Impaired Renal Function," that, on its face, the '362 patent identifies Katayoun Zomorodi as the inventor, and that a purported copy of the '362 patent is attached as Exhibit D. Alkem denies that the '362 patent was "duly and lawfully issued," and further denies any remaining allegations of Paragraph 10.

The Sunosi® Drug Product

11. Axsome holds an approved New Drug Application ("NDA") under Section 505(a) of the Federal Food Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 355(a), for solriamfetol oral tablets, Eq. 75 mg base and Eq. 150 mg base ("NDA No. 211230"), which is sold under the trademark Sunosi®. Sunosi® is a DNRI indicated to improve wakefulness in adult patients with excessive daytime sleepiness associated with narcolepsy or obstructive sleep apnea. The claims of

the patents-in-suit cover, *inter alia*, methods of using Sunosi® to improve wakefulness in adult patients with excessive daytime sleepiness associated with narcolepsy or obstructive sleep apnea.

ANSWER: Upon information and belief, Alkem admits that Axsome is identified by the electronic version of the FDA's "Approved Drug Products with Therapeutic Equivalence Evaluations" ("Orange Book") as the holder of New Drug Application ("NDA") No. 211230 by which the FDA granted approval for the manufacture and sale of solriamfetol oral tablets, Eq. 75 mg base and Eq. 150 mg base. Alkem admits that the FDA-approved labeling for Sunosi® states the full and complete FDA-approved indications for Sunosi® and that the labeling speaks for itself. Alkem denies the remaining allegations in Paragraph 11 of the Complaint.

12. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the patents-in-suit are listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to Sunosi®.

ANSWER: Upon information and belief, Alkem admits that FDA's Orange Book lists the patents-in-suit as covering Axsome's Sunosi®. Alkem lacks knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of Paragraph 12 and, therefore, denies those allegations.

Jurisdiction and Venue

13. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

ANSWER: Paragraph 13 contains legal conclusions to which no answer is required. To the extent an answer is required, and solely to conserve the resources of the parties and the Court, Alkem does not contest personal jurisdiction for the limited purpose of this action only. Alkem denies all remaining allegations of Paragraph 13 of the Complaint.

14. As set forth below, the Court has personal jurisdiction over Alkem by virtue of, *inter alia*, its systematic and continuous contacts with the State of New Jersey.

ANSWER: Paragraph 14 contains legal conclusions to which no answer is required. To the extent an answer is required, and solely to conserve the resources of the parties and the Court, Alkem does not contest personal jurisdiction for the limited purpose of this action only. Alkem denies all remaining allegations of Paragraph 14 of the Complaint.

15. On information and belief, Alkem purposefully has conducted and continues to conduct business in this Judicial District.

ANSWER: Paragraph 15 contains legal conclusions to which no answer is required. To the extent an answer is required, and solely to conserve the resources of the parties and the Court, Alkem does not contest personal jurisdiction for the limited purpose of this action only. Alkem denies all remaining allegations of Paragraph 15 of the Complaint.

16. On information and belief, Alkem is in the business of, among other things, manufacturing, marketing, importing, offering for sale, and selling pharmaceutical products, including generic drug products, throughout the United States, including in this Judicial District.

ANSWER: Paragraph 16 contains legal conclusions to which no answer is required. To the extent an answer is required, and solely to conserve the resources of the parties and the Court, Alkem does not contest personal jurisdiction for the limited purpose of this action only. Alkem denies all remaining allegations of Paragraph 16 of the Complaint.

17. On information and belief, this Judicial District will be a destination for the generic version of Axsome's solriamfetol oral tablets drug products for which Alkem seeks FDA approval to manufacture, market, import, offer for sale, and/or sell pursuant to ANDA No. 218722 ("Alkem's Proposed Product").

ANSWER: Paragraph 17 contains legal conclusions to which no answer is required. To the extent an answer is required, and solely to conserve the resources of the parties and the Court, Alkem does not contest personal jurisdiction for the limited purpose of this action only. Alkem denies all remaining allegations of Paragraph 17 of the Complaint.

18. On information and belief, Alkem is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business ID No. 0400132325.

ANSWER: Admitted.

19. Alkem has consented to personal jurisdiction in this Court in numerous recent actions arising out of its ANDA submissions and has filed counterclaims in such cases. *See*, *e.g.*, *Azurity Pharm., Inc. v. Alkem Labs. Ltd.*, Civil Action No. 22-cv-0143 (D.N.J.); *Celgene Corp. v. Alkem Labs. Ltd.*, Civil Action No. 18-cv-11265 (D.N.J.); *Valeant Pharm. N. Am. LLC v. Alkem Labs. Ltd.*, Civil Action No. 18-cv-13905 (D.N.J.); *Sumitomo Dainippon Pharma Co. v. Alkem Labs. Ltd.*, Civil Action No. 18- cv-14787 (D.N.J.). Alkem has purposefully availed itself of the rights, benefits, and privileges of New Jersey by asserting counterclaims in this Court.

ANSWER: Paragraph 19 contains legal conclusions to which no answer is required. To the extent an answer is required, and solely to conserve the resources of the parties and the Court, Alkem does not contest personal jurisdiction for the limited purpose of this action only. Alkem denies all remaining allegations of Paragraph 19 of the Complaint.

20. Alkem did not contest personal jurisdiction in this Court in related actions *Axsome Malta Ltd., et al v. Alkem Laboratories Ltd., et al.*, Civil Action No. 23-20354 (MCA)(LDW) (D.N.J.) (consolidated) or *Axsome Malta Ltd., et al v. Alkem Laboratories Ltd., et al.*, Civil Action No. 24-10617 (MCA)(LDW) (D.N.J.) (consolidated).

ANSWER: Paragraph 20 contains legal conclusions to which no answer is required. To the extent an answer is required, and solely to conserve the resources of the parties and the Court, Alkem does not contest personal jurisdiction for the limited purpose of this action only. Alkem denies all remaining allegations of Paragraph 20 of the Complaint.

21. In the alternative, this Court has personal jurisdiction over Alkem because the requirements of Federal Rule of Civil Procedure 4(k)(2) are met as (a) Axsome's claims arise under federal law; (b) Alkem is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Alkem has sufficient contacts with the United States as a whole, including, but not limited to, preparing and submitting ANDAs to the FDA and/or manufacturing, importing, offering to sell, or selling pharmaceutical products that are distributed throughout the United States, such that this Court's exercise of jurisdiction over Alkem satisfies due process.

ANSWER: Paragraph 21 contains legal conclusions to which no answer is required. To the extent an answer is required, and solely to conserve the resources of the parties and the Court, Alkem does not contest personal jurisdiction for the limited purpose of this action only. Alkem denies all remaining allegations of Paragraph 21 of the Complaint.

22. At least because, on information and belief, Alkem is a foreign company, venue is proper in this Judicial District pursuant to 28 U.S.C. § 1391(c)(3) and 28 U.S.C. § 1400(b).

ANSWER: Paragraph 22 contains legal conclusions to which no answer is required. To the extent an answer is required, and solely to conserve the resources of the parties and the Court, Alkem does not contest venue for the limited purpose of this action only. Alkem denies all remaining allegations of Paragraph 22 of the Complaint.

Acts Giving Rise To This Suit

23. Pursuant to Section 505 of the FFDCA, Alkem submitted ANDA No. 218722 seeking approval to engage in the commercial manufacture, use, sale, offer for sale, or importation of Alkem's Proposed Product, before the patents-in-suit expire.

ANSWER: Alkem admits that it submitted ANDA No. 218722 seeking approval to market Alkem's Proposed Product. Alkem denies all remaining allegations of Paragraph 23 of the Complaint.

24. On information and belief, following FDA approval of Alkem's ANDA, Alkem will make, use, offer to sell, or sell Alkem's Proposed Product throughout the United States, or import such a generic product into the United States.

ANSWER: Denied.

25. On information and belief, in connection with the submission of its ANDA as described above, Alkem provided written certifications to the FDA, as called for by Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Alkem's Paragraph IV Certifications"), alleging, *inter alia*, that the claims of United States Patent Nos. 8,440,715, 10,195,151, 10,512,609, 10,912,754, 10,940,133, 10,959,976, 11,160,779, 11,439,597, 11,560,354, 11,648,232, 11,771,666, 11,771,667, 11,779,554, 11,793,776, 11,839,598, 11,839,599, 11,850,226, 11,850,227, 11,850,228, 11,857,528, 11,865,098, 11,872,203, 11,872,204, 11,969,404, 11,986,454, 11,986,455, 11,998,639, 12,005,036, 12,036,194, 12,064,411, 12,090,126, 12,102,609, 12,194,016, 12,263,145, and 12,318,362 are invalid and/or will not be infringed by the activities described in Alkem's ANDA.

ANSWER: Admitted.

26. No earlier than August 11, 2023, Alkem sent written notice of a Paragraph IV Certification ("Alkem's First Notice Letter") to Axsome. Alkem's First Notice Letter alleged, *inter alia*, that the claims of United States Patent Nos. 8,440,715, 10,195,151, 10,512,609, 10,912,754, 10,940,133, 10,959,976, 11,160,779, 11,439,597, 11,560,354, and 11,648,232 are invalid and/or will not be infringed by the activities described in Alkem's ANDA. Alkem's First Notice Letter also informed Axsome that Alkem seeks approval to market Alkem's Proposed Product before the expiration of United States Patent Nos. 8,440,715, 10,195,151, 10,512,609, 10,912,754, 10,940,133, 10,959,976, 11,160,779, 11,439,597, 11,560,354, and 11,648,232.

ANSWER: Alkem admits that it sent written notice of a Paragraph IV Certification ("Alkem's First Notice Letter") to Axsome on or around August 11, 2023. Alkem's Notice Letter speaks for itself. Alkem denies all remaining allegations of Paragraph 26 of the Complaint.

27. No earlier than March 29, 2024, Alkem sent written notice of a Paragraph IV Certification ("Alkem's Second Notice Letter") to Axsome. Alkem's Second Notice Letter alleged, *inter alia*, that the claims of United States Patent Nos. 11,839,598, 11,839,599, 11,850,226, 11,850,227, 11,850,228, 11,857,528, and 11,865,098 are invalid and/or will not be infringed by the activities described in Alkem's ANDA. Alkem's Second Notice Letter also informed Axsome that Alkem seeks approval to market Alkem's Proposed Product before the expiration of United States Patent Nos. 11,839,598, 11,839,599, 11,850,226, 11,850,227, 11,850,228, 11,857,528, and 11,865,098.

ANSWER: Alkem admits that it sent written notice of a Paragraph IV Certification ("Alkem's Second Notice Letter") to Axsome on or around March 29, 2024. Alkem's Notice Letter speaks for itself. Alkem denies all remaining allegations of Paragraph 27 of the Complaint.

28. No earlier than June 26, 2024, Alkem sent written notice of a Paragraph IV Certification ("Alkem's Third Notice Letter") to Axsome. Alkem's Third Notice Letter alleged, *inter alia*, that the claims of United States Patent Nos. 11,771,666, 11,771,667, 11,779,554, 11,793,776, 11,872,203, 11,872,204, 11,969,404, 11,986,454, 11,986,455, 11,998,639, and 12,005,036 are invalid and/or will not be infringed by the activities described in Alkem's ANDA. Alkem's Third Notice Letter also informed Axsome that Alkem seeks approval to market Alkem's Proposed Product before the expiration of United States Patent Nos. 11,771,666, 11,771,667, 11,779,554, 11,793,776, 11,872,203, 11,872,204, 11,969,404, 11,986,454, 11,986,455, 11,998,639, and 12,005,036.

ANSWER: Alkem admits that it sent written notice of a Paragraph IV Certification ("Alkem's Third Notice Letter") to Axsome on or around June 26, 2024. Alkem's Notice Letter speaks for itself. Alkem denies all remaining allegations of Paragraph 28 of the Complaint.

29. No earlier than October 15, 2024, Alkem sent written notice of a Paragraph IV Certification ("Alkem's Fourth Notice Letter") to Axsome. Alkem's Fourth Notice Letter alleged, *inter alia*, that the claims of United States Patent Nos. 12,036,194, 12,064,411, and 12,090,126 are invalid and/or will not be infringed by the activities described in Alkem's ANDA. Alkem's Fourth Notice Letter also informed Axsome that Alkem seeks approval to market Alkem's Proposed Product before the expiration of United States Patent Nos. 12,036,194, 12,064,411, and 12,090,126.

ANSWER: Alkem admits that it sent written notice of a Paragraph IV Certification ("Alkem's Fourth Notice Letter") to Axsome on or around October 15, 2024. Alkem's Notice Letter speaks for itself. Alkem denies all remaining allegations of Paragraph 29 of the Complaint.

30. No earlier than July 3, 2025, Alkem sent written notice of a Paragraph IV Certification ("Alkem's Fifth Notice Letter") to Axsome. Alkem's Fifth Notice Letter alleged, *inter alia*, that the claims of United States Patent Nos. 12,102,609, 12,194,016, 12,263,145, and 12,318,362 are invalid and/or will not be infringed by the activities described in Alkem's ANDA. Alkem's Fifth Notice Letter also informed Axsome that Alkem seeks approval to market Alkem's Proposed Product before the expiration of United States Patent Nos. 12,102,609, 12,194,016, 12,263,145, and 12,318,362.

ANSWER: Alkem admits that it sent written notice of a Paragraph IV Certification ("Alkem's Fifth Notice Letter") to Axsome on or around July 3, 2025. Alkem's Notice Letter speaks for itself. Alkem denies all remaining allegations of Paragraph 30 of the Complaint.

Count I: Infringement of the '609 Patent

31. Axsome repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

ANSWER: Alkem incorporates its answers to the preceding paragraphs as if fully set forth herein.

32. Alkem's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Alkem's Proposed Product, prior to the expiration of the '609 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

ANSWER: Denied.

33. A justiciable controversy exists between Axsome and Alkem as to the infringement of the '609 patent.

ANSWER: Paragraph 33 contains legal conclusions to which no answer is required. To the extent an answer is required, Alkem admits that there is a justiciable controversy. Alkem denies the remaining allegations of Paragraph 33.

34. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem will infringe one or more claims of the '609 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Alkem's Proposed Product in the United States.

ANSWER: Denied.

35. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem will induce infringement of one or more claims of the '609 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Alkem's Proposed Product in the United States. On information and belief, upon FDA approval of Alkem's ANDA, Alkem will intentionally encourage acts of direct infringement with knowledge of the '609 patent and knowledge that its acts are encouraging infringement.

ANSWER: Denied.

36. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem will contributorily infringe one or more claims of the '609 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Alkem's Proposed Product in the United States. On information and belief, Alkem knew and knows that Alkem's Proposed Product is designed for a use that infringes one or more claims of the '609 patent, and Alkem's Proposed Product lacks a substantial non-infringing use.

ANSWER: Denied.

37. Failure to enjoin Alkem's infringement of the '609 patent will substantially and irreparably damage and harm Axsome.

ANSWER: Denied.

38. Axsome does not have an adequate remedy at law.

ANSWER: Denied.

39. This case is an exceptional one, and Axsome is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

ANSWER: Denied.

Count II: Infringement of the '016 Patent

40. Axsome repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

ANSWER: Alkem incorporates its answers to the preceding paragraphs as if fully set forth herein.

41. Alkem's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Alkem's Proposed Product, prior to the expiration of the '016 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

ANSWER: Denied.

42. A justiciable controversy exists between Axsome and Alkem as to the infringement of the '016 patent.

ANSWER: Paragraph 42 contains legal conclusions to which no answer is required. To the extent an answer is required, Alkem admits that there is a justiciable controversy. Alkem denies the remaining allegations of Paragraph 42.

43. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem will infringe one or more claims of the '016 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Alkem's Proposed Product in the United States.

ANSWER: Denied.

44. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem will induce infringement of one or more claims of the '016 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Alkem's Proposed Product in the United States. On information and belief, upon FDA approval of Alkem's ANDA, Alkem will intentionally encourage acts of direct infringement with knowledge of the '016 patent and knowledge that its acts are encouraging infringement.

ANSWER: Denied.

45. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem will contributorily infringe one or more claims of the '016 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Alkem's Proposed Product in the United States. On information and belief, Alkem knew and knows that Alkem's Proposed Product is designed for a use that infringes one or more claims of the '016 patent, and Alkem's Proposed Product lacks a substantial non-infringing use.

ANSWER: Denied.

46. Failure to enjoin Alkem's infringement of the '016 patent will substantially and irreparably damage and harm Axsome.

ANSWER: Denied.

47. Axsome does not have an adequate remedy at law.

ANSWER: Denied.

48. This case is an exceptional one, and Axsome is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

ANSWER: Denied.

Count III: Infringement of the '145 Patent

49. Axsome repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

ANSWER: Alkem incorporates its answers to the preceding paragraphs as if fully set forth herein.

50. Alkem's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Alkem's Proposed Product, prior to the expiration of the '145 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

ANSWER: Denied.

51. A justiciable controversy exists between Axsome and Alkem as to the infringement of the '145 patent.

ANSWER: Paragraph 51 contains legal conclusions to which no answer is required. To the extent an answer is required, Alkem admits that there is a justiciable controversy. Alkem denies the remaining allegations of Paragraph 51.

52. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem will infringe one or more claims of the '145 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Alkem's Proposed Product in the United States.

ANSWER: Denied.

53. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem will induce infringement of one or more claims of the '145 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Alkem's Proposed Product in the United States. On information and belief, upon FDA approval of Alkem's ANDA, Alkem will intentionally encourage acts of direct infringement with knowledge of the '145 patent and knowledge that its acts are encouraging infringement.

ANSWER: Denied.

54. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem will contributorily infringe one or more claims of the '145 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Alkem's Proposed Product in the United States. On information and belief, Alkem knew and knows that Alkem's Proposed Product is designed for a use that infringes one or more claims of the '145 patent, and Alkem's Proposed Product lacks a substantial non-infringing use.

ANSWER: Denied.

55. Failure to enjoin Alkem's infringement of the '145 patent will substantially and irreparably damage and harm Axsome.

ANSWER: Denied.

56. Axsome does not have an adequate remedy at law.

ANSWER: Denied.

57. This case is an exceptional one, and Axsome is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

ANSWER: Denied.

Count IV: Infringement of the '362 Patent

58. Axsome repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

ANSWER: Alkem incorporates its answers to the preceding paragraphs as if fully set forth herein.

59. Alkem's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Alkem's Proposed Product, prior to the expiration of the '362 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

ANSWER: Denied.

60. A justiciable controversy exists between Axsome and Alkem as to the infringement of the '362 patent.

ANSWER: Paragraph 60 contains legal conclusions to which no answer is required. To the extent an answer is required, Alkem admits that there is a justiciable controversy. Alkem denies the remaining allegations of Paragraph 60.

61. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem will infringe one or more claims of the '362 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Alkem's Proposed Product in the United States.

ANSWER: Denied.

62. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem will induce infringement of one or more claims of the '362 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Alkem's Proposed

Product in the United States. On information and belief, upon FDA approval of Alkem's ANDA, Alkem will intentionally encourage acts of direct infringement with knowledge of the '362 patent and knowledge that its acts are encouraging infringement.

ANSWER: Denied.

63. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem will contributorily infringe one or more claims of the '362 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Alkem's Proposed Product in the United States. On information and belief, Alkem knew and knows that Alkem's Proposed Product is designed for a use that infringes one or more claims of the '362 patent, and Alkem's Proposed Product lacks a substantial non-infringing use.

ANSWER: Denied.

64. Failure to enjoin Alkem's infringement of the '362 patent will substantially and irreparably damage and harm Axsome.

ANSWER: Denied.

65. Axsome does not have an adequate remedy at law.

ANSWER: Denied.

66. This case is an exceptional one, and Axsome is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

ANSWER: Denied.

General Denial and Response to Prayer for Relief

To the extent not specifically admitted above, Alkem hereby denies all allegations in the Complaint. Alkem further denies that Plaintiffs are entitled to any relief whatsoever. Alkem denies

that Plaintiffs are entitled to the judgment or other relief prayed for in Paragraphs A-K of the Complaint under the heading PRAYER FOR RELIEF.

Alkem's Defenses

Without prejudice to the denials set forth in its Answer, without admitting allegations of the Complaint not otherwise admitted, and without undertaking any of the burdens imposed by law on Plaintiffs, Alkem avers and asserts the following separate defenses to the Complaint:

FIRST SEPARATE DEFENSE
(INVALIDITY OF THE '609 PATENT)

The claims of the '609 Patent are invalid and/or unenforceable under 35 U.S.C. §§ 101, *et seq*. including, *inter alia*, §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation.

SECOND SEPARATE DEFENSE
(NO DIRECT INFRINGEMENT OF THE '609 PATENT)

The manufacture, use, offer for sale, sale, or importation of the products described in ANDA No. 218722 do not and will not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '609 Patent.

THIRD SEPARATE DEFENSE
(NO INDIRECT INFRINGEMENT OF THE '609 PATENT)

The manufacture, use, offer for sale, sale, or importation of the products described in ANDA No. 218722 do not and will not induce the infringement of, and have not, do not, and will not contribute to the infringement of any valid and enforceable claim of the '609 Patent.

FOURTH SEPARATE DEFENSE
(INVALIDITY OF THE '016 PATENT)

The claims of the '016 Patent are invalid and/or unenforceable under 35 U.S.C. §§ 101, *et seq*. including, *inter alia*, §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation.

FIFTH SEPARATE DEFENSE
(NO DIRECT INFRINGEMENT OF THE '016 PATENT)

The manufacture, use, offer for sale, sale, or importation of the products described in ANDA No. 218722 do not and will not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '016 Patent.

SIXTH SEPARATE DEFENSE
(NO INDIRECT INFRINGEMENT OF THE '016 PATENT)

The manufacture, use, offer for sale, sale, or importation of the products described in ANDA No. 218722 do not and will not induce the infringement of, and have not, do not, and will not contribute to the infringement of any valid and enforceable claim of the '016 Patent.

SEVENTH SEPARATE DEFENSE
(INVALIDITY OF THE '145 PATENT)

The claims of the '145 Patent are invalid and/or unenforceable under 35 U.S.C. §§ 101, *et seq*. including, *inter alia*, §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation.

EIGHTH SEPARATE DEFENSE
(NO DIRECT INFRINGEMENT OF THE '145 PATENT)

The manufacture, use, offer for sale, sale, or importation of the products described in ANDA No. 218722 do not and will not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '145 Patent.

NINTH SEPARATE DEFENSE
(NO INDIRECT INFRINGEMENT OF THE '145 PATENT)

The manufacture, use, offer for sale, sale, or importation of the products described in ANDA No. 218722 do not and will not induce the infringement of, and have not, do not, and will not contribute to the infringement of any valid and enforceable claim of the '145 Patent.

TENTH SEPARATE DEFENSE
(INVALIDITY OF THE '362 PATENT)

The claims of the '362 Patent are invalid and/or unenforceable under 35 U.S.C. §§ 101, *et seq*. including, *inter alia*, §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation.

ELEVENTH SEPARATE DEFENSE
(NO DIRECT INFRINGEMENT OF THE '362 PATENT)

The manufacture, use, offer for sale, sale, or importation of the products described in ANDA No. 218722 do not and will not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '362 Patent.

TWELFTH SEPARATE DEFENSE
(NO INDIRECT INFRINGEMENT OF THE '362 PATENT)

The manufacture, use, offer for sale, sale, or importation of the products described in ANDA No. 218722 do not and will not induce the infringement of, and have not, do not, and will not contribute to the infringement of any valid and enforceable claim of the '362 Patent.

THIRTEENTH SEPARATE DEFENSE
(FAILURE TO STATE A CLAIM)

Plaintiffs' Complaint, in whole and/or in part, fails to state a claim upon which relief can be granted.

FOURTEENTH SEPARATE DEFENSE
(LACK OF SUBJECT MATTER JURISDICTION)

Plaintiffs' Complaint lacks subject matter jurisdiction over any and all claims asserted under 35 U.S.C. § 271(a), (b), and/or (c).

FIFTEENTH SEPARATE DEFENSE
(FAILURE TO STATE A CLAIM FOR EXCEPTIONAL OR WILLFUL INFRINGEMENT)

Plaintiffs fail to state a proper claim for an exceptional case and/or willful infringement.

SIXTEENTH AFFIRMATIVE DEFENSE

Plaintiffs are not entitled to injunctive relief against Alkem because Plaintiffs' alleged damages are not immediate or irreparable, and therefore Plaintiffs have an adequate remedy at law. Moreover, considering the balance of hardships between the parties, and the public interest in fostering the prompt introduction of generic pharmaceuticals to the market, the equitable remedy of a permanent injunction is not warranted in any event.

SEVENTEENTH AFFIRMATIVE DEFENSE

Plaintiffs are not entitled to attorney's fees against Alkem because Plaintiffs have not sufficiently alleged, and cannot prove, that this is an exceptional case under 35 U.S.C. § 285.

EIGHTEENTH AFFIRMATIVE DEFENSE

35 U.S.C. § 288 prevents Plaintiffs from recovering any costs associated with this action.

NINETEENTH AFFIRMATIVE DEFENSE

Plaintiffs' allegations are barred, in whole or in part, by the doctrines of waiver, estoppel and/or prosecution history estoppel.

RESERVATION OF ADDITIONAL SEPARATE DEFENSES

Alkem reserves the right to plead additional separate defenses or counterclaims that may be revealed through the course of discovery, including unenforceability.

ALKEM'S COUNTERCLAIMS

Defendant Alkem Laboratories Ltd. ("Alkem"), through counsel, hereby submits the following Counterclaims against Plaintiffs Axsome Malta Ltd. and Axsome Therapeutics, Inc. (collectively, "Axsome" or "Plaintiffs.").

PARTIES

1. On information and belief, Axsome Malta Ltd. is a corporation organized and existing under the laws of the Republic of Malta, having a principal place of business at Pinto Business Centre, Level 4, Office 4, Mill Street, Qormi, Triq il-Mithna Hal, Malta, QRM 3104.

2. On information and belief, Axsome Therapeutics, Inc., is a corporation organized and existing under the laws of Delaware, having a principal place of business at One World Trade Center, 22nd Floor, New York, New York 10007.

3. Alkem Laboratories Ltd. is a corporation organized and existing under the laws of India, having a principal place of business at Devashish Building, Alkem House, Senapati Bapat Road, Lower Parel, Mumbai, 400 013, Maharashtra, India.

NATURE OF THE ACTION

4. Alkem seeks declaratory judgment under the patent laws of the United States, 35 U.S.C. § 100, *et seq.* and the Declaratory Judgment Act, 28 U.S.C. § 2201, *et seq.*, that United States Patent Nos. 12,102,609 ("the '609 patent"), 12,194,016 ("the '016 patent"), 12,263,145 ("the '145 patent"), and 12,318,362 ("the '362 patent") (collectively, "the patents-in-suit") are invalid and/or not infringed.

JURISDICTION AND VENUE

5. This Court has jurisdiction over these counterclaims under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

6. This Court has personal jurisdiction over Axsome because, among other reasons, Axsome subjected itself to the jurisdiction of this Court by filing its complaint here.

7. Venue is proper in this Court under 28 U.S.C. §§ 1391(b) and 1400(b), and by Axsome's choice of forum.

8. There is an actual and justiciable controversy between the parties as to the infringement and invalidity of the patents-in-suit.

THE CONTROVERSY

9. Alkem holds Abbreviated New Drug Application ("ANDA") No. 218722 for solriamfetol oral tablets.

10. On or about August 15, 2025, Axsome filed the present action against Alkem alleging infringement of the patents-in-suit. Accordingly, there is a real, substantial, and continuing justiciable controversy between the parties concerning the patents-in-suit.

11. Alkem and Axsome have adverse legal interests with respect to the patents-in-suit of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

COUNT I
Declaratory Judgment of Invalidity of the '609 Patent

12. Alkem repeats and incorporates by reference the preceding paragraphs of its Counterclaims as if fully set forth herein.

13. Each and every asserted claim of United States Patent No. 12,102,609 is invalid for failing to satisfy one or more conditions of patentability set forth in Title 35, United States Code, including without limitation, §§ 101, 102, 103, 112 and/or 116, and/or is invalid under any other ground provided by 35 U.S.C. § 282 and/or based on other judicially-created bases for invalidity.

COUNT II
Declaratory Judgment of Noninfringement of the '609 Patent

14. Alkem repeats and incorporates by reference the preceding paragraphs of its Counterclaims as if fully set forth herein.

15. Alkem has not infringed, induced infringement, or contributed to the infringement, and Alkem will not infringe, induce infringement, or contribute to the infringement, either literally or under the doctrine of equivalents, of any valid and enforceable asserted claim of U.S. Patent No. 12,102,609.

COUNT III
Declaratory Judgment of Invalidity of the '016 Patent

16. Alkem repeats and incorporates by reference the preceding paragraphs of its Counterclaims as if fully set forth herein.

17. Each and every asserted claim of United States Patent No. 12,194,016 is invalid for failing to satisfy one or more conditions of patentability set forth in Title 35, United States Code, including without limitation, §§ 101, 102, 103, 112 and/or 116, and/or is invalid under any other ground provided by 35 U.S.C. § 282 and/or based on other judicially-created bases for invalidity.

COUNT IV
Declaratory Judgment of Noninfringement of the '016 Patent

18. Alkem repeats and incorporates by reference the preceding paragraphs of its Counterclaims as if fully set forth herein.

19. Alkem has not infringed, induced infringement, or contributed to the infringement, and Alkem will not infringe, induce infringement, or contribute to the infringement, either literally or under the doctrine of equivalents, of any valid and enforceable asserted claim of U.S. Patent No. 12,194,016.

COUNT V
Declaratory Judgment of Invalidity of the '145 Patent

20. Alkem repeats and incorporates by reference the preceding paragraphs of its Counterclaims as if fully set forth herein.

21. Each and every asserted claim of United States Patent No. 12,263,145 is invalid for failing to satisfy one or more conditions of patentability set forth in Title 35, United States Code, including without limitation, §§ 101, 102, 103, 112 and/or 116, and/or is invalid under any other ground provided by 35 U.S.C. § 282 and/or based on other judicially-created bases for invalidity.

COUNT VI
Declaratory Judgment of Noninfringement of the '145 Patent

22. Alkem repeats and incorporates by reference the preceding paragraphs of its Counterclaims as if fully set forth herein.

23. Alkem has not infringed, induced infringement, or contributed to the infringement, and Alkem will not infringe, induce infringement, or contribute to the infringement, either literally or under the doctrine of equivalents, of any valid and enforceable asserted claim of U.S. Patent No. 12,263,145.

COUNT VII
Declaratory Judgment of Invalidity of the '362 Patent

24. Alkem repeats and incorporates by reference the preceding paragraphs of its Counterclaims as if fully set forth herein.

25. Each and every asserted claim of United States Patent No. 12,318,362 is invalid for failing to satisfy one or more conditions of patentability set forth in Title 35, United States Code, including without limitation, §§ 101, 102, 103, 112 and/or 116, and/or is invalid under any other ground provided by 35 U.S.C. § 282 and/or based on other judicially-created bases for invalidity.

COUNT VIII
Declaratory Judgment of Noninfringement of the '362 Patent

26. Alkem repeats and incorporates by reference the preceding paragraphs of its Counterclaims as if fully set forth herein.

27. Alkem has not infringed, induced infringement, or contributed to the infringement, and Alkem will not infringe, induce infringement, or contribute to the infringement, either literally or under the doctrine of equivalents, of any valid and enforceable asserted claim of U.S. Patent No. 12,318,362.

ALKEM'S REQUEST FOR RELIEF

WHEREFORE, Alkem respectfully requests that:

(a) Judgment be entered that the Complaint against Alkem is dismissed with prejudice and that Plaintiffs take nothing thereby;

(b) Judgment be entered that each claim of the patents-in-suit is invalid;

(c) The Court permanently enjoin Plaintiffs or any of their assigns or successors from asserting that the commercial manufacture, use, offer to sell, sale or import of the products which are the subject of Alkem's ANDA No. 218722 infringe or will infringe any valid claim of the patents-in-suit;

(d) This case be deemed an exceptional case within the meaning of 35 U.S.C. § 285;

(e) Alkem be awarded its reasonable costs and attorney fees; and

(f) The Court award Alkem such other and further relief as this Court may deem necessary, just and proper.

Respectfully submitted,

Dated: November 3, 2025

/s/ Rebekah R. Conroy

Rebekah R. Conroy, Esq.
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Attorneys for Defendant Alkem Laboratories, Ltd.

CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 11.2

Pursuant to Local Civil Rule 11.2, Defendant Alkem Laboratories Ltd., by and through its undersigned counsel, hereby certifies that the matter in controversy is not subject to any other action pending in any court, or any pending arbitration or administrative proceeding known to Defendant, other than the matter captioned *Axsome v. Alkem, et al.*, Civil Action No. 23-cv-20354 (MCA)(LDW), *Axsome v. Alkem, et al.*, Civil Action No. 24-cv-04608 (MCA)(LDW), *Axsome v. Alkem, et al.*, Civil Action No. 24-cv-08365 (MCA)(LDW), *Axsome v. Alkem, et al.*, Civil Action No. 24-cv-09209 (MCA)(LDW), and *Axsome v. Alkem, et al.*, Civil Action No. 24-cv-10617 (MCA)(LDW) which also involve allegations regarding generic versions of Axsome's solriamfetol oral tablets drug products.

Respectfully submitted,

Dated: November 3, 2025

/s/ Rebekah R. Conroy
Rebekah R. Conroy, Esq.
STONE CONROY LLC
25A Hanover Road, Suite 301
Florham Park, New Jersey 07932
rconroy@stoneconroy.com

Attorneys for Defendant Alkem Laboratories, Ltd.

CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 201.1

Pursuant to Local Civil Rule 201.1, Defendant Alkem Laboratories Ltd., by and through its undersigned counsel, hereby certifies that this action seeks declaratory and injunctive relief, and therefore this action is not appropriate for compulsory arbitration.

Respectfully submitted,

Dated: November 3, 2025

/s/ Rebekah R. Conroy
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