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**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

AXSOME MALTA LTD. and AXSOME

THERAPEUTICS, INC.,

Plaintiffs,

v.

ALKEM LABORATORIES LTD.,

Defendant.

Civil Action No. _____

**COMPLAINT FOR PATENT
INFRINGEMENT**

(Filed Electronically)

Plaintiffs Axsome Malta Ltd. and Axsome Therapeutics, Inc. (together, “Axsome”), by their undersigned attorneys, for their Complaint against defendant Alkem Laboratories Ltd. (“Alkem”), allege as follows:

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”) No. 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. 12,384,743 (“the ’743 patent”) and 12,390,419 (“the ’419 patent”) (together, “the patents-in-suit”). Axsome is the owner of the patents-in-suit.

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.

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.

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.

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.

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.

The Patents-in-Suit

7. On August 12, 2025, the United States Patent and Trademark Office (“USPTO”) duly and lawfully issued the ’743 patent, entitled, “Compositions Comprising (R)-2-Amino-3-

Phenylpropyl Carbamate and Uses Thereof.” The face of the ’743 patent identifies Fionn Hurley as the inventor. A copy of the ’743 patent is attached hereto as Exhibit A.

8. On August 19, 2025, the USPTO duly and lawfully issued the ’419 patent, entitled, “Formulations of (R)-2-Amino-3-Phenylpropyl Carbamate.” The face of the ’419 patent identifies Clark Patrick Allphin and Edwin Gerard Walsh as the inventors. A copy of the ’419 patent is attached hereto as Exhibit B.

The Sunosi® Drug Product

9. 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*, solid forms of solriamfetol, formulations of solriamfetol, and methods of using solriamfetol to improve wakefulness in adult patients with excessive daytime sleepiness associated with narcolepsy or obstructive sleep apnea.

10. 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®.

Jurisdiction and Venue

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

12. 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.

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

14. 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.

15. 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").

16. 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.

17. 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.

18. 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) and *Axsome Malta Ltd., et al. v. Alkem Lab'ys Ltd., et al.*, Civil Action No. 24-10617 (MCA)(LDW) (D.N.J.) (consolidated).

19. 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.

20. 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).

Acts Giving Rise To This Suit

21. 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.

22. 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.

23. 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, 12,318,362, 12,384,743, and 12,390,419 are invalid and/or will not be infringed by the activities described in Alkem's ANDA.

24. No earlier than August 11, 2023, Alkem sent written notice of Alkem's first Paragraph IV Certification to Axsome ("Alkem's First Notice Letter"). 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.

25. No earlier than March 29, 2024, Alkem sent written notice of Alkem's second Paragraph IV Certification to Axsome ("Alkem's Second Notice Letter"). 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.

26. No earlier than June 26, 2024, Alkem sent written notice of Alkem's third Paragraph IV Certification to Axsome ("Alkem's Third Notice Letter"). 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.

27. No earlier than October 15, 2024, Alkem sent written notice of Alkem's fourth Paragraph IV Certification to Axsome ("Alkem's Fourth Notice Letter"). 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.

28. No earlier than July 3, 2025, Alkem sent written notice of Alkem's fifth Paragraph IV Certification to Axsome ("Alkem's Fifth Notice Letter"). Alkem's Fifth Notice Letter alleged, *inter alia*, that the claims of United States Patent Nos. 12,194,016, 12,102,609, 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. 12,194,016, 12,102,609, 12,263,145, and 12,318,362.

29. No earlier than October 1, 2025, Alkem sent written notice of Alkem's sixth Paragraph IV Certification to Axsome ("Alkem's Sixth Notice Letter"). Alkem's Sixth Notice Letter alleged, *inter alia*, that the claims of the patents-in-suit are invalid and/or will not be infringed by the activities described in Alkem's ANDA. Alkem's Sixth Notice Letter also informed Axsome that Alkem seeks approval to market Alkem's Proposed Product before the expiration of the patents-in-suit.

Count I: Infringement of the '743 Patent

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

31. 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 '743 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.

32. A justiciable controversy exists between Axsome and Alkem as to the infringement of the '743 patent.

33. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem will infringe one or more claims of the '743 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.

34. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem will induce infringement of one or more claims of the '743 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 '743 patent and knowledge that its acts are encouraging infringement.

35. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem will contributorily infringe one or more claims of the '743 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 '743 patent, and Alkem's Proposed Product lacks a substantial non-infringing use.

36. Failure to enjoin Alkem's infringement of the '743 patent will substantially and irreparably damage and harm Axsome.

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

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

Count II: Infringement of the '419 Patent

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

40. 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 '419 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.

41. A justiciable controversy exists between Axsome and Alkem as to the infringement of the '419 patent.

42. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem will infringe one or more claims of the '419 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.

43. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem will induce infringement of one or more claims of the '419 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 '419 patent and knowledge that its acts are encouraging infringement.

44. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem will contributorily infringe one or more claims of the '419 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 '419 patent, and Alkem's Proposed Product lacks a substantial non-infringing use.

45. Failure to enjoin Alkem's infringement of the '419 patent will substantially and irreparably damage and harm Axsome.

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

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

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Axsome respectfully requests the following relief:

- (A) A Judgment that Alkem infringed one or more claims of the patents-in-suit by submitting ANDA No. 218722;
- (B) A Judgment that Alkem has infringed, and that Alkem's making, using, offering to sell, selling, or importing Alkem's Proposed Product will infringe one or more claims of the patents-in-suit;
- (C) An Order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of FDA approval of ANDA No. 218722 be a date no earlier than the later of the expiration of the patents-in-suit, or any later expiration of exclusivity to which Axsome is or becomes entitled;
- (D) Preliminary and permanent injunctions enjoining Alkem and its officers, agents, attorneys and employees, and those acting in privity and/or concert with them, from making, using, offering to sell, selling, or importing Alkem's Proposed Product until after the expiration of the patents-in-suit, or any later expiration of exclusivity to which Axsome is or becomes entitled;
- (E) A permanent injunction, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Alkem, its officers, agents, attorneys and employees, and those acting in privity and/or concert with them, from practicing any solid form, formulation, or method claimed in the patents-in-suit, or from actively inducing or contributing to the infringement of any claim of the patents-in-suit, until after the expiration of the patents-in-suit, or any later expiration of exclusivity to which Axsome is or becomes entitled;
- (F) A Judgment that the commercial manufacture, use, importation into the United States, offer for sale, and/or sale of Alkem's Proposed Product will directly infringe, induce and/or contribute to infringement of one or more claims of the patents-in-suit;

(G) To the extent that Alkem has committed any acts with respect to the solid forms, formulations, or methods claimed in the patents-in-suit, a Judgment awarding Axsome damages for such acts;

(H) If Alkem engages in the manufacture, use, importation into the United States, offer for sale, and/or sale of Alkem's Proposed Product prior to the expiration of the patents-in-suit, a Judgment awarding damages to Axsome resulting from such infringement, together with interest;

(I) A Judgment declaring that the patents-in-suit remain valid and enforceable;

(J) A Judgment that this is an exceptional case pursuant to 35 U.S.C. § 285 and awarding Axsome its attorneys' fees, costs, and expenses incurred in this action; and

(K) Such further and other relief as this Court may deem just and proper.

Dated: November 12, 2025

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CERTIFICATION PURSUANT TO L. CIV. R. 11.2 & 40.1

Pursuant to Local Civil Rules 11.2 and 40.1, I hereby certify that the matters captioned *Axsome Malta Ltd., et al. v. Alkem Lab'ys Ltd., et al.*, Civil Action No. 23-20354 (MCA)(LDW) (D.N.J.) (consolidated), *Axsome Malta Ltd., et al. v. Alkem Lab'ys Ltd., et al.*, Civil Action No. 24-10617 (MCA)(LDW) (D.N.J.) (consolidated), and *Axsome Malta Ltd., et al. v. Alkem Lab'ys Ltd.*, Civil Action No. 25-14694 (MCA)(LDW) (D.N.J.) are related to the matter in controversy because the matter in controversy involves the same plaintiffs and one of the same defendants, and because Alkem is seeking FDA approval to market a generic version of the same pharmaceutical product.

Dated: November 12, 2025

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