Rebekah R. Conroy, Esq.
STONE CONROY LLC
25A Hanover Road, Suite 301
Florham Park, New Jersey 07932
Tel: 973-400-4181
rconroy@stoneconroy.com

Attorneys for Defendant Alkem Laboratories, Ltd.

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

AXSOME MALTA LTD. and AXSOME THERAPEUTICS, INC.,

Plaintiffs,

v.

ALKEM LABORATORIES, LTD., AUROBINO PHARMA USA, INC., AURO BINDO PHARMA LIMITED, HETERO USA INC., HETERO LABS LIMITED UNIT-V, HETERO LABS LTD., and HIKMA PHARMACEUTICALS USA INC.,

Defendants.

Civil Action No. 2:24-CV-9209

DEFENDANT ALKEM LABORATORIES LTD.'S ANSWER TO THE COMPLAINT, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS

Defendant Alkem Laboratories Ltd. ("Alkem"), by its undersigned attorneys, for its Answer to the Complaint for Patent Infringement filed by Plaintiffs Axsome Malta Ltd. and Axsome Therapeutics, Inc. (collectively "Axsome" or "Plaintiffs"), states 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 Defendants' submission of their respective Abbreviated New Drug Application ("ANDA") Nos. 218722 ("Alkem's ANDA"), 218725 ("Aurobindo's ANDA"), 218654 ("Hetero's ANDA"), and 218016 ("Hikma'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 one or more of United States Patent Nos. 11,969,404 ("the '404 patent"), 11,986,454 ("the '454 patent"), 11,986,455 ("the '455 patent"), 11,998,639 ("the '639 patent"), 12,005,036 ("the '036 patent"), 12,036,194 ("the '194 patent"), and 12,064,411 ("the '411 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[1]

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 Delaware, having its principal place of business at One World Trade Center, 22nd 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.

[1] Paragraphs 6-11, 33-70, 77-98, and 117-260 of the Complaint do not state allegations against Alkem, and therefore no response is required to those paragraphs.

5. On information and belief, Defendant 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.

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12. On information and belief, Defendants are all pharmaceutical companies that formulate, manufacture, package, and market 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 12 of the Complaint.

The Patents-in-Suit

13. On April 30, 2024, the USPTO duly and lawfully issued the ’404 patent, entitled, “Methods of Providing Solriamfetol Therapy to Subjects with Impaired Renal Function.” The face of the ’404 patent identifies Katayoun Zomorodi as the inventor. A copy of the ’404 patent is attached hereto as Exhibit A.

ANSWER: Paragraph 13 contains legal conclusions to which no answer is required. To the extent an answer is required, Alkem admits that the ’404 patent is entitled “Methods of Providing Solriamfetol Therapy to Subjects with Impaired Renal Function,” that, on its face, the ’404 patent identifies Katayoun Zomorodi as the inventor, and that a purported copy of the ’404 patent is attached as Exhibit A. Alkem denies that the ’404 patent was “duly and lawfully issued,” and further denies any remaining allegations of Paragraph 7.

14. On May 21, 2024, the USPTO duly and lawfully issued the ’454 patent, entitled, “Methods of Providing Solriamfetol Therapy to Subjects with Impaired Renal Function.” The face of the ’454 patent identifies Katayoun Zomorodi as the inventor. A copy of the ’454 patent is attached hereto as Exhibit B.

ANSWER: Paragraph 14 contains legal conclusions to which no answer is required. To the extent an answer is required, Alkem admits that the ’454 patent is entitled “Methods of Providing Solriamfetol Therapy to Subjects with Impaired Renal Function,” that, on its face, the ’454 patent identifies Katayoun Zomorodi as the inventor, and that a purported copy of the ’454 patent is attached as Exhibit B. Alkem denies that the ’454 patent was “duly and lawfully issued,” and further denies any remaining allegations of Paragraph 14.

15. On May 21, 2024, the USPTO duly and lawfully issued the ’455 patent, entitled, “Methods of Providing Solriamfetol Therapy to Subjects with Impaired Renal Function.” The face of the ’455 patent identifies Katayoun Zomorodi as the inventor. A copy of the ’455 patent is attached hereto as Exhibit C.

ANSWER: Paragraph 15 contains legal conclusions to which no answer is required. To the extent an answer is required, Alkem admits that the ’455 patent is entitled “Methods of Providing Solriamfetol Therapy to Subjects with Impaired Renal Function,” that, on its face, the ’455 patent identifies Katayoun Zomorodi as the inventor, and that a purported copy of the ’455 patent is attached as Exhibit C. Alkem denies that the ’455 patent was “duly and lawfully issued,” and further denies any remaining allegations of Paragraph 15.

16. On June 4, 2024, the USPTO duly and lawfully issued the ’639 patent, entitled, “Formulations of (R)-2-Amino-Phenylpropyl Carbamate.” The face of the ’639 patent identifies

Clark Patrick Allphin and Edwin Gerard Walsh as the inventors. A copy of the '639 patent is attached hereto as Exhibit D.

ANSWER: Paragraph 16 contains legal conclusions to which no answer is required. To the extent an answer is required, Alkem admits that the '639 patent is entitled "Formulations of (R)-2-Amino-Phenylpropyl Carbamate," that, on its face, the '639 patent identifies Clark Patrick Allphin and Edwin Gerard Walsh as the inventors, and that a purported copy of the '639 patent is attached as Exhibit D. Alkem denies that the '639 patent was "duly and lawfully issued," and further denies any remaining allegations of Paragraph 16.

17. On June 11, 2024, the USPTO duly and lawfully issued the '036 patent, entitled, "Methods of Administering Solriamfetol to Lactating Women." The face of the '036 patent identifies Herriot Tabuteau as the inventor. A copy of the '036 patent is attached hereto as Exhibit E.

ANSWER: Paragraph 17 contains legal conclusions to which no answer is required. To the extent an answer is required, Alkem admits that the '036 patent is entitled "Methods of Administering Solriamfetol to Lactating Women," that, on its face, the '036 patent identifies Herriot Tabuteau as the inventor, and that a purported copy of the '036 patent is attached as Exhibit E. Alkem denies that the '036 patent was "duly and lawfully issued," and further denies any remaining allegations of Paragraph 17.

18. On July 16, 2024, the USPTO duly and lawfully issued the '194 patent, entitled, "Methods of Administering Solriamfetol to Lactating Women." The face of the '194 patent identifies Herriot Tabuteau as the inventor. A copy of the '194 patent is attached hereto as Exhibit F.

ANSWER: Paragraph 18 contains legal conclusions to which no answer is required. To the extent an answer is required, Alkem admits that the '194 patent is entitled "Methods of Administering Solriamfetol to Lactating Women," that, on its face, the '194 patent identifies Herriot Tabuteau as the inventor, and that a purported copy of the '194 patent is attached as Exhibit F. Alkem denies that the '194 patent was "duly and lawfully issued," and further denies any remaining allegations of Paragraph 18.

19. On August 20, 2024, the USPTO duly and lawfully issued the '411 patent, entitled, "Methods of Administering Solriamfetol to Lactating Women." The face of the '411 patent identifies Herriot Tabuteau as the inventor. A copy of the '411 patent is attached hereto as Exhibit G.

ANSWER: Paragraph 19 contains legal conclusions to which no answer is required. To the extent an answer is required, Alkem admits that the '411 patent is entitled "Methods of Administering Solriamfetol to Lactating Women," that, on its face, the '411 patent identifies Herriot Tabuteau as the inventor, and that a purported copy of the '411 patent is attached as Exhibit G. Alkem denies that the '411 patent was "duly and lawfully issued," and further denies any remaining allegations of Paragraph 19.

The Sunosi® Drug Product

20. 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,* 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.

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 20 of the Complaint.

21. 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 21 and, therefore, denies those allegations.

Jurisdiction and Venue

22. 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 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 personal jurisdiction for the limited purpose of this action only. Alkem denies all remaining allegations of Paragraph 22 of the Complaint.

23. 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 23 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 23 of the Complaint.

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

ANSWER: Paragraph 24 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 24 of the Complaint.

25. 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 25 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 25 of the Complaint.

26. 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 26 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 26 of the Complaint.

27. This Court has personal jurisdiction over Alkem because, *inter alia*, it: (1) has purposefully availed itself of the privilege of doing business in the State of New Jersey; and (2) maintains extensive and systematic contacts with the State of New Jersey, including through the marketing, distribution, and/or sale of generic pharmaceutical drugs in New Jersey.

ANSWER:

28. 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.

29. 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 29 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 29 of the Complaint.

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

ANSWER: Paragraph 30 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 30 of the Complaint.

31. 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 31 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 31 of the Complaint.

32. At least because, on information and belief, Alkem is a foreign company, venue is proper in this Judicial District with respect to Alkem pursuant to 28 U.S.C. § 1391(c)(3) and 28 U.S.C. § 1400(b). Also, for at least the reasons set forth above in Paragraphs 24-30, venue is

proper in this Judicial District with respect to Alkem pursuant to 28 U.S.C. § 1391(c)(3) and 28 U.S.C. § 1400(b).

ANSWER: Paragraph 32 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 32 of the Complaint.

Acts Giving Rise To Counts I-II Against Alkem

71. 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 71 of the Complaint.

72. No earlier than August 11, 2023, Alkem sent written notice of a Paragraph IV Certification ("Alkem's First Notice Letter") to Axsome. According to Alkem's First Notice Letter, Alkem submitted an ANDA pursuant to Section 505 of the FFDCA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Alkem's Proposed Product before expiration of certain patents listed in the Orange Book with respect to Sunosi®.

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 72 of the Complaint.

73. No earlier than March 29, 2024, Alkem sent written notice of a Paragraph IV Certification ("Alkem's Second Notice Letter") to Axsome. According to Alkem's Second Notice Letter, Alkem submitted an ANDA pursuant to Section 505 of the FFDCA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Alkem's Proposed Product before expiration of certain patents listed in the Orange Book with respect to Sunosi®.

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 73 of the Complaint.

74. No earlier than June 26, 2024, Alkem sent written notice of a Paragraph IV Certification ("Alkem's Third Notice Letter") to Axsome. According to Alkem's Third Notice Letter, Alkem submitted an ANDA pursuant to Section 505 of the FFDCA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Alkem's Proposed Product before expiration of certain patents listed in the Orange Book with respect to Sunosi®.

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 74 of the Complaint.

75. On information and belief, Alkem provided a written certification to the FDA, as called for by Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), indicating that it seeks to obtain approval of its ANDA to engage in the commercial manufacture, use, or sale of Alkem's Proposed Product before the expiration of the Orange Book patents with respect to Sunosi®.

ANSWER: Paragraph 75 contains legal conclusions to which no answer is required. To the extent an answer is required, Alkem admits that it provided a written certification to the FDA pursuant to Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV) regarding Alkem's ANDA Product. Alkem denies the remaining allegations in paragraph 75 of the Complaint.

76. 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.

Count I: Infringement of the '194 Patent by Alkem

99. 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.

100. 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 '194 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.

101. A justiciable controversy exists between Axsome and Alkem as to the infringement of the '194 patent.

ANSWER: Paragraph 101 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 101.

102. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem will infringe one or more claims of the '194 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.

103. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem will induce infringement of one or more claims of the '194 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 '194 patent and knowledge that its acts are encouraging infringement.

ANSWER: Denied.

104. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem will contributorily infringe one or more claims of the '194 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 '194 patent, and Alkem's Proposed Product lacks a substantial non-infringing use.

ANSWER: Denied.

105. Failure to enjoin Alkem's infringement of the '194 patent will substantially and irreparably damage and harm Axsome.

ANSWER: Denied.

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

ANSWER: Denied.

107. 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 '411 Patent by Alkem

108. 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.

109. 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 '411 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.

110. A justiciable controversy exists between Axsome and Alkem as to the infringement of the '411 patent.

ANSWER: Paragraph 110 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 110.

111. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem will infringe one or more claims of the '411 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.

112. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem will induce infringement of one or more claims of the '411 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 '411 patent and knowledge that its acts are encouraging infringement.

ANSWER: Denied.

113. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem will contributorily infringe one or more claims of the '411 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 '411 patent, and Alkem's Proposed Product lacks a substantial non-infringing use.

ANSWER: Denied.

114. Failure to enjoin Alkem's infringement of the '411 patent will substantially and irreparably damage and harm Axsome.

ANSWER: Denied.

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

ANSWER: Denied.

116. 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 AGAINST ALKEM.

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 '194 PATENT)

1. The claims of the '194 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 '194 PATENT)

2. 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 '194 Patent.

THIRD SEPARATE DEFENSE
(NO INDIRECT INFRINGEMENT OF THE '194 PATENT)

3. 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 '194 Patent.

FOURTH SEPARATE DEFENSE
(INVALIDITY OF THE '411 PATENT)

4. The claims of the '411 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 '411 PATENT)

5. 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 '411 Patent.

SIXTH SEPARATE DEFENSE
(NO INDIRECT INFRINGEMENT OF THE '411 PATENT)

6. 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 '411 Patent.

SEVENTH SEPARATE DEFENSE
(FAILURE TO STATE A CLAIM)

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

EIGHTH SEPARATE DEFENSE
(LACK OF SUBJECT MATTER JURISDICTION)

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

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

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

TENTH AFFIRMATIVE DEFENSE

10. 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.

ELEVENTH AFFIRMATIVE DEFENSE

11. 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.

TWELFTH AFFIRMATIVE DEFENSE

12. 35 U.S.C. § 288 prevents Plaintiffs from recovering any costs associated with this action.

THIRTEENTH AFFIRMATIVE DEFENSE

13. 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

14. 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. 12,036,194 ("the '194 patent") and 12,064,411 ("the '411 patent") (collectively, "the patents-in-suit") are invalid and/or not infringed.

NATURE OF THE ACTION

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 September 16, 2024, 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 '194 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. 12,036,194 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 '194 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 12,036,194.

COUNT III
Declaratory Judgment of Invalidity of the '411 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. 12,064,411 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 '411 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. 12,064,411.

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: September 24, 2024

/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 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 matters 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), and *Axsome v. Alkem, et al.*, Civil Action No. 24-cv-08365 (MCA)(LDW), which also involve allegations regarding generic versions of Axsome's solriamfetol oral tablets drug products.

Respectfully submitted,

Dated: September 23, 2024

/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: September 23, 2024

/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.