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

**AXSOME MALTA LTD. and AXSOME
THERAPEUTICS, INC.,**

Plaintiffs,

v.

**ALKEM LABORATORIES LTD.,
HIKMA PHARMACEUTICALS USA
INC., SANDOZ INC., and UNICHEM
LABORATORIES LTD.,**

Defendants.

Civil Action No. 2:24-CV-04608 (MCA)(LDW)

**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”), 218016

(“Hikma’s ANDA”), 218610 (“Sandoz’s ANDA”), and 218761 (“Unichem’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. 11,771,666 (“the ’666 patent”), 11,771,667 (“the ’667 patent”), 11,779,554 (“the ’554 patent”), 11,793,776 (“the ’776 patent”), 11,839,598 (“the ’598 patent”), 11,839,599 (“the ’599 patent”), 11,850,226 (“the ’226 patent”), 11,850,227 (“the ’227 patent”), 11,850,228 (“the ’228 patent”), 11,857,528 (“the ’528 patent”), 11,865,098 (“the ’098 patent”), 11,872,203 (“the ’203 patent”), and 11,872,204 (“the ’204 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 Parties¹

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

¹ Paragraphs 6-8, 35-63, 69-83, and 201-434 of the Complaint do not state allegations against Alkem, and therefore no response is required to those paragraphs.

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 a 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 a 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.

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.

9. 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 9 of the Complaint.

The Patents-in-Suit

10. On October 3, 2023, the USPTO duly and lawfully issued the '666 patent, entitled, "Methods of Administering Solriamfetol to Lactating Women." The face of the '666 patent identifies Herriot Tabuteau as the inventor. A copy of the '666 patent is attached hereto as Exhibit A.

ANSWER: Paragraph 10 contains legal conclusions to which no answer is required. To the extent an answer is required, Alkem admits that the '666 patent is entitled "Methods of Administering Solriamfetol to Lactating Women," that, on its face, the '666 patent identifies Herriot Tabuteau as the inventor, and that a purported copy of the '666 patent is attached as Exhibit A. Alkem denies that the '666 patent was "duly and lawfully issued," and further denies any remaining allegations of Paragraph 10.

11. On October 3, 2023, the USPTO duly and lawfully issued the '667 patent, entitled, "Methods of Administering Solriamfetol to Lactating Women." The face of the '667 patent identifies Herriot Tabuteau as the inventor. A copy of the '667 patent is attached hereto as Exhibit B.

ANSWER: Paragraph 11 contains legal conclusions to which no answer is required. To the extent an answer is required, Alkem admits that the '667 patent is entitled "Methods of Administering Solriamfetol to Lactating Women," that, on its face, the '667 patent identifies

Herriot Tabuteau as the inventor, and that a purported copy of the '667 patent is attached as Exhibit B. Alkem denies that the '667 patent was "duly and lawfully issued," and further denies any remaining allegations of Paragraph 11.

12. On October 10, 2023, the USPTO duly and lawfully issued the '554 patent, entitled, "Methods of Administering Solriamfetol to Lactating Women." The face of the '554 patent identifies Herriot Tabuteau as the inventor. A copy of the '554 patent is attached hereto as Exhibit C.

ANSWER: Paragraph 12 contains legal conclusions to which no answer is required. To the extent an answer is required, Alkem admits that the '554 patent is entitled "Methods of Administering Solriamfetol to Lactating Women," that, on its face, the '554 patent identifies Herriot Tabuteau as the inventor, and that a purported copy of the '554 patent is attached as Exhibit C. Alkem denies that the '554 patent was "duly and lawfully issued," and further denies any remaining allegations of Paragraph 12.

13. On October 24, 2023, the USPTO duly and lawfully issued the '776 patent, entitled, "Methods of Administering Solriamfetol to Lactating Women." The face of the '776 patent identifies Herriot Tabuteau as the inventor. A copy of the '776 patent is attached hereto as Exhibit D.

ANSWER: Paragraph 13 contains legal conclusions to which no answer is required. To the extent an answer is required, Alkem admits that the '776 patent is entitled "Methods of Administering Solriamfetol to Lactating Women," that, on its face, the '776 patent identifies Herriot Tabuteau as the inventor, and that a purported copy of the '776 patent is attached as Exhibit D. Alkem denies that the '776 patent was "duly and lawfully issued," and further denies any remaining allegations of Paragraph 13.

14. On December 12, 2023, the USPTO duly and lawfully issued the '598 patent, entitled, "Methods of Providing Solriamfetol Therapy to Subjects with Impaired Renal Function." The face of the '598 patent identifies Katayoun Zomorodi as the inventor. A copy of the '598 patent is attached hereto as Exhibit E.

ANSWER: Paragraph 14 contains legal conclusions to which no answer is required. To the extent an answer is required, Alkem admits that the '598 patent is entitled "Methods of Providing Solriamfetol Therapy to Subjects with Impaired Renal Function," that, on its face, the '598 patent identifies Katayoun Zomorodi as the inventor, and that a purported copy of the '598 patent is attached as Exhibit E. Alkem denies that the '598 patent was "duly and lawfully issued," and further denies any remaining allegations of Paragraph 14.

15. On December 12, 2023, the USPTO duly and lawfully issued the '599 patent, entitled, "Methods of Providing Solriamfetol Therapy to Subjects with Impaired Renal Function." The face of the '599 patent identifies Katayoun Zomorodi as the inventor. A copy of the '599 patent is attached hereto as Exhibit F.

ANSWER: Paragraph 15 contains legal conclusions to which no answer is required. To the extent an answer is required, Alkem admits that the '599 patent is entitled "Methods of Providing Solriamfetol Therapy to Subjects with Impaired Renal Function," that, on its face, the '599 patent identifies Katayoun Zomorodi as the inventor, and that a purported copy of the '599 patent is attached as Exhibit F. Alkem denies that the '599 patent was "duly and lawfully issued," and further denies any remaining allegations of Paragraph 15.

16. On December 26, 2023, the USPTO duly and lawfully issued the '226 patent, entitled, "Methods of Providing Solriamfetol Therapy to Subjects with Impaired Renal Function."

The face of the '226 patent identifies Katayoun Zomorodi as the inventor. A copy of the '226 patent is attached hereto as Exhibit G.

ANSWER: Paragraph 16 contains legal conclusions to which no answer is required. To the extent an answer is required, Alkem admits that the '226 patent is entitled "Methods of Providing Solriamfetol Therapy to Subjects with Impaired Renal Function," that, on its face, the '226 patent identifies Katayoun Zomorodi as the inventor, and that a purported copy of the '226 patent is attached as Exhibit G. Alkem denies that the '226 patent was "duly and lawfully issued," and further denies any remaining allegations of Paragraph 16.

17. On December 26, 2023, the USPTO duly and lawfully issued the '227 patent, entitled, "Methods of Providing Solriamfetol Therapy to Subjects with Impaired Renal Function." The face of the '227 patent identifies Katayoun Zomorodi as the inventor. A copy of the '227 patent is attached hereto as Exhibit H.

ANSWER: Paragraph 17 contains legal conclusions to which no answer is required. To the extent an answer is required, Alkem admits that the '227 patent is entitled "Methods of Providing Solriamfetol Therapy to Subjects with Impaired Renal Function," that, on its face, the '227 patent identifies Katayoun Zomorodi as the inventor, and that a purported copy of the '227 patent is attached as Exhibit H. Alkem denies that the '227 patent was "duly and lawfully issued," and further denies any remaining allegations of Paragraph 17.

18. On December 26, 2023, the USPTO duly and lawfully issued the '228 patent, entitled, "Methods of Providing Solriamfetol Therapy to Subjects with Impaired Renal Function." The face of the '228 patent identifies Katayoun Zomorodi as the inventor. A copy of the '228 patent is attached hereto as Exhibit I.

ANSWER: Paragraph 18 contains legal conclusions to which no answer is required. To the extent an answer is required, Alkem admits that the '228 patent is entitled "Methods of Providing Solriamfetol Therapy to Subjects with Impaired Renal Function," that, on its face, the '228 patent identifies Katayoun Zomorodi as the inventor, and that a purported copy of the '228 patent is attached as Exhibit I. Alkem denies that the '228 patent was "duly and lawfully issued," and further denies any remaining allegations of Paragraph 18.

19. On January 2, 2024, the USPTO duly and lawfully issued the '528 patent, entitled, "Methods of Providing Solriamfetol Therapy to Subjects with Impaired Renal Function." The face of the '528 patent identifies Katayoun Zomorodi as the inventor. A copy of the '528 patent is attached hereto as Exhibit J.

ANSWER: Paragraph 19 contains legal conclusions to which no answer is required. To the extent an answer is required, Alkem admits that the '528 patent is entitled "Methods of Providing Solriamfetol Therapy to Subjects with Impaired Renal Function," that, on its face, the '528 patent identifies Katayoun Zomorodi as the inventor, and that a purported copy of the '528 patent is attached as Exhibit J. Alkem denies that the '528 patent was "duly and lawfully issued," and further denies any remaining allegations of Paragraph 19.

20. On January 9, 2024, the USPTO duly and lawfully issued the '098 patent, entitled, "Methods and Compositions for Treating Excessive Sleepiness." The face of the '098 patent identifies Lawrence Patrick Carter, Yuan Lu, and Katayoun Zomorodi as the inventors. A copy of the '098 patent is attached hereto as Exhibit K.

ANSWER: Paragraph 20 contains legal conclusions to which no answer is required. To the extent an answer is required, Alkem admits that the '098 patent is entitled "Methods and Compositions for Treating Excessive Sleepiness," that, on its face, the '098 patent identifies

Lawrence Patrick Carter, Yuan Lu, and Katayoun Zomorodi as the inventors, and that a purported copy of the '098 patent is attached as Exhibit K. Alkem denies that the '098 patent was "duly and lawfully issued," and further denies any remaining allegations of Paragraph 20.

21. On January 16, 2024, the USPTO duly and lawfully issued the '203 patent, entitled, "Methods of Administering Solriamfetol to Lactating Women." The face of the '203 patent identifies Herriot Tabuteau as the inventor. A copy of the '203 patent is attached hereto as Exhibit L.

ANSWER: Paragraph 21 contains legal conclusions to which no answer is required. To the extent an answer is required, Alkem admits that the '203 patent is entitled "Methods of Administering Solriamfetol to Lactating Women," that, on its face, the '203 patent identifies Herriot Tabuteau as the inventor, and that a purported copy of the '203 patent is attached as Exhibit L. Alkem denies that the '203 patent was "duly and lawfully issued," and further denies any remaining allegations of Paragraph 21.

22. On January 16, 2024, the USPTO duly and lawfully issued the '204 patent, entitled, "Methods of Administering Solriamfetol to Lactating Women." The face of the '204 patent identifies Herriot Tabuteau as the inventor. A copy of the '204 patent is attached hereto as Exhibit M.

ANSWER: Paragraph 22 contains legal conclusions to which no answer is required. To the extent an answer is required, Alkem admits that the '204 patent is entitled "Methods of Administering Solriamfetol to Lactating Women," that, on its face, the '204 patent identifies Herriot Tabuteau as the inventor, and that a purported copy of the '204 patent is attached as Exhibit M. Alkem denies that the '204 patent was "duly and lawfully issued," and further denies any remaining allegations of Paragraph 22.

The Sunosi® Drug Product

23. 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 23 of the Complaint.

24. 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 24 and, therefore, denies those allegations.

Jurisdiction and Venue: Alkem

25. This Court has jurisdiction over the subject matter of Counts I through XIII against Alkem pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

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

ANSWER: Paragraph 27 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 27 of the Complaint.

28. 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 28 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 28 of the Complaint.

29. 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 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. 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.

31. 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 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. 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.).

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 personal jurisdiction for the limited purpose of this action only. Alkem denies all remaining allegations of Paragraph 32 of the Complaint.

33. 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 33 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 33 of the Complaint.

34. 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).

ANSWER: Paragraph 34 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 34 of the Complaint.

Acts Giving Rise to Counts I-XIII Against Alkem

64. 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 64 of the Complaint.

65. No earlier than August 11, 2023, Alkem sent written notice of a Paragraph IV Certification ("Alkem's Notice Letter") to Axsome. According to Alkem's 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 Notice Letter") to Axsome on or around August 11, 2023. Alkem's Notice Letter speaks for itself. Alkem denies all remaining allegations of Paragraph 65 of the Complaint.

66. 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 66 of the Complaint.

67. On information and belief, in connection with the filing of its ANDA as described above, 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®, including the patents-in-suit.

ANSWER: Admitted.

68. 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 '666 Patent by Alkem

84. 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.

85. 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 '666 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.

86. A justiciable controversy exists between Axsome and Alkem as to the infringement of the '666 patent.

ANSWER: Paragraph 86 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 86.

87. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem will infringe one or more claims of the '666 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.

88. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem will induce infringement of one or more claims of the '666 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 '666 patent and knowledge that its acts are encouraging infringement.

ANSWER: Denied.

89. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem will contributorily infringe one or more claims of the '666 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 '666 patent, and Alkem's Proposed Product lacks a substantial non-infringing use.

ANSWER: Denied.

90. Failure to enjoin Alkem's infringement of the '666 patent will substantially and irreparably damage and harm Axsome.

ANSWER: Denied.

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

ANSWER: Denied.

92. 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 '667 Patent by Alkem

93. 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.

94. 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 '667 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.

95. A justiciable controversy exists between Axsome and Alkem as to the infringement of the '667 patent.

ANSWER: Paragraph 95 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 95.

96. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem will infringe one or more claims of the '667 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.

97. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem will induce infringement of one or more claims of the '667 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 '667 patent and knowledge that its acts are encouraging infringement.

ANSWER: Denied.

98. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem will contributorily infringe one or more claims of the '667 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 '667 patent, and Alkem's Proposed Product lacks a substantial non-infringing use.

ANSWER: Denied.

99. Failure to enjoin Alkem's infringement of the '667 patent will substantially and irreparably damage and harm Axsome.

ANSWER: Denied.

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

ANSWER: Denied.

101. 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 '554 Patent by Alkem

102. 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.

103. 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 '554 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.

104. A justiciable controversy exists between Axsome and Alkem as to the infringement of the '554 patent.

ANSWER: Paragraph 104 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 104.

105. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem will infringe one or more claims of the '554 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.

106. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem will induce infringement of one or more claims of the '554 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 '554 patent and knowledge that its acts are encouraging infringement.

ANSWER: Denied.

107. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem will contributorily infringe one or more claims of the '554 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 '554 patent, and Alkem's Proposed Product lacks a substantial non-infringing use.

ANSWER: Denied.

108. Failure to enjoin Alkem's infringement of the '554 patent will substantially and irreparably damage and harm Axsome.

ANSWER: Denied.

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

ANSWER: Denied.

110. 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 '776 Patent by Alkem

111. 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.

112. 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 '776 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.

113. A justiciable controversy exists between Axsome and Alkem as to the infringement of the '776 patent.

ANSWER: Paragraph 113 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 113.

114. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem will infringe one or more claims of the '776 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.

115. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem will induce infringement of one or more claims of the '776 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 '776 patent and knowledge that its acts are encouraging infringement.

ANSWER: Denied.

116. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem will contributorily infringe one or more claims of the '776 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 '776 patent, and Alkem's Proposed Product lacks a substantial non-infringing use.

ANSWER: Denied.

117. Failure to enjoin Alkem's infringement of the '776 patent will substantially and irreparably damage and harm Axsome.

ANSWER: Denied.

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

ANSWER: Denied.

119. 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 V: Infringement of the '598 Patent by Alkem

120. 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.

121. 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 '598 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.

122. A justiciable controversy exists between Axsome and Alkem as to the infringement of the '598 patent.

ANSWER: Paragraph 122 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 122.

123. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem will infringe one or more claims of the '598 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.

124. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem will induce infringement of one or more claims of the '598 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 '598 patent and knowledge that its acts are encouraging infringement.

ANSWER: Denied.

125. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem will contributorily infringe one or more claims of the '598 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 '598 patent, and Alkem's Proposed Product lacks a substantial non-infringing use.

ANSWER: Denied.

126. Failure to enjoin Alkem's infringement of the '598 patent will substantially and irreparably damage and harm Axsome.

ANSWER: Denied.

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

ANSWER: Denied.

128. 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 VI: Infringement of the '599 Patent by Alkem

129. 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.

130. 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 '599 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.

131. A justiciable controversy exists between Axsome and Alkem as to the infringement of the '599 patent.

ANSWER: Paragraph 131 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 131.

132. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem will infringe one or more claims of the '599 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.

133. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem will induce infringement of one or more claims of the '599 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 '599 patent and knowledge that its acts are encouraging infringement.

ANSWER: Denied.

134. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem will contributorily infringe one or more claims of the '599 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 '599 patent, and Alkem's Proposed Product lacks a substantial non-infringing use.

ANSWER: Denied.

135. Failure to enjoin Alkem's infringement of the '599 patent will substantially and irreparably damage and harm Axsome.

ANSWER: Denied.

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

ANSWER: Denied.

137. 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 VII: Infringement of the '226 Patent by Alkem

138. 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.

139. 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 '226 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.

140. A justiciable controversy exists between Axsome and Alkem as to the infringement of the '226 patent.

ANSWER: Paragraph 140 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 140.

141. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem will infringe one or more claims of the '226 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.

142. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem will induce infringement of one or more claims of the '226 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 '226 patent and knowledge that its acts are encouraging infringement.

ANSWER: Denied.

143. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem will contributorily infringe one or more claims of the '226 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 '226 patent, and Alkem's Proposed Product lacks a substantial non-infringing use.

ANSWER: Denied.

144. Failure to enjoin Alkem's infringement of the '226 patent will substantially and irreparably damage and harm Axsome.

ANSWER: Denied.

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

ANSWER: Denied.

146. 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 VIII: Infringement of the '227 Patent by Alkem

147. 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.

148. 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 '227 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.

149. A justiciable controversy exists between Axsome and Alkem as to the infringement of the '227 patent.

ANSWER: Paragraph 149 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 149.

150. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem will infringe one or more claims of the '227 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.

151. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem will induce infringement of one or more claims of the '227 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 '227 patent and knowledge that its acts are encouraging infringement.

ANSWER: Denied.

152. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem will contributorily infringe one or more claims of the '227 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 '227 patent, and Alkem's Proposed Product lacks a substantial non-infringing use.

ANSWER: Denied.

153. Failure to enjoin Alkem's infringement of the '227 patent will substantially and irreparably damage and harm Axsome.

ANSWER: Denied.

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

ANSWER: Denied.

155. 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 IX: Infringement of the '228 Patent by Alkem

156. 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.

157. 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 '228 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.

158. A justiciable controversy exists between Axsome and Alkem as to the infringement of the '228 patent.

ANSWER: Paragraph 158 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 158.

159. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem will infringe one or more claims of the '228 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.

160. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem will induce infringement of one or more claims of the '228 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 '228 patent and knowledge that its acts are encouraging infringement.

ANSWER: Denied.

161. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem will contributorily infringe one or more claims of the '228 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 '228 patent, and Alkem's Proposed Product lacks a substantial non-infringing use.

ANSWER: Denied.

162. Failure to enjoin Alkem's infringement of the '228 patent will substantially and irreparably damage and harm Axsome.

ANSWER: Denied.

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

ANSWER: Denied.

164. 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 X: Infringement of the '528 Patent by Alkem

165. 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.

166. 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 '528 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.

167. A justiciable controversy exists between Axsome and Alkem as to the infringement of the '528 patent.

ANSWER: Paragraph 167 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 167.

168. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem will infringe one or more claims of the '528 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.

169. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem will induce infringement of one or more claims of the '528 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 '528 patent and knowledge that its acts are encouraging infringement.

ANSWER: Denied.

170. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem will contributorily infringe one or more claims of the '528 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 '528 patent, and Alkem's Proposed Product lacks a substantial non-infringing use.

ANSWER: Denied.

171. Failure to enjoin Alkem's infringement of the '528 patent will substantially and irreparably damage and harm Axsome.

ANSWER: Denied.

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

ANSWER: Denied.

173. 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 XI: Infringement of the '098 Patent by Alkem

174. 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.

175. 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 '098 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.

176. A justiciable controversy exists between Axsome and Alkem as to the infringement of the '098 patent.

ANSWER: Paragraph 176 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 176.

177. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem will infringe one or more claims of the '098 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.

178. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem will induce infringement of one or more claims of the '098 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 '098 patent and knowledge that its acts are encouraging infringement.

ANSWER: Denied.

179. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem will contributorily infringe one or more claims of the '098 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 '098 patent, and Alkem's Proposed Product lacks a substantial non-infringing use.

ANSWER: Denied.

180. Failure to enjoin Alkem's infringement of the '098 patent will substantially and irreparably damage and harm Axsome.

ANSWER: Denied.

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

ANSWER: Denied.

182. 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 XII: Infringement of the '203 Patent by Alkem

183. 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.

184. 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 '203 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.

185. A justiciable controversy exists between Axsome and Alkem as to the infringement of the '203 patent.

ANSWER: Paragraph 185 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 185.

186. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem will infringe one or more claims of the '203 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.

187. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem will induce infringement of one or more claims of the '203 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 '203 patent and knowledge that its acts are encouraging infringement.

ANSWER: Denied.

188. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem will contributorily infringe one or more claims of the '203 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 '203 patent, and Alkem's Proposed Product lacks a substantial non-infringing use.

ANSWER: Denied.

189. Failure to enjoin Alkem's infringement of the '203 patent will substantially and irreparably damage and harm Axsome.

ANSWER: Denied.

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

ANSWER: Denied.

191. 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 XIII: Infringement of the '204 Patent by Alkem

192. 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.

193. 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 '204 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.

194. A justiciable controversy exists between Axsome and Alkem as to the infringement of the '204 patent.

ANSWER: Paragraph 194 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 194.

195. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem will infringe one or more claims of the '204 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.

196. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem will induce infringement of one or more claims of the '204 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 '204 patent and knowledge that its acts are encouraging infringement.

ANSWER: Denied.

197. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem will contributorily infringe one or more claims of the '204 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 '204 patent, and Alkem's Proposed Product lacks a substantial non-infringing use.

ANSWER: Denied.

198. Failure to enjoin Alkem's infringement of the '204 patent will substantially and irreparably damage and harm Axsome.

ANSWER: Denied.

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

ANSWER: Denied.

200. 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. The remaining paragraphs under that heading do not relate to allegations against Alkem, and no response to those paragraphs is required.

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 '666 PATENT)**

1. The claims of the '666 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 '666 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 '666 Patent.

**THIRD SEPARATE DEFENSE
(NO INDIRECT INFRINGEMENT OF THE '666 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 '666 Patent.

**FOURTH SEPARATE DEFENSE
(INVALIDITY OF THE '667 PATENT)**

4. The claims of the '667 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 '667 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 '667 Patent.

**SIXTH SEPARATE DEFENSE
(NO INDIRECT INFRINGEMENT OF THE '667 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 '667 Patent.

**SEVENTH SEPARATE DEFENSE
(INVALIDITY OF THE '554 PATENT)**

7. The claims of the '554 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 '554 PATENT)**

8. 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 '554 Patent.

**NINTH SEPARATE DEFENSE
(NO INDIRECT INFRINGEMENT OF THE '554 PATENT)**

9. 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 '554 Patent.

**TENTH SEPARATE DEFENSE
(INVALIDITY OF THE '776 PATENT)**

10. The claims of the '776 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 '776 PATENT)**

11. 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 '776 Patent.

**TWELFTH SEPARATE DEFENSE
(NO INDIRECT INFRINGEMENT OF THE '776 PATENT)**

12. 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 '776 Patent.

**THIRTEENTH SEPARATE DEFENSE
(INVALIDITY OF THE '598 PATENT)**

13. The claims of the '598 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.

**FOURTEENTH SEPARATE DEFENSE
(NO DIRECT INFRINGEMENT OF THE '598 PATENT)**

14. 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 '598 Patent.

**FIFTEENTH SEPARATE DEFENSE
(NO INDIRECT INFRINGEMENT OF THE '598 PATENT)**

15. 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 '598 Patent.

**SIXTEENTH SEPARATE DEFENSE
(INVALIDITY OF THE '599 PATENT)**

16. The claims of the '599 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.

**SEVENTEENTH SEPARATE DEFENSE
(NO DIRECT INFRINGEMENT OF THE '599 PATENT)**

17. 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 '599 Patent.

**EIGHTEENTH SEPARATE DEFENSE
(NO INDIRECT INFRINGEMENT OF THE '599 PATENT)**

18. 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 '599 Patent.

**NINTEENTH SEPARATE DEFENSE
(INVALIDITY OF THE '226 PATENT)**

19. The claims of the '226 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.

**TWENTIETH SEPARATE DEFENSE
(NO DIRECT INFRINGEMENT OF THE '226 PATENT)**

20. 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 '226 Patent.

**TWENTY-FIRST SEPARATE DEFENSE
(NO INDIRECT INFRINGEMENT OF THE '226 PATENT)**

21. 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 '226 Patent.

**TWENTY-SECOND SEPARATE DEFENSE
(INVALIDITY OF THE '227 PATENT)**

22. The claims of the '227 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.

**TWENTY-THIRD SEPARATE DEFENSE
(NO DIRECT INFRINGEMENT OF THE '227 PATENT)**

23. 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 '227 Patent.

**TWENTY-FOURTH SEPARATE DEFENSE
(NO INDIRECT INFRINGEMENT OF THE '227 PATENT)**

24. 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 '227 Patent.

**TWENTY-FIFTH SEPARATE DEFENSE
(INVALIDITY OF THE '228 PATENT)**

25. The claims of the '228 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.

**TWENTY-SIXTH SEPARATE DEFENSE
(NO DIRECT INFRINGEMENT OF THE '228 PATENT)**

26. 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 '228 Patent.

**TWENTY-SEVENTH SEPARATE DEFENSE
(NO INDIRECT INFRINGEMENT OF THE '228 PATENT)**

27. 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 '228 Patent.

**TWENTY-EIGHTH SEPARATE DEFENSE
(INVALIDITY OF THE '528 PATENT)**

28. The claims of the '528 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.

**TWENTY-NINTH SEPARATE DEFENSE
(NO DIRECT INFRINGEMENT OF THE '528 PATENT)**

29. 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 '528 Patent.

**THIRTIETH SEPARATE DEFENSE
(NO INDIRECT INFRINGEMENT OF THE '528 PATENT)**

30. 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 '528 Patent.

**THIRTY-FIRST SEPARATE DEFENSE
(INVALIDITY OF THE '098 PATENT)**

31. The claims of the '098 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.

**THIRTY-SECOND SEPARATE DEFENSE
(NO DIRECT INFRINGEMENT OF THE '098 PATENT)**

32. 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 '098 Patent.

**THIRTY-THIRD SEPARATE DEFENSE
(NO INDIRECT INFRINGEMENT OF THE '098 PATENT)**

33. 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 '098 Patent.

**THIRTY-FOURTH SEPARATE DEFENSE
(INVALIDITY OF THE '203 PATENT)**

34. The claims of the '203 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.

**THIRTY-FIFTH SEPARATE DEFENSE
(NO DIRECT INFRINGEMENT OF THE '203 PATENT)**

35. 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 '203 Patent.

**THIRTY-SIXTH SEPARATE DEFENSE
(NO INDIRECT INFRINGEMENT OF THE '203 PATENT)**

36. 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 '203 Patent.

**THIRTY-SEVENTH SEPARATE DEFENSE
(INVALIDITY OF THE '204 PATENT)**

37. The claims of the '204 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.

**THIRTY-EIGHTH SEPARATE DEFENSE
(NO DIRECT INFRINGEMENT OF THE '204 PATENT)**

38. 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 '204 Patent.

**THIRTY-NINTH SEPARATE DEFENSE
(NO INDIRECT INFRINGEMENT OF THE '204 PATENT)**

39. 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 '204 Patent.

**FORTIETH SEPARATE DEFENSE
(FAILURE TO STATE A CLAIM)**

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

**FORTY-FIRST SEPARATE DEFENSE
(LACK OF SUBJECT MATTER JURISDICTION)**

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

**FORTY-SECOND SEPARATE DEFENSE
(FAILURE TO STATE A CLAIM FOR EXCEPTIONAL OR WILLFUL
INFRINGEMENT)**

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

FORTY-THIRD AFFIRMATIVE DEFENSE

43. 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.

FORTY-FOURTH AFFIRMATIVE DEFENSE

44. 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.

FORTY-FIFTH AFFIRMATIVE DEFENSE

45. 35 U.S.C. § 288 prevents Plaintiffs from recovering any costs associated with this action.

FORTY-SIXTH AFFIRMATIVE DEFENSE

46. 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. 11,771,666 (“the ’666 patent”), 11,771,667 (“the ’667 patent”), 11,779,554 (“the ’554 patent”), 11,793,776 (“the ’776 patent”), 11,839,598 (“the ’598 patent”), 11,839,599 (“the ’599 patent”), 11,850,226 (“the ’226 patent”), 11,850,227 (“the ’227 patent”), 11,850,228

(“the ‘228 patent”), 11,857,528 (“the ‘528 patent”), 11,865,098 (“the ‘098 patent”), 11,872,203 (“the ‘203 patent”), and 11,872,204 (“the ‘204 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 April 5, 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 ‘666 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. 11,771,666 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 ‘666 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. 11,771,666.

COUNT III
Declaratory Judgment of Invalidity of the ‘667 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. 11,771,667 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 ‘667 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. 11,771,667.

COUNT V
Declaratory Judgment of Invalidity of the ‘554 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. 11,779,554 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 ‘554 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. 11,779,554.

COUNT VII
Declaratory Judgment of Invalidity of the ‘776 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. 11,793,776 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 '776 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. 11,793,776.

COUNT IX
Declaratory Judgment of Invalidity of the '598 Patent

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

29. Each and every asserted claim of United States Patent No. 11,839,598 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 X
Declaratory Judgment of Noninfringement of the '598 Patent

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

31. 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. 11,839,598.

COUNT XI
Declaratory Judgment of Invalidity of the ‘599 Patent

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

33. Each and every asserted claim of United States Patent No. 11,839,599 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 XII
Declaratory Judgment of Noninfringement of the ‘599 Patent

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

35. 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. 11,839,599.

COUNT XIII
Declaratory Judgment of Invalidity of the ‘226 Patent

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

37. Each and every asserted claim of United States Patent No. 11,850,226 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 XIV
Declaratory Judgment of Noninfringement of the '226 Patent

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

39. 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. 11,850,226.

COUNT XV
Declaratory Judgment of Invalidity of the '227 Patent

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

41. Each and every asserted claim of United States Patent No. 11,850,227 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 XVI
Declaratory Judgment of Noninfringement of the '227 Patent

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

43. 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. 11,850,227.

COUNT XVII
Declaratory Judgment of Invalidity of the ‘228 Patent

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

45. Each and every asserted claim of United States Patent No. 11,850,228 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 XVIII
Declaratory Judgment of Noninfringement of the ‘228 Patent

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

47. 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. 11,850,228.

COUNT XIX
Declaratory Judgment of Invalidity of the ‘528 Patent

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

49. Each and every asserted claim of United States Patent No. 11,857,528 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 XX
Declaratory Judgment of Noninfringement of the ‘528 Patent

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

51. 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. 11,857,528.

COUNT XXI
Declaratory Judgment of Invalidity of the ‘098 Patent

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

53. Each and every asserted claim of United States Patent No. 11,865,098 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 XXII
Declaratory Judgment of Noninfringement of the ‘098 Patent

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

55. 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. 11,865,098.

COUNT XXIII
Declaratory Judgment of Invalidity of the ‘203 Patent

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

57. Each and every asserted claim of United States Patent No. 11,872,203 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 XXIV
Declaratory Judgment of Noninfringement of the ‘203 Patent

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

59. 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. 11,872,203.

COUNT XXV
Declaratory Judgment of Invalidity of the ‘204 Patent

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

61. Each and every asserted claim of United States Patent No. 11,872,204 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 XXVI
Declaratory Judgment of Noninfringement of the ‘204 Patent

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

63. 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. 11,872,204.

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: April 26, 2024

/s/ Rebekah R. Conroy
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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), which also involves allegations regarding generic versions of Axsome's solriamfetol oral tablets drug products.

Respectfully submitted,

Dated: April 26, 2024

/s/ Rebekah R. Conroy
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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: April 26, 2024

/s/ Rebekah R. Conroy
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