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Sandoz Inc.*

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

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

*Plaintiffs,*

v.

SANDOZ INC.,

*Defendant.*

Civil Action No. 2:24-cv-00860-MCA-LDW

**DEFENDANT SANDOZ, INC.'S ANSWER TO PLAINTIFFS'  
COMPLAINT FOR PATENT INFRINGEMENT, AND COUNTERCLAIMS**

Defendant Sandoz Inc. ("Sandoz") answers the Complaint in Civil Action No. 24-860 (Dkt. 1) brought by Plaintiffs Axsome Malta Ltd. and Axsome Therapeutics, Inc. (together, "Axsome" or "Plaintiffs").

With respect to the allegations made in the Complaint, Sandoz states as follows:

### **NATURE OF THE ACTION**

1. This complaint is an action for patent infringement under the patent laws of the United States, 35 U.S.C. §100, et seq., arising from Sandoz’s submission of Abbreviated New Drug Application (“ANDA”) No. 218610 (“Sandoz’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 (“666 patent”), 11,771,667 (“667 patent”), 11,779,554 (“554 patent”), 11,793,776 (“776 patent”), 11,839,598 (“598 patent”), 11,839,599 (“599 patent”), 11,850,226 (“226 patent”), 11,850,227 (“227 patent”), and 11,850,228 (“228 patent”) (collectively, “the patents-in-suit”). Axsome is the owner of the patents-in-suit.

**ANSWER:** Sandoz admits that this purports to be an action for patent infringement of United States Patent Nos. 11,771,666 (“666 patent”), 11,771,667 (“667 patent”), 11,779,554 (“554 patent”), 11,793,776 (“776 patent”), 11,839,598 (“598 patent”), 11,839,599 (“599 patent”), 11,850,226 (“226 patent”), 11,850,227 (“227 patent”), and 11,850,228 (“228 patent”) (collectively, “the patents-in-suit”) arising under the patent laws of the United States, Title 35 of the United States Code. Sandoz further admits that it submitted Abbreviated New Drug Application (“ANDA”) No. 218610 to the United States Food and Drug Administration (“FDA”) seeking approval for the manufacture and sale of solriamfetol oral tablet drug products prior to the expiration of the patents-in-suit. Sandoz denies any remaining allegations in this paragraph.

### **THE PARTIES**

2. Plaintiff Axsome is a biopharmaceutical company focused on developing novel therapies for central nervous system (“CNS”) conditions that have limited treatment options. One such therapy, Sunosi® (solriamfetol) oral tablets, is a dopamine and norepinephrine reuptake

inhibitor (“DNRI”) indicated to improve wakefulness in adult patients with excessive daytime sleepiness associated with narcolepsy or obstructive sleep apnea.

**ANSWER:** Sandoz admits that Sunosi® is a DNRI, indicated to improve wakefulness in adult patients with excessive daytime sleepiness associated with narcolepsy or obstructive sleep apnea. Sandoz lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in this paragraph and therefore denies them.

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:** Sandoz lacks knowledge or information sufficient to form a belief as to the truth of Plaintiffs’ allegations and therefore denies them.

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:** Sandoz lacks knowledge or information sufficient to form a belief as to the truth of Plaintiffs’ allegations and therefore denies them.

5. On information and belief, Defendant Sandoz is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 100 College Road West, Princeton, New Jersey 08540.

**ANSWER:** Admitted.

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

**ANSWER:** Sandoz admits that part of Sandoz’s business is the sale of generic medicines in the United States, including in this Judicial District. Sandoz denies any remaining allegations in this paragraph.

**THE PATENTS-IN-SUIT**

7. 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:** Sandoz admits that the face of the ’666 patent states that it was issued on October 3, 2023, bears the title “Methods of Administering Solriamfetol to Lactating Women,” and lists Herriot Tabuteau as the inventor. Sandoz further admits that what appears to be a copy of the ’666 patent is attached as Exhibit A to the Complaint. Sandoz denies any remaining allegations in this paragraph.

8. 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:** Sandoz admits that the face of the ’667 patent states that it was issued on October 3, 2023, bears the title “Methods of Administering Solriamfetol to Lactating Women,” and lists Herriot Tabuteau as the inventor. Sandoz further admits that what appears to be a copy of the ’667 patent is attached as Exhibit B to the Complaint. Sandoz denies any remaining allegations in this paragraph.

9. 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:** Sandoz admits that the face of the '554 patent states that it was issued on October 10, 2023, bears the title "Methods of Administering Solriamfetol to Lactating Women," and lists Herriot Tabuteau as the inventor. Sandoz further admits that what appears to be a copy of the '554 patent is attached as Exhibit C to the Complaint. Sandoz denies any remaining allegations in this paragraph.

10. 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:** Sandoz admits that the face of the '776 patent states that it was issued on October 24, 2023, bears the title "Methods of Administering Solriamfetol to Lactating Women," and lists Herriot Tabuteau as the inventor. Sandoz further admits that what appears to be a copy of the '776 patent is attached as Exhibit D to the Complaint. Sandoz denies any remaining allegations in this paragraph.

11. 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:** Sandoz admits that the face of the '598 patent states that it was issued on December 12, 2023, bears the title "Methods of Providing Solriamfetol Therapy to Subjects with Impaired Renal Function," and lists Katayoun Zomorodi as the inventor. Sandoz

further admits that what appears to be a copy of the '598 patent is attached as Exhibit E to the Complaint. Sandoz denies any remaining allegations in this paragraph.

12. 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:** Sandoz admits that the face of the '599 patent states that it was issued on December 12, 2023, bears the title "Methods of Providing Solriamfetol Therapy to Subjects with Impaired Renal Function," and lists Katayoun Zomorodi as the inventor. Sandoz further admits that what appears to be a copy of the '599 patent is attached as Exhibit F to the Complaint. Sandoz denies any remaining allegations in this paragraph.

13. 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:** Sandoz admits that the face of the '226 patent states that it was issued on December 26, 2023, bears the title "Methods of Providing Solriamfetol Therapy to Subjects with Impaired Renal Function," and lists Katayoun Zomorodi as the inventor. Sandoz further admits that what appears to be a copy of the '226 patent is attached as Exhibit G to the Complaint. Sandoz denies any remaining allegations in this paragraph.

14. 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:** Sandoz admits that the face of the '227 patent states that it was issued on December 26, 2023, bears the title “Methods of Providing Solriamfetol Therapy to Subjects with Impaired Renal Function,” and lists Katayoun Zomorodi as the inventor. Sandoz further admits that what appears to be a copy of the '227 patent is attached as Exhibit H to the Complaint. Sandoz denies any remaining allegations in this paragraph.

15. 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:** Sandoz admits that the face of the '228 patent states that it was issued on December 26, 2023, bears the title “Methods of Providing Solriamfetol Therapy to Subjects with Impaired Renal Function,” and lists Katayoun Zomorodi as the inventor. Sandoz further admits that what appears to be a copy of the '228 patent is attached as Exhibit I to the Complaint. Sandoz denies any remaining allegations in this paragraph.

### **THE SUNOSI® DRUG PRODUCT**

16. 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 trade name 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*, solriamfetol pharmaceutical compositions and methods of

using Sunosi® to improve wakefulness in adult patients with excessive daytime sleepiness associated with narcolepsy or obstructive sleep apnea.

**ANSWER:** Sandoz admits that Axsome is identified by the FDA as the holder of NDA No. 211230 for solriamfetol oral tablets, which are sold under the trade name Sunosi®. Sandoz further admits that Sunosi® is FDA approved and indicated to improve wakefulness in adult patients with excessive daytime sleepiness associated with narcolepsy or obstructive sleep apnea. Sandoz denies any remaining allegations in this paragraph.

17. 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:** Sandoz admits that the patents-in-suit are listed in the Orange Book entry for Sunosi®. Sandoz denies any remaining allegations in this paragraph.

#### **JURISDICTION AND VENUE**

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

**ANSWER:** The allegations in this paragraph constitute conclusions of law to which no answer is required. To the extent an answer is required, Sandoz does not contest that the court has subject matter jurisdiction over this action. Sandoz denies any remaining allegations in this paragraph.

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

**ANSWER:** The allegations in this paragraph constitute conclusions of law to which no answer is required. To the extent an answer is required, Sandoz does not contest, for the



purposes of this action only, that the Court has personal jurisdiction over it. Sandoz denies any remaining allegations in this paragraph.

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

**ANSWER:** Admitted.

21. On information and belief, Sandoz 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:** Sandoz admits that part of Sandoz's business is the sale of generic medicines in the United States, including in this Judicial District. Sandoz denies any remaining allegations in this paragraph.

22. 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 Sandoz seeks FDA approval to manufacture, market, import, offer for sale, and/or sell pursuant to ANDA No. 218610 ("Sandoz's Proposed Product").

**ANSWER:** Sandoz admits that part of Sandoz's business is the sale of generic medicines that are distributed in the United States, including in this Judicial District. Sandoz denies any remaining allegations in this paragraph.

23. This Court has personal jurisdiction over Sandoz because, *inter alia*, on information and belief, Sandoz maintains a regular and established, physical place of business at 100 College Road West, Princeton, New Jersey 08540.

**ANSWER:** The allegations in this paragraph constitute conclusions of law to which no answer is required. To the extent an answer is required, Sandoz does not contest, for the

purposes of this action only, that the Court has personal jurisdiction over it. Sandoz denies any remaining allegations in this paragraph.

24. On information and belief, Sandoz 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. 0100097265.

**ANSWER:** Admitted.

25. Sandoz 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., Teva Pharmaceuticals USA, Inc., et al., v. Sandoz Inc., et al.*, Civil Action No. 17-275 (FLW)(DEA) (D.N.J.); *Amgen, Inc. v. Sandoz Inc., et al.*, Civil Action No. 18-11026 (MAS)(DEA) (D.N.J.); *Immunex Corp., et al. v. Sandoz Inc., et al.*, Civil Action No. 16-1118 (CCC) (D.N.J.). Sandoz has purposefully availed itself of the rights, benefits, and privileges of New Jersey by asserting counterclaims in this Court.

**ANSWER:** The allegations in this paragraph constitute conclusions of law to which no answer is required. To the extent an answer is required, Sandoz does not contest, for the purposes of this action only, that the Court has personal jurisdiction over it. Sandoz further admits that it consented to personal jurisdiction in New Jersey for the purposes of Civil Action Nos. 16-1118 and 18-11026. Sandoz denies any remaining allegations in this paragraph.

26. Sandoz 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) (D.N.J.).

**ANSWER:** Admitted.

27. For at least the reasons set forth above in Paragraphs 18-26, venue is proper in this Judicial District with respect to Sandoz pursuant to 28 U.S.C. § 1400(b).

**ANSWER:** The allegations in this paragraph constitute conclusions of law to which no answer is required. To the extent an answer is required, Sandoz does not contest, for the purposes of this action only, that venue is proper in this Judicial District. Sandoz denies any remaining allegations in this paragraph.

**ACTS GIVING RISE TO THIS SUIT**

28. Pursuant to Section 505 of the FFDCA, Sandoz submitted ANDA No. 218610 seeking approval to engage in the commercial manufacture, use, sale, offer for sale, or importation of Sandoz's Proposed Product, before the patents-in-suit expire.

**ANSWER:** Sandoz admits that it filed with the FDA ANDA No. 218610 seeking approval to sell Sandoz's Proposed Product. Sandoz respectfully refers the Court to ANDA No. 218610 for a full and accurate statement of its contents and denies the allegations of this paragraph to the extent they are inconsistent with this document. Sandoz denies any remaining allegations in this paragraph.

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

**ANSWER:** Admitted.

30. On information and belief, in connection with the submission of its ANDA as described above, Sandoz provided written certifications to the FDA, as called for by Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Sandoz's Paragraph IV Certifications"), alleging, *inter alia*, that the claims of United States Patent Nos. Nos. 8,440,715, 10,195,151, 10,512,609, 10,912,754, 10,940,133, 10,959,976, 11,160,779, 11,439,597, 11,560,354,

11,648,232, 11,771,666, 11,771,667, 11,779,554, 11,793,776, 11,839,598, 11,839,599, 11,850,226, 11,850,227, and 11,850,228 are invalid and/or will not be infringed by the activities described in Sandoz's ANDA.

**ANSWER:** Sandoz admits that it filed with the FDA ANDA No. 218610 seeking approval to sell Sandoz's Proposed Product. Sandoz respectfully refers the Court to ANDA No. 218610 for a full and accurate statement of its contents and denies the allegations of this paragraph to the extent they are inconsistent with this document. Sandoz denies any remaining allegations in this paragraph.

31. No earlier than August 15, 2023, Sandoz sent written notice of Sandoz's first Paragraph IV Certification to Axsome ("Sandoz's First Notice Letter"). Sandoz's First Notice Letter alleged, *inter alia*, that the claims of United States Patent Nos. 8,440,715, 10,195,151, 10,512,609, 10,912,754, 10,940,133, 10,959,976, 11,160,779, 11,439,597, 11,560,354, and 11,648,232 are invalid and/or will not be infringed by the activities described in Sandoz's ANDA. Sandoz's First Notice Letter also informed Axsome that Sandoz seeks approval to market Sandoz's Proposed Product before the expiration of United States Patent Nos. 8,440,715, 10,195,151, 10,512,609, 10,912,754, 10,940,133, 10,959,976, 11,160,779, 11,439,597, 11,560,354, and 11,648,232.

**ANSWER:** Sandoz admits that it sent a Notice Letter to Axsome no earlier than August 15, 2023 ("Sandoz's First Notice Letter"). Sandoz's First Notice Letter speaks for itself and contains a complete and accurate statement of its contents. Sandoz denies the allegations of this paragraph to the extent they are inconsistent with Sandoz's First Notice Letter. Sandoz denies any remaining allegations in this paragraph.

32. No earlier than January 12, 2024, Sandoz sent written notice of Sandoz's second Paragraph IV Certification to Axsome ("Sandoz's Second Notice Letter"). Sandoz's Second Notice Letter alleged that the claims of United States Patent Nos. 11,771,666, 11,771,667, 11,779,554, 11,793,776, 11,839,598, 11,839,599, 11,850,226, 11,850,227, and 11,850,228 are invalid and/or will not be infringed by the activities described in Sandoz's ANDA. Sandoz's Second Notice Letter also informed Axsome that Sandoz seeks approval to market Sandoz's Proposed Product before the expiration of United States Patent Nos. 11,771,666, 11,771,667, 11,779,554, 11,793,776, 11,839,598, 11,839,599, 11,850,226, 11,850,227, and 11,850,228.

**ANSWER:** Sandoz admits that it sent a Notice Letter to Axsome no earlier than January 12, 2024 ("Sandoz's Second Notice Letter"). Sandoz's Second Notice Letter speaks for itself and contains a complete and accurate statement of its contents. Sandoz denies the allegations of this paragraph to the extent they are inconsistent with Sandoz's Second Notice Letter. Sandoz denies any remaining allegations in this paragraph.

**COUNT I: INFRINGEMENT OF THE '666 PATENT**

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

**ANSWER:** In response to this paragraph, Sandoz incorporates by reference the preceding paragraphs of this Answer as if fully set forth herein.

34. Sandoz's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Sandoz'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.

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

**ANSWER:** Admitted.

36. Unless enjoined by this Court, upon FDA approval of Sandoz's ANDA, Sandoz 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 Sandoz's Proposed Product in the United States.

**ANSWER:** Denied.

37. Unless enjoined by this Court, upon FDA approval of Sandoz's ANDA, Sandoz 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 Sandoz's Proposed Product in the United States. On information and belief, upon FDA approval of Sandoz's ANDA, Sandoz will intentionally encourage acts of direct infringement with knowledge of the '666 patent and knowledge that its acts are encouraging infringement.

**ANSWER:** Denied.

38. Unless enjoined by this Court, upon FDA approval of Sandoz's ANDA, Sandoz 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 Sandoz's Proposed Product in the United States. On information and belief, Sandoz knew and knows that Sandoz's Proposed Product is designed for a use that infringes one or more claims of the '666 patent, and Sandoz's Proposed Product lacks a substantial non-infringing use.

**ANSWER:** Denied.

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

**ANSWER:** Denied.

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

**ANSWER:** Denied.

41. 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**

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

**ANSWER:** In response to this paragraph, Sandoz incorporates by reference the preceding paragraphs of this Answer as if fully set forth herein.

43. Sandoz's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Sandoz'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.

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

**ANSWER:** Admitted.

45. Unless enjoined by this Court, upon FDA approval of Sandoz's ANDA, Sandoz 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 Sandoz's Proposed Product in the United States.

**ANSWER:** Denied.

46. Unless enjoined by this Court, upon FDA approval of Sandoz's ANDA, Sandoz 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 Sandoz's Proposed Product in the United States. On information and belief, upon FDA approval of Sandoz's ANDA, Sandoz will intentionally encourage acts of direct infringement with knowledge of the '667 patent and knowledge that its acts are encouraging infringement.

**ANSWER:** Denied.

47. Unless enjoined by this Court, upon FDA approval of Sandoz's ANDA, Sandoz 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 Sandoz's Proposed Product in the United States. On information and belief, Sandoz knew and knows that Sandoz's Proposed Product is designed for a use that infringes one or more claims of the '667 patent, and Sandoz's Proposed Product lacks a substantial non-infringing use.

**ANSWER:** Denied.

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

**ANSWER:** Denied.

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

**ANSWER:** Denied.



50. 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**

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

**ANSWER:** In response to this paragraph, Sandoz incorporates by reference the preceding paragraphs of this Answer as if fully set forth herein.

52. Sandoz's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Sandoz'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.

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

**ANSWER:** Admitted.

54. Unless enjoined by this Court, upon FDA approval of Sandoz's ANDA, Sandoz 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 Sandoz's Proposed Product in the United States.

**ANSWER:** Denied.

55. Unless enjoined by this Court, upon FDA approval of Sandoz's ANDA, Sandoz 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 Sandoz's

Proposed Product in the United States. On information and belief, upon FDA approval of Sandoz's ANDA, Sandoz will intentionally encourage acts of direct infringement with knowledge of the '554 patent and knowledge that its acts are encouraging infringement.

**ANSWER:** Denied.

56. Unless enjoined by this Court, upon FDA approval of Sandoz's ANDA, Sandoz 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 Sandoz's Proposed Product in the United States. On information and belief, Sandoz knew and knows that Sandoz's Proposed Product is designed for a use that infringes one or more claims of the '554 patent, and Sandoz's Proposed Product lacks a substantial non-infringing use.

**ANSWER:** Denied.

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

**ANSWER:** Denied.

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

**ANSWER:** Denied.

59. 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**

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

**ANSWER:** In response to this paragraph, Sandoz incorporates by reference the preceding paragraphs of this Answer as if fully set forth herein.

61. Sandoz's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Sandoz'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.

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

**ANSWER:** Admitted.

63. Unless enjoined by this Court, upon FDA approval of Sandoz's ANDA, Sandoz 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 Sandoz's Proposed Product in the United States.

**ANSWER:** Denied.

64. Unless enjoined by this Court, upon FDA approval of Sandoz's ANDA, Sandoz 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 Sandoz's Proposed Product in the United States. On information and belief, upon FDA approval of Sandoz's ANDA, Sandoz will intentionally encourage acts of direct infringement with knowledge of the '776 patent and knowledge that its acts are encouraging infringement.

**ANSWER:** Denied.

65. Unless enjoined by this Court, upon FDA approval of Sandoz's ANDA, Sandoz 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 Sandoz's

Proposed Product in the United States. On information and belief, Sandoz knew and knows that Sandoz's Proposed Product is designed for a use that infringes one or more claims of the '776 patent, and Sandoz's Proposed Product lacks a substantial non-infringing use.

**ANSWER:** Denied.

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

**ANSWER:** Denied.

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

**ANSWER:** Denied.

68. 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**

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

**ANSWER:** In response to this paragraph, Sandoz incorporates by reference the preceding paragraphs of this Answer as if fully set forth herein.

70. Sandoz's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Sandoz'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.

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

**ANSWER:** Admitted.

72. Unless enjoined by this Court, upon FDA approval of Sandoz's ANDA, Sandoz 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 Sandoz's Proposed Product in the United States.

**ANSWER:** Denied.

73. Unless enjoined by this Court, upon FDA approval of Sandoz's ANDA, Sandoz 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 Sandoz's Proposed Product in the United States. On information and belief, upon FDA approval of Sandoz's ANDA, Sandoz will intentionally encourage acts of direct infringement with knowledge of the '598 patent and knowledge that its acts are encouraging infringement.

**ANSWER:** Denied.

74. Unless enjoined by this Court, upon FDA approval of Sandoz's ANDA, Sandoz 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 Sandoz's Proposed Product in the United States. On information and belief, Sandoz knew and knows that Sandoz's Proposed Product is designed for a use that infringes one or more claims of the '598 patent, and Sandoz's Proposed Product lacks a substantial non-infringing use.

**ANSWER:** Denied.

75. Failure to enjoin Sandoz's infringement of the '598 patent will substantially and irreparably damage and harm Axxome.

**ANSWER:** Denied.

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

**ANSWER:** Denied.

77. 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**

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

**ANSWER:** In response to this paragraph, Sandoz incorporates by reference the preceding paragraphs of this Answer as if fully set forth herein.

79. Sandoz's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Sandoz'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.

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

**ANSWER:** Admitted.

81. Unless enjoined by this Court, upon FDA approval of Sandoz's ANDA, Sandoz 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 Sandoz's Proposed Product in the United States.

**ANSWER:** Denied.

82. Unless enjoined by this Court, upon FDA approval of Sandoz's ANDA, Sandoz 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 Sandoz's Proposed Product in the United States. On information and belief, upon FDA approval of Sandoz's ANDA, Sandoz will intentionally encourage acts of direct infringement with knowledge of the '599 patent and knowledge that its acts are encouraging infringement.

**ANSWER:** Denied.

83. Unless enjoined by this Court, upon FDA approval of Sandoz's ANDA, Sandoz 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 Sandoz's Proposed Product in the United States. On information and belief, Sandoz knew and knows that Sandoz's Proposed Product is designed for a use that infringes one or more claims of the '599 patent, and Sandoz's Proposed Product lacks a substantial non-infringing use.

**ANSWER:** Denied.

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

**ANSWER:** Denied.

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

**ANSWER:** Denied.

86. 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**

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

**ANSWER:** In response to this paragraph, Sandoz incorporates by reference the preceding paragraphs of this Answer as if fully set forth herein.

88. Sandoz's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Sandoz'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.

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

**ANSWER:** Admitted.

90. Unless enjoined by this Court, upon FDA approval of Sandoz's ANDA, Sandoz 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 Sandoz's Proposed Product in the United States.

**ANSWER:** Denied.

91. Unless enjoined by this Court, upon FDA approval of Sandoz's ANDA, Sandoz 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 Sandoz's Proposed Product in the United States. On information and belief, upon FDA approval of Sandoz's ANDA, Sandoz will intentionally encourage acts of direct infringement with knowledge of the '226 patent and knowledge that its acts are encouraging infringement.



**ANSWER:** Denied.

92. Unless enjoined by this Court, upon FDA approval of Sandoz's ANDA, Sandoz 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 Sandoz's Proposed Product in the United States. On information and belief, Sandoz knew and knows that Sandoz's Proposed Product is designed for a use that infringes one or more claims of the '226 patent, and Sandoz's Proposed Product lacks a substantial non-infringing use.

**ANSWER:** Denied.

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

**ANSWER:** Denied.

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

**ANSWER:** Denied.

95. 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**

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

**ANSWER:** In response to this paragraph, Sandoz incorporates by reference the preceding paragraphs of this Answer as if fully set forth herein.

97. Sandoz's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Sandoz'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.

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

**ANSWER:** Admitted.

99. Unless enjoined by this Court, upon FDA approval of Sandoz's ANDA, Sandoz 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 Sandoz's Proposed Product in the United States.

**ANSWER:** Denied.

100. Unless enjoined by this Court, upon FDA approval of Sandoz's ANDA, Sandoz 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 Sandoz's Proposed Product in the United States. On information and belief, upon FDA approval of Sandoz's ANDA, Sandoz will intentionally encourage acts of direct infringement with knowledge of the '227 patent and knowledge that its acts are encouraging infringement.

**ANSWER:** Denied.

101. Unless enjoined by this Court, upon FDA approval of Sandoz's ANDA, Sandoz 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 Sandoz's Proposed Product in the United States. On information and belief, Sandoz knew and knows that

Sandoz's Proposed Product is designed for a use that infringes one or more claims of the '227 patent, and Sandoz's Proposed Product lacks a substantial non-infringing use.

**ANSWER:** Denied.

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

**ANSWER:** Denied.

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

**ANSWER:** Denied.

104. 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**

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

**ANSWER:** In response to this paragraph, Sandoz incorporates by reference the preceding paragraphs of this Answer as if fully set forth herein.

106. Sandoz's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Sandoz'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.

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

**ANSWER:** Admitted.

108. Unless enjoined by this Court, upon FDA approval of Sandoz's ANDA, Sandoz 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 Sandoz's Proposed Product in the United States.

**ANSWER:** Denied.

109. Unless enjoined by this Court, upon FDA approval of Sandoz's ANDA, Sandoz 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 Sandoz's Proposed Product in the United States. On information and belief, upon FDA approval of Sandoz's ANDA, Sandoz will intentionally encourage acts of direct infringement with knowledge of the '228 patent and knowledge that its acts are encouraging infringement.

**ANSWER:** Denied.

110. Unless enjoined by this Court, upon FDA approval of Sandoz's ANDA, Sandoz 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 Sandoz's Proposed Product in the United States. On information and belief, Sandoz knew and knows that Sandoz's Proposed Product is designed for a use that infringes one or more claims of the '228 patent, and Sandoz's Proposed Product lacks a substantial non-infringing use.

**ANSWER:** Denied.

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

**ANSWER:** Denied.

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

**ANSWER:** Denied.

113. 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.

**PRAYER FOR RELIEF**

Sandoz denies that Plaintiffs are entitled to any of the requested relief or any other relief against Sandoz.

**GENERAL DENIAL**

Each averment and allegation contained in Plaintiffs' Complaint that is not specifically admitted in this Answer is denied.

**AFFIRMATIVE AND OTHER DEFENSES**

**FIRST DEFENSE**  
**(FAILURE TO STATE A CLAIM)**

Plaintiffs fail to state a claim upon which relief can be granted.

**SECOND DEFENSE**  
**(NONINFRINGEMENT OF THE '666 PATENT)**

Sandoz has not infringed, directly or indirectly, any valid claim of the '666 patent and is not liable for any infringement thereof.

**THIRD DEFENSE**  
**(INVALIDITY OF THE '666 PATENT)**

Each claim of the '666 patent is invalid for failure to satisfy one or more of the conditions for patentability under the patent laws of the United States, including, without limitation, 35 U.S.C. §§ 101, 102, 103, and 112.

**FOURTH DEFENSE**  
**(NONINFRINGEMENT OF THE '667 PATENT)**

Sandoz has not infringed, directly or indirectly, any valid claim of the '667 patent and is not liable for any infringement thereof.

**FIFTH DEFENSE**  
**(INVALIDITY OF THE '667 PATENT)**

Each claim of the '667 patent is invalid for failure to satisfy one or more of the conditions for patentability under the patent laws of the United States, including, without limitation, 35 U.S.C. §§ 101, 102, 103, and 112.

**SIXTH DEFENSE**  
**(NONINFRINGEMENT OF THE '554 PATENT)**

Sandoz has not infringed, directly or indirectly, any valid claim of the '554 patent and is not liable for any infringement thereof.

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

Each claim of the '554 patent is invalid for failure to satisfy one or more of the conditions for patentability under the patent laws of the United States, including, without limitation, 35 U.S.C. §§ 101, 102, 103, and 112.

**EIGHTH DEFENSE**  
**(NONINFRINGEMENT OF THE '776 PATENT)**

Sandoz has not infringed, directly or indirectly, any valid claim of the '776 patent and is not liable for any infringement thereof.

**NINTH DEFENSE**  
**(INVALIDITY OF THE '776 PATENT)**

Each claim of the '776 patent is invalid for failure to satisfy one or more of the conditions for patentability under the patent laws of the United States, including, without limitation, 35 U.S.C. §§ 101, 102, 103, and 112.

**TENTH DEFENSE**  
**(NONINFRINGEMENT OF THE '598 PATENT)**

Sandoz has not infringed, directly or indirectly, any valid claim of the '598 patent and is not liable for any infringement thereof.

**ELEVENTH DEFENSE**  
**(INVALIDITY OF THE '598 PATENT)**

Each claim of the '598 patent is invalid for failure to satisfy one or more of the conditions for patentability under the patent laws of the United States, including, without limitation, 35 U.S.C. §§ 101, 102, 103, and 112.

**TWELFTH DEFENSE**  
**(NONINFRINGEMENT OF THE '599 PATENT)**

Sandoz has not infringed, directly or indirectly, any valid claim of the '599 patent and is not liable for any infringement thereof.

**THIRTEENTH DEFENSE**  
**(INVALIDITY OF THE '599 PATENT)**

Each claim of the '599 patent is invalid for failure to satisfy one or more of the conditions for patentability under the patent laws of the United States, including, without limitation, 35 U.S.C. §§ 101, 102, 103, and 112.

**FOURTEENTH DEFENSE**  
**(NONINFRINGEMENT OF THE '226 PATENT)**

Sandoz has not infringed, directly or indirectly, any valid claim of the '226 patent and is not liable for any infringement thereof.

**FIFTEENTH DEFENSE**  
**(INVALIDITY OF THE '226 PATENT)**

Each claim of the '226 patent is invalid for failure to satisfy one or more of the conditions for patentability under the patent laws of the United States, including, without limitation, 35 U.S.C. §§ 101, 102, 103, and 112.

**SIXTEENTH DEFENSE**  
**(NONINFRINGEMENT OF THE '227 PATENT)**

Sandoz has not infringed, directly or indirectly, any valid claim of the '227 patent and is not liable for any infringement thereof.

**SEVENTEENTH DEFENSE**  
**(INVALIDITY OF THE '227 PATENT)**

Each claim of the '227 patent is invalid for failure to satisfy one or more of the conditions for patentability under the patent laws of the United States, including, without limitation, 35 U.S.C. §§ 101, 102, 103, and 112.

**EIGHTEEN DEFENSE**  
**(NONINFRINGEMENT OF THE '228 PATENT)**

Sandoz has not infringed, directly or indirectly, any valid claim of the '228 patent and is not liable for any infringement thereof.



**NINETEENTH DEFENSE**  
**(INVALIDITY OF THE '228 PATENT)**

Each claim of the '228 patent is invalid for failure to satisfy one or more of the conditions for patentability under the patent laws of the United States, including, without limitation, 35 U.S.C. §§ 101, 102, 103, and 112.

**RESERVATION OF DEFENSES**

Sandoz reserves the right to assert additional defenses as may be warranted by discovery or further factual investigation in this action.

### **SANDOZ INC.’S COUNTERCLAIMS**

Defendant and Counterclaim-Plaintiff Sandoz Inc. (“Sandoz”) asserts the following counterclaims against Axsome Malta Ltd. and Axsome Therapeutics, Inc. (together, “Axsome” or “Counterclaim-Defendants”).

### **NATURE OF THE COUNTERCLAIMS**

1. These counterclaims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; the Patent Laws of the United States, 35 U.S.C. § 100, *et seq.* (including 35 U.S.C. § 271(e)(5)); and 21 U.S.C. § 355(j)(5)(C), based on an actual controversy between the parties to declare that Sandoz is free to continue to seek approval of its Abbreviated New Drug Application (“ANDA”) No. 218610, and upon approval by the U.S. Food and Drug Administration (“FDA”) to engage in commercial manufacture, importation, sale, and/or offer for sale of the products described in ANDA No. 218610.

### **THE PARTIES**

2. Sandoz is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 100 College Road West, Princeton, New Jersey 08540.

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

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

### **JURISDICTION AND VENUE**

5. These counterclaims arise under the patent laws of the United States, 35 U.S.C. § 1

*et seq.*, and the Declaratory Judgment Act, 28 U.S.C. § 2201–02.

6. This Court has subject matter jurisdiction over these counterclaims pursuant to 28 U.S.C. §§ 1331, 1338(a), and 2201.

7. Axsome has availed itself of this forum in this action and is therefore subject to personal jurisdiction in this district for purposes of these counterclaims.

8. Upon information and belief, Axsome, either directly or through one or more of their agents, develop, manufacture, market, distribute, sell, and import branded pharmaceutical products throughout the United States, including this Judicial District.

9. Axsome Therapeutics, Inc. is registered with the State of New Jersey's Department of Health as a wholesale drug distributor under Registration No. 5006024.

10. Axsome Therapeutics, Inc. is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business in the State of New Jersey under Entity Identification No. 0101060643.

11. Upon information and belief, Axsome Malta Ltd. and Axsome Therapeutics, Inc. are agents of each other with respect to importing pharmaceutical products into the United States and are commercially manufacturing, marketing, distributing, and selling pharmaceutical products throughout the United States, including Sunosi®.

12. Upon information and belief, Axsome Malta Ltd. and Axsome Therapeutics, Inc. are acting in concert with each other with respect to importing pharmaceutical products into the United States and are commercially manufacturing, marketing, distributing, and selling pharmaceutical products throughout the United States, including Sunosi®.

13. Upon information and belief, Axsome Therapeutics, Inc. maintains distribution channels throughout the United States, including in this Judicial District, which are used by

Axsome to commercially manufacture, use, offer to sell, sell, and import Sunosi®.

14. This Court has personal jurisdiction over Axsome Malta Ltd. because, *inter alia*, Axsome Malta Ltd.: (1) has purposely availed itself of the privilege of doing business in New Jersey directly or indirectly through its subsidiary, agent, and alter ego; (2) upon information and belief, maintains pervasive, continuous, and systematic contacts with the State of New Jersey, including the marketing, distribution, and sale of generic pharmaceutical drugs in New Jersey; (3) upon information and belief, derives substantial revenue from the sale of its products in New Jersey; and (4) upon information and belief, markets, sells, or distributes Sunosi® in New Jersey directly or indirectly through its subsidiary, agent, and alter ego.

15. Alternatively, this Court may exercise jurisdiction over Axsome Malta Ltd. pursuant to Federal Rule of Civil Procedure 4(k)(2), because (1) Sandoz's claims arise under federal law; (2) Axsome Malta Ltd. is a foreign defendant not subject to personal jurisdiction in any state's court of general jurisdiction; and (3) Axsome Malta Ltd. has sufficient contacts within the United States as a whole, including, but not limited to, manufacturing, importing, offering to sell, or selling pharmaceutical products throughout the United States, such that this Court's exercise of jurisdiction over Axsome Malta Ltd. satisfies due process.

16. This Court has personal jurisdiction over Axsome Therapeutics, Inc. because Axsome Therapeutics, Inc.: (1) has purposely availed itself of the privilege of doing business in New Jersey, including by registering with the State of New Jersey's Division of Revenue and Enterprise Services to do business in the State of New Jersey under Entity Identification No. 0101060643 and with the State of New Jersey's Department of Health as a wholesale drug distributor under Registration No. 5006024; (2) imports branded pharmaceutical products for sale and use throughout the United States, including in the State of New Jersey; (3) markets, distributes,

and sells branded pharmaceutical products throughout the United States, including in the State of New Jersey; and (4) upon information and belief, derives substantial revenue from the sale of its products in New Jersey.

17. For at least the reasons given in Paragraphs 7 through 13 and 16 of these counterclaims, venue is proper in this Court as to Axsome Therapeutics, Inc. under 28 U.S.C. §§ 1391 and 1400. Venue is proper in this Court as to Axsome Malta Ltd. under 28 U.S.C. §§ 1391(c)(3) and 1400(b) because Axsome Malta Ltd. is a foreign corporation and may be sued in any judicial district in the United States in which Axsome Malta Ltd. is subject to the court's personal jurisdiction.

18. To the extent that venue is proper in connection with Axsome's Complaint, it is equally proper for these counterclaims under 28 U.S.C. §§ 1391 and 1400.

### **FACTUAL BACKGROUND**

19. On information and belief, Axsome is the owner of or exclusive licensee for all substantial rights in U.S. 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"), and 11,850,228 ("the '228 patent") (collectively, "the counterclaim patents").

20. The '666 patent is titled "Methods of Administering Solriamfetol to Lactating Women" and issued on October 3, 2023.

21. The '667 patent is titled "Methods of Administering Solriamfetol to Lactating Women" and issued on October 3, 2023.

22. The '554 patent is titled "Methods of Administering Solriamfetol to Lactating Women" and issued on October 10, 2023.

23. The '776 patent is titled "Methods of Administering Solriamfetol to Lactating

Women” and issued on October 24, 2023.

24. The ’598 patent is titled “Methods of Providing Solriamfetol Therapy to Subjects with Impaired Renal Function” and issued on December 12, 2023.

25. The ’599 patent is titled “Methods of Providing Solriamfetol Therapy to Subjects with Impaired Renal Function” and issued on December 12, 2023.

26. The ’226 patent is titled “Methods of Providing Solriamfetol Therapy to Subjects with Impaired Renal Function” and issued on December 26, 2023.

27. The ’227 patent is titled “Methods of Providing Solriamfetol Therapy to Subjects with Impaired Renal Function” and issued on December 26, 2023.

28. The ’228 patent is titled “Methods of Providing Solriamfetol Therapy to Subjects with Impaired Renal Function” and issued on December 26, 2023.

29. The Approved Drug Products with Therapeutic Equivalence Evaluations (“Orange Book”) lists Axsome Malta Ltd. as the holder of the New Drug Application (“NDA”) No. 211230 for Sunosi®. On information and belief, the active ingredient in Sunosi® is solriamfetol.

30. Sandoz submitted ANDA No. 218610 under 21 U.S.C. § 355(j), seeking approval from the FDA for solriamfetol tablets, 75 mg and 150 mg, (“Sandoz’s ANDA Product”) prior to the expiration of the counterclaim patents.

31. Pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), Sandoz submitted a certification in ANDA No. 218610 alleging that the claims of the counterclaim patents are invalid and will not be infringed by the manufacture, use, offer for sale, sale, or importation of Sandoz’s ANDA Product.

32. On February 14, 2024, Axsome sued Sandoz in the District of New Jersey, alleging infringement of the counterclaim patents.

**COUNT I**  
**(DECLARATORY JUDGMENT OF NONINFRINGEMENT OF THE '666 PATENT)**

33. Sandoz realleges and incorporates by reference Paragraphs 1 through 32 of these counterclaims as if fully set forth herein.

34. A present, genuine, and justiciable controversy exists between Axsome and Sandoz regarding, *inter alia*, whether the manufacture, use, offer for sale, sale, or importation of Sandoz's ANDA Product would infringe any valid and enforceable claim of the '666 patent.

35. The manufacture, use, offer for sale, sale, or importation of Sandoz's ANDA Product would not directly or indirectly infringe any valid and enforceable claim of the '666 patent, either literally or under the doctrine of equivalents.

36. Sandoz is entitled to a judicial declaration that the manufacture, use, offer for sale, sale, or importation of Sandoz's ANDA Product would not infringe any valid and enforceable claim of the '666 patent.

**COUNT II**  
**(DECLARATORY JUDGMENT OF INVALIDITY OF THE '666 PATENT)**

37. Sandoz realleges and incorporates by reference Paragraphs 1 through 36 of these counterclaims as if fully set forth herein.

38. Axsome has alleged in this action that Sandoz infringed the '666 patent by filing ANDA No. 218610 and that Sandoz's manufacture, use, offer for sale, sale, or importation of the proposed drug products described in ANDA No. 218610 would infringe the '666 patent.

39. The '666 patent is invalid for failure to comply with one or more requirements of 35 U.S.C. §§ 101, 102, 103, and 112.

40. Accordingly, a present, genuine, and justiciable controversy exists between Sandoz and Axsome regarding, *inter alia*, the validity of the claims of the '666 patent.

41. Sandoz is entitled to a declaration by the Court that one or more of the claims of

the '666 patent are invalid.

42. Sandoz is entitled to further necessary or proper relief based on the Court's declaratory judgment or decree.

**COUNT III**  
**(DECLARATORY JUDGMENT OF NONINFRINGEMENT OF THE '667 PATENT)**

43. Sandoz realleges and incorporates by reference Paragraphs 1 through 42 of these counterclaims as if fully set forth herein.

44. A present, genuine, and justiciable controversy exists between Axsome and Sandoz regarding, *inter alia*, whether the manufacture, use, offer for sale, sale, or importation of Sandoz's ANDA Product would infringe any valid and enforceable claim of the '667 patent.

45. The manufacture, use, offer for sale, sale, or importation of Sandoz's ANDA Product would not directly or indirectly infringe any valid and enforceable claim of the '667 patent, either literally or under the doctrine of equivalents.

46. Sandoz is entitled to a judicial declaration that the manufacture, use, offer for sale, sale, or importation of Sandoz's ANDA Product would not infringe any valid and enforceable claim of the '667 patent.

**COUNT IV**  
**(DECLARATORY JUDGMENT OF INVALIDITY OF THE '667 PATENT)**

47. Sandoz realleges and incorporates by reference Paragraphs 1 through 46 of these counterclaims as if fully set forth herein.

48. Axsome has alleged in this action that Sandoz infringed the '667 patent by filing ANDA No. 218610 and that Sandoz's manufacture, use, offer for sale, sale, or importation of the proposed drug products described in ANDA No. 218610 would infringe the '667 patent.

49. The '667 patent is invalid for failure to comply with one or more requirements of 35 U.S.C. §§ 101, 102, 103, and 112.



50. Accordingly, a present, genuine, and justiciable controversy exists between Sandoz and Axsome regarding, *inter alia*, the validity of the claims of the '667 patent.

51. Sandoz is entitled to a declaration by the Court that one or more of the claims of the '667 patent are invalid.

52. Sandoz is entitled to further necessary or proper relief based on the Court's declaratory judgment or decree.

**COUNT V**  
**(DECLARATORY JUDGMENT OF NONINFRINGEMENT OF THE '554 PATENT)**

53. Sandoz realleges and incorporates by reference Paragraphs 1 through 52 of these counterclaims as if fully set forth herein.

54. A present, genuine, and justiciable controversy exists between Axsome and Sandoz regarding, *inter alia*, whether the manufacture, use, offer for sale, sale, or importation of Sandoz's ANDA Product would infringe any valid and enforceable claim of the '554 patent.

55. The manufacture, use, offer for sale, sale, or importation of Sandoz's ANDA Product would not directly or indirectly infringe any valid and enforceable claim of the '554 patent, either literally or under the doctrine of equivalents.

56. Sandoz is entitled to a judicial declaration that the manufacture, use, offer for sale, sale, or importation of Sandoz's ANDA Product would not infringe any valid and enforceable claim of the '554 patent.

**COUNT VI**  
**(DECLARATORY JUDGMENT OF INVALIDITY OF THE '554 PATENT)**

57. Sandoz realleges and incorporates by reference Paragraphs 1 through 56 of these counterclaims as if fully set forth herein.

58. Axsome has alleged in this action that Sandoz infringed the '554 patent by filing ANDA No. 218610 and that Sandoz's manufacture, use, offer for sale, sale, or importation of the

proposed drug products described in ANDA No. 218610 would infringe the '554 patent.

59. The '554 patent is invalid for failure to comply with one or more requirements of 35 U.S.C. §§ 101, 102, 103, and 112.

60. Accordingly, a present, genuine, and justiciable controversy exists between Sandoz and Axsome regarding, *inter alia*, the validity of the claims of the '554 patent.

61. Sandoz is entitled to a declaration by the Court that one or more of the claims of the '554 patent are invalid.

62. Sandoz is entitled to further necessary or proper relief based on the Court's declaratory judgment or decree.

**COUNT VII**  
**(DECLARATORY JUDGMENT OF NONINFRINGEMENT OF THE '776 PATENT)**

63. Sandoz realleges and incorporates by reference Paragraphs 1 through 62 of these counterclaims as if fully set forth herein.

64. A present, genuine, and justiciable controversy exists between Axsome and Sandoz regarding, *inter alia*, whether the manufacture, use, offer for sale, sale, or importation of Sandoz's ANDA Product would infringe any valid and enforceable claim of the '776 patent.

65. The manufacture, use, offer for sale, sale, or importation of Sandoz's ANDA Product would not directly or indirectly infringe any valid and enforceable claim of the '776 patent, either literally or under the doctrine of equivalents.

66. Sandoz is entitled to a judicial declaration that the manufacture, use, offer for sale, sale, or importation of Sandoz's ANDA Product would not infringe any valid and enforceable claim of the '776 patent.

**COUNT VIII**  
**(DECLARATORY JUDGMENT OF INVALIDITY OF THE '776 PATENT)**

67. Sandoz realleges and incorporates by reference Paragraphs 1 through 66 of these

counterclaims as if fully set forth herein.

68. Axsome has alleged in this action that Sandoz infringed the '776 patent by filing ANDA No. 218610 and that Sandoz's manufacture, use, offer for sale, sale, or importation of the proposed drug products described in ANDA No. 218610 would infringe the '776 patent.

69. The '776 patent is invalid for failure to comply with one or more requirements of 35 U.S.C. §§ 101, 102, 103, and 112.

70. Accordingly, a present, genuine, and justiciable controversy exists between Sandoz and Axsome regarding, *inter alia*, the validity of the claims of the '776 patent.

71. Sandoz is entitled to a declaration by the Court that one or more of the claims of the '776 patent are invalid.

72. Sandoz is entitled to further necessary or proper relief based on the Court's declaratory judgment or decree.

**COUNT IX**  
**(DECLARATORY JUDGMENT OF NONINFRINGEMENT OF THE '598 PATENT)**

73. Sandoz realleges and incorporates by reference Paragraphs 1 through 72 of these counterclaims as if fully set forth herein.

74. A present, genuine, and justiciable controversy exists between Axsome and Sandoz regarding, *inter alia*, whether the manufacture, use, offer for sale, sale, or importation of Sandoz's ANDA Product would infringe any valid and enforceable claim of the '598 patent.

75. The manufacture, use, offer for sale, sale, or importation of Sandoz's ANDA Product would not directly or indirectly infringe any valid and enforceable claim of the '598 patent, either literally or under the doctrine of equivalents.

76. Sandoz is entitled to a judicial declaration that the manufacture, use, offer for sale, sale, or importation of Sandoz's ANDA Product would not infringe any valid and enforceable

claim of the '598 patent.

**COUNT X**  
**(DECLARATORY JUDGMENT OF INVALIDITY OF THE '598 PATENT)**

77. Sandoz realleges and incorporates by reference Paragraphs 1 through 76 of these counterclaims as if fully set forth herein.

78. Axsome has alleged in this action that Sandoz infringed the '598 patent by filing ANDA No. 218610 and that Sandoz's manufacture, use, offer for sale, sale, or importation of the proposed drug products described in ANDA No. 218610 would infringe the '598 patent.

79. The '598 patent is invalid for failure to comply with one or more requirements of 35 U.S.C. §§ 101, 102, 103, and 112.

80. Accordingly, a present, genuine, and justiciable controversy exists between Sandoz and Axsome regarding, *inter alia*, the validity of the claims of the '598 patent.

81. Sandoz is entitled to a declaration by the Court that one or more of the claims of the '598 patent are invalid.

82. Sandoz is entitled to further necessary or proper relief based on the Court's declaratory judgment or decree.

**COUNT XI**  
**(DECLARATORY JUDGMENT OF NONINFRINGEMENT OF THE '599 PATENT)**

83. Sandoz realleges and incorporates by reference Paragraphs 1 through 82 of these counterclaims as if fully set forth herein.

84. A present, genuine, and justiciable controversy exists between Axsome and Sandoz regarding, *inter alia*, whether the manufacture, use, offer for sale, sale, or importation of Sandoz's ANDA Product would infringe any valid and enforceable claim of the '599 patent.

85. The manufacture, use, offer for sale, sale, or importation of Sandoz's ANDA Product would not directly or indirectly infringe any valid and enforceable claim of the '599 patent,

either literally or under the doctrine of equivalents.

86. Sandoz is entitled to a judicial declaration that the manufacture, use, offer for sale, sale, or importation of Sandoz's ANDA Product would not infringe any valid and enforceable claim of the '599 patent.

**COUNT XII**  
**(DECLARATORY JUDGMENT OF INVALIDITY OF THE '599 PATENT)**

87. Sandoz realleges and incorporates by reference Paragraphs 1 through 86 of these counterclaims as if fully set forth herein.

88. Axsome has alleged in this action that Sandoz infringed the '599 patent by filing ANDA No. 218610 and that Sandoz's manufacture, use, offer for sale, sale, or importation of the proposed drug products described in ANDA No. 218610 would infringe the '599 patent.

89. The '599 patent is invalid for failure to comply with one or more requirements of 35 U.S.C. §§ 101, 102, 103, and 112.

90. Accordingly, a present, genuine, and justiciable controversy exists between Sandoz and Axsome regarding, *inter alia*, the validity of the claims of the '599 patent.

91. Sandoz is entitled to a declaration by the Court that one or more of the claims of the '599 patent are invalid.

92. Sandoz is entitled to further necessary or proper relief based on the Court's declaratory judgment or decree.

**COUNT XIII**  
**(DECLARATORY JUDGMENT OF NONINFRINGEMENT OF THE '226 PATENT)**

93. Sandoz realleges and incorporates by reference Paragraphs 1 through 92 of these counterclaims as if fully set forth herein.

94. A present, genuine, and justiciable controversy exists between Axsome and Sandoz regarding, *inter alia*, whether the manufacture, use, offer for sale, sale, or importation of Sandoz's

ANDA Product would infringe any valid and enforceable claim of the '226 patent.

95. The manufacture, use, offer for sale, sale, or importation of Sandoz's ANDA Product would not directly or indirectly infringe any valid and enforceable claim of the '226 patent, either literally or under the doctrine of equivalents.

96. Sandoz is entitled to a judicial declaration that the manufacture, use, offer for sale, sale, or importation of Sandoz's ANDA Product would not infringe any valid and enforceable claim of the '226 patent.

**COUNT XIV**  
**(DECLARATORY JUDGMENT OF INVALIDITY OF THE '226 PATENT)**

97. Sandoz realleges and incorporates by reference Paragraphs 1 through 96 of these counterclaims as if fully set forth herein.

98. Axsome has alleged in this action that Sandoz infringed the '226 patent by filing ANDA No. 218610 and that Sandoz's manufacture, use, offer for sale, sale, or importation of the proposed drug products described in ANDA No. 218610 would infringe the '226 patent.

99. The '226 patent is invalid for failure to comply with one or more requirements of 35 U.S.C. §§ 101, 102, 103, and 112.

100. Accordingly, a present, genuine, and justiciable controversy exists between Sandoz and Axsome regarding, *inter alia*, the validity of the claims of the '226 patent.

101. Sandoz is entitled to a declaration by the Court that one or more of the claims of the '226 patent are invalid.

102. Sandoz is entitled to further necessary or proper relief based on the Court's declaratory judgment or decree.

**COUNT XV**  
**(DECLARATORY JUDGMENT OF NONINFRINGEMENT OF THE '227 PATENT)**

103. Sandoz realleges and incorporates by reference Paragraphs 1 through 102 of these

counterclaims as if fully set forth herein.

104. A present, genuine, and justiciable controversy exists between Axsome and Sandoz regarding, *inter alia*, whether the manufacture, use, offer for sale, sale, or importation of Sandoz's ANDA Product would infringe any valid and enforceable claim of the '227 patent.

105. The manufacture, use, offer for sale, sale, or importation of Sandoz's ANDA Product would not directly or indirectly infringe any valid and enforceable claim of the '227 patent, either literally or under the doctrine of equivalents.

106. Sandoz is entitled to a judicial declaration that the manufacture, use, offer for sale, sale, or importation of Sandoz's ANDA Product would not infringe any valid and enforceable claim of the '227 patent.

**COUNT XVI**  
**(DECLARATORY JUDGMENT OF INVALIDITY OF THE '227 PATENT)**

107. Sandoz realleges and incorporates by reference Paragraphs 1 through 106 of these counterclaims as if fully set forth herein.

108. Axsome has alleged in this action that Sandoz infringed the '227 patent by filing ANDA No. 218610 and that Sandoz's manufacture, use, offer for sale, sale, or importation of the proposed drug products described in ANDA No. 218610 would infringe the '227 patent.

109. The '227 patent is invalid for failure to comply with one or more requirements of 35 U.S.C. §§ 101, 102, 103, and 112.

110. Accordingly, a present, genuine, and justiciable controversy exists between Sandoz and Axsome regarding, *inter alia*, the validity of the claims of the '227 patent.

111. Sandoz is entitled to a declaration by the Court that one or more of the claims of the '227 patent are invalid.

112. Sandoz is entitled to further necessary or proper relief based on the Court's

declaratory judgment or decree.

**COUNT XVII**  
**(DECLARATORY JUDGMENT OF NONINFRINGEMENT OF THE '228 PATENT)**

113. Sandoz realleges and incorporates by reference Paragraphs 1 through 112 of these counterclaims as if fully set forth herein.

114. A present, genuine, and justiciable controversy exists between Axsome and Sandoz regarding, *inter alia*, whether the manufacture, use, offer for sale, sale, or importation of Sandoz's ANDA Product would infringe any valid and enforceable claim of the '228 patent.

115. The manufacture, use, offer for sale, sale, or importation of Sandoz's ANDA Product would not directly or indirectly infringe any valid and enforceable claim of the '228 patent, either literally or under the doctrine of equivalents.

116. Sandoz is entitled to a judicial declaration that the manufacture, use, offer for sale, sale, or importation of Sandoz's ANDA Product would not infringe any valid and enforceable claim of the '228 patent.

**COUNT XVIII**  
**(DECLARATORY JUDGMENT OF INVALIDITY OF THE '228 PATENT)**

117. Sandoz realleges and incorporates by reference Paragraphs 1 through 116 of these counterclaims as if fully set forth herein.

118. Axsome has alleged in this action that Sandoz infringed the '228 patent by filing ANDA No. 218610 and that Sandoz's manufacture, use, offer for sale, sale, or importation of the proposed drug products described in ANDA No. 218610 would infringe the '228 patent.

119. The '228 patent is invalid for failure to comply with one or more requirements of 35 U.S.C. §§ 101, 102, 103, and 112.

120. Accordingly, a present, genuine, and justiciable controversy exists between Sandoz and Axsome regarding, *inter alia*, the validity of the claims of the '228 patent.



121. Sandoz is entitled to a declaration by the Court that one or more of the claims of the '228 patent are invalid.

122. Sandoz is entitled to further necessary or proper relief based on the Court's declaratory judgment or decree.

**PRAYER FOR RELIEF**

WHEREFORE, Sandoz prays that the court enter judgment ordering as follows:

(a) That a judgment be entered declaring that the manufacture, sale, offer for sale, use, or importation of Sandoz's ANDA Product does not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid and enforceable claim of the '666 patent;

(b) That a judgment be entered declaring that the claims of the '666 patent are invalid;

(c) That a judgment be entered declaring that the manufacture, sale, offer for sale, use or importation of Sandoz's ANDA Product does not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid and enforceable claim of the '667 patent;

(d) That a judgment be entered declaring that the claims of the '667 patent are invalid;

(e) That a judgment be entered declaring that the manufacture, sale, offer for sale, use, or importation of Sandoz's ANDA Product does not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid and enforceable claim of the '554 patent;

(f) That a judgment be entered declaring that the claims of the '554 patent are invalid;

(g) That a judgment be entered declaring that the manufacture, sale, offer for sale, use, or importation of Sandoz's ANDA Product does not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid and enforceable claim of the '776 patent;

(h) That a judgment be entered declaring that the claims of the '776 patent are invalid;

(i) That a judgment be entered declaring that the manufacture, sale, offer for sale, use, or importation of Sandoz's ANDA Product does not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid and enforceable claim of the '598 patent;

(j) That a judgment be entered declaring that the claims of the '598 patent are invalid;

(k) That a judgment be entered declaring that the manufacture, sale, offer for sale, use, or importation of Sandoz's ANDA Product does not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid and enforceable claim of the '599 patent;

(l) That a judgment be entered declaring that the claims of the '599 patent are invalid;

(m) That a judgment be entered declaring that the manufacture, sale, offer for sale, use, or importation of Sandoz's ANDA Product does not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid and enforceable claim of the '226 patent;

(n) That a judgment be entered declaring that the claims of the '226 patent are invalid;

(o) That a judgment be entered declaring that the manufacture, sale, offer for sale, use, or importation of Sandoz's ANDA Product does not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid and enforceable claim of the '227 patent;

(p) That a judgment be entered declaring that the claims of the '227 patent are invalid;

(q) That a judgment be entered declaring that the manufacture, sale, offer for sale, use, or importation of Sandoz's ANDA Product does not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid and enforceable claim of the '228 patent;

(r) That a judgment be entered declaring that the claims of the '228 patent are invalid;

(s) That an order be entered dismissing Axsome's Complaint with prejudice and entering judgment in favor of Sandoz;

(t) If the facts demonstrate that the case is exceptional within the meaning of 35 U.S.C. § 285, awarding Sandoz reasonable attorney fees and costs reasonably incurred in prosecuting this action; and

(u) Granting Sandoz such other and further relief as the Court deems just and appropriate.

Dated: April 23, 2024

Respectfully Submitted by:

/s/ Eric Abraham

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**CERTIFICATION PURSUANT TO L. CIV. R. 11.2**

Pursuant to Local Civil Rule 11.2, Defendant Sandoz Inc., through its counsel, certifies that the matter in controversy is also the subject of the following other pending actions:

- *Axsome Malta Ltd., et al v. Alkem Laboratories Ltd., et al.*, Civil Action No. 23-20354 (MCA)(LDW) (D.N.J.)
- *Axsome Malta Ltd., et al v. Alkem Laboratories Ltd., et al.*, Civil Action No. 24-4608 (MCA)(LDW) (D.N.J.)

Dated: April 23, 2024

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**CERTIFICATE OF SERVICE**

I, the undersigned, hereby certify that on April 23, 2024, a true and correct copy of the foregoing DEFENDANT SANDOZ INC.'S ANSWER TO PLAINTIFFS' COMPLAINT FOR PATENT INFRINGEMENT, AND COUNTERCLAIMS were filed via ECF and were served via electronic mail upon:

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Dated: April 23, 2024

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