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Hetero Labs Limited Unit-V, and
Hetero Labs Ltd.*

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

AXSOME MALTA LTD. and AXSOME
THERAPEUTICS, INC.,

Plaintiffs,

Case No. 2:24-cv-03999-MCA-LDW

v.

HETERO USA INC., HETERO LABS
LIMITED UNIT-V, and HETERO LABS
LTD.,

Defendants.

**DEFENDANTS HETERO USA INC., HETERO LABS LIMITED UNIT-V, AND
HETERO LABS LTD.'S ANSWER, AFFIRMATIVE DEFENSES, AND
COUNTERCLAIMS TO PLAINTIFFS' COMPLAINT**

Defendants Hetero USA Inc., Hetero Labs Limited Unit-V, and Hetero Labs Ltd. (collectively, "Hetero"), by and through their undersigned counsel, file this Answer, Affirmative Defenses, and Counterclaims to Plaintiffs Axsome Malta Ltd. and Axsome Therapeutics, Inc.'s (collectively, "Axsome" or "Plaintiffs") Complaint, and state as follows:

GENERAL DENIAL

Pursuant to Fed. R. Civ. P. 8(b)(3), Hetero denies all allegations in Axsome's Complaint except those specifically 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 Abbreviated New Drug Application ("ANDA") No. 218654 ("Hetero'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. 11,839,598 ("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: Hetero admits that Axsome filed a civil action alleging Hetero infringed U.S. Patent Nos. 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") under the patent laws of the United States, Title 35, United States Code. Hetero admits that it had filed an Abbreviated New Drug Application ("ANDA") No. 218654 to the U.S. Food and Drug Administration ("FDA"). Except as expressly admitted, Hetero is without knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 1, and on that basis denies these allegations.

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: Hetero admits that Sunosi® is approved by FDA as 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. Except as expressly admitted, Hetero lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 2, and on that basis denies these 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: Paragraph 3 contains legal conclusions to which no answer is required. To the extent that Hetero is required to answer, on information and belief, Hetero admits 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. Hetero lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 3, and on that basis denies any and all remaining allegations of Paragraph 3.

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: Paragraph 4 contains legal conclusions to which no answer is required. To the extent that Hetero is required to answer, on information and belief, Hetero admits 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. Hetero lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 4, and on that basis denies any and all remaining allegations of Paragraph 4.

5. On information and belief, Defendant Hetero USA Inc. is a corporation organized and existing under the laws of Delaware, having a principal place of business at 1035 Centennial Avenue, Piscataway, NJ 08854.

ANSWER: Hetero admits that Hetero USA Inc. is a corporation organized and existing under the laws of Delaware, having a principal place of business at 1035 Centennial Avenue, Piscataway, NJ 08854.

6. On information and belief, Defendant Hetero Labs Limited Unit-V is a corporation organized and existing under the laws of India, having a principal place of business at Polepally, Jadcherla, Mahabubnagar – 509301, Andhra Pradesh, India.

ANSWER: Hetero admits that Hetero Labs Limited Unit-V is a corporation organized and existing under the laws of India, having a principal place of business at Polepally, Jadcherla, Mahabubnagar – 509301, Andhra Pradesh, India.

7. On information and belief, Defendant Hetero Labs Ltd. is a corporation organized and existing under the laws of India, having a principal place of business at 7-2-A2, Hetero Corporate Industrial Estates, Sanath Nagar, Hyderabad 500 018, Andhra Pradesh, India.

ANSWER: Hetero admits that Hetero Labs Ltd. is a corporation organized and existing under the laws of India, having a principal place of business at 7-2-A2, Hetero Corporate Industrial Estates, Sanath Nagar, Hyderabad 500 018, Andhra Pradesh, India.

8. 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: Paragraph 8 contains legal conclusions to which no response is required. To the extent an answer is required, Hetero lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 8, and on that basis denies any and all remaining allegations of Paragraph 8.

The Patents-in-Suit

9. 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 A.

ANSWER: Hetero admits that the '598 patent is titled "Methods of Providing Solriamfetol Therapy to Subjects with Impaired Renal Function." Hetero admits that the face of the '598 patent identifies Katayoun Zomorodi as the inventor, and that the '598 patent was issued by the USPTO on or about December 12, 2023. What appears to be an uncertified copy of the '598 patent was attached to Plaintiffs' Complaint as Exhibit A. Hetero denies the remaining allegations in Paragraph 9.

10. 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 B.

ANSWER: Hetero admits that the '599 patent is titled "Methods of Providing Solriamfetol Therapy to Subjects with Impaired Renal Function." Hetero admits that the face of the '599 patent identifies Katayoun Zomorodi as the inventor, and that the '599 patent was issued by the USPTO on or about December 12, 2023. What appears to be an uncertified copy of the '599 patent was attached to Plaintiffs' Complaint as Exhibit B. Hetero denies the remaining allegations in Paragraph 10.

11. 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 C.

ANSWER: Hetero admits that the '226 patent is titled "Methods of Providing Solriamfetol Therapy to Subjects with Impaired Renal Function." Hetero admits that the face of

the '226 patent identifies Katayoun Zomorodi as the inventor, and that the '226 patent was issued by the USPTO on or about December 26, 2023. What appears to be an uncertified copy of the '226 patent was attached to Plaintiffs' Complaint as Exhibit C. Hetero denies the remaining allegations in Paragraph 11.

12. 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 D.

ANSWER: Hetero admits that the '227 patent is titled "Methods of Providing Solriamfetol Therapy to Subjects with Impaired Renal Function." Hetero admits that the face of the '227 patent identifies Katayoun Zomorodi as the inventor, and that the '227 patent was issued by the USPTO on or about December 26, 2023. What appears to be an uncertified copy of the '227 patent was attached to Plaintiffs' Complaint as Exhibit D. Hetero denies the remaining allegations in Paragraph 12.

13. 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 E.

ANSWER: Hetero admits that the '228 patent is titled "Methods of Providing Solriamfetol Therapy to Subjects with Impaired Renal Function." Hetero admits that the face of the '228 patent identifies Katayoun Zomorodi as the inventor, and that the '228 patent was issued by the USPTO on or about December 26, 2023. What appears to be an uncertified copy of the '228 patent was attached to Plaintiffs' Complaint as Exhibit E. Hetero denies the remaining allegations in Paragraph 13.

14. 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 F.

ANSWER: Hetero admits that the ’528 patent is titled “Methods of Providing Solriamfetol Therapy to Subjects with Impaired Renal Function.” Hetero admits that the face of the ’528 patent identifies Katayoun Zomorodi as the inventor, and that the ’528 patent was issued by the USPTO on or about January 2, 2024. What appears to be an uncertified copy of the ’528 patent was attached to Plaintiffs’ Complaint as Exhibit F. Hetero denies the remaining allegations in Paragraph 14.

15. 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 G.

ANSWER: Hetero admits that the ’098 patent is titled “Methods and Compositions for Treating Excessive Sleepiness.” Hetero admits that the face of the ’098 patent identifies Lawrence Patrick Carter, Yuan Lu, and Katayoun Zomorodi as the inventors, and that the ’098 patent was issued by the USPTO on or about January 9, 2024. What appears to be an uncertified copy of the ’098 patent was attached to Plaintiffs’ Complaint as Exhibit G. Hetero denies the remaining allegations in Paragraph 15.

16. 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 H.

ANSWER: Hetero admits that the ’203 patent is titled “Methods of Administering Solriamfetol to Lactating Women.” Hetero admits that the face of the ’203 patent identifies Herriot Tabuteau as the inventor, and that the ’203 patent was issued by the USPTO on or about January 16, 2024. What appears to be an uncertified copy of the ’203 patent was attached to Plaintiffs’ Complaint as Exhibit H. Hetero denies the remaining allegations in Paragraph 16.

17. 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 I.

ANSWER: Hetero admits that the '204 patent is titled "Methods of Administering Solriamfetol to Lactating Women." Hetero admits that the face of the '204 patent identifies Herriot Tabuteau as the inventor, and that the '204 patent was issued by the USPTO on or about January 16, 2024. What appears to be an uncertified copy of the '204 patent was attached to Plaintiffs' Complaint as Exhibit I. Hetero denies the remaining allegations in Paragraph 17.

The Sunosi® Drug Product

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

ANSWER: Paragraph 18 contains legal conclusions and allegations to which no answer is required. Hetero admits that the FDA publication, the "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), lists Axsome Malta Ltd. as the holder of NDA No. 211230 for Sunosi® (solriamfetol hydrochloride) in oral tablets, Eq. 75 mg base and Eq. 150 mg base. Hetero admits that Sunosi® is approved by FDA as a DNRI indicated to improve wakefulness in adult patients with excessive daytime sleepiness associated with narcolepsy or obstructive sleep apnea. Except as expressly admitted, Hetero is without knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 18, and on that basis denies these allegations.

19. 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: Hetero admits that, according to the Orange Book, the patents-in-suit are listed in connection with Sunosi® (solriamfetol hydrochloride) in oral tablets, Eq. 75 mg base and Eq. 150 mg base. Except as expressly admitted, Hetero is without knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 19, and on that basis denies these allegations.

Jurisdiction and Venue

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

ANSWER: Paragraph 20 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero does not contest subject matter jurisdiction in this Court for the limited purposes of this action only. Except as expressly admitted, Hetero denies the remaining allegations of Paragraph 20.

21. As set forth below, the Court has personal jurisdiction over each of Hetero USA Inc., Hetero Labs Limited Unit-V, and Hetero Labs Ltd. by virtue of, *inter alia*, their systematic and continuous contacts with the State of New Jersey.

ANSWER: Paragraph 21 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero does not contest personal jurisdiction in this Court for the limited purposes of this action only. Except as expressly admitted, Hetero denies the remaining allegations of Paragraph 21.

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

ANSWER: To the extent an answer is required, Hetero does not contest personal jurisdiction in this Court for the limited purposes of this action only. Except as expressly admitted, Hetero denies the remaining allegations of Paragraph 22.

23. On information and belief, Hetero 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: Hetero Labs Limited Unit-V and Hetero Labs Ltd. admit that it develops and manufactures high-quality generic pharmaceutical products that are ultimately used by consumers in the United States. Hetero does not contest personal jurisdiction in this Court for the limited purposes of this action only. Except as expressly admitted, Hetero denies the remaining allegations of Paragraph 23.

24. 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 Hetero seeks FDA approval to manufacture, market, import, offer for sale, and/or sell pursuant to ANDA No. 218654 ("Hetero's Proposed Product").

ANSWER: Hetero admits that it seeks regulatory approval from the FDA for ANDA No. 218654. The content of Hetero's ANDA speaks for itself. Hetero does not contest personal jurisdiction in this Court for the limited purposes of this action only. Except as expressly admitted, Hetero denies the remaining allegations of Paragraph 24.

25. This Court has personal jurisdiction over Hetero Labs Ltd. because, *inter alia*, it: (1) has purposefully availed itself of the privilege of doing business in the State of New Jersey, including directly or indirectly through its subsidiary, agent, and/or alter ego, Hetero USA Inc., a company with a regular and established physical place of business in New Jersey; and (2) maintains extensive and systematic contacts with the State of New Jersey, including through the marketing, distribution, and/or sale of generic pharmaceutical drugs in New Jersey including through, directly or indirectly, Hetero USA Inc.

ANSWER: Paragraph 25 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero Labs Ltd. admits that it develops and manufactures high-quality generic pharmaceutical products that are ultimately used by consumers in the United States. Hetero does not contest personal jurisdiction in this Court for the limited

purposes of this action only. Except as expressly admitted, Hetero denies the remaining allegations of Paragraph 25.

26. This Court has personal jurisdiction over Hetero Labs Limited Unit-V because, *inter alia*, it: (1) has purposefully availed itself of the privilege of doing business in the State of New Jersey, including directly or indirectly through its subsidiary, agent, and/or alter ego, Hetero USA Inc., a company with a regular and established physical place of business in New Jersey; and (2) maintains extensive and systematic contacts with the State of New Jersey, including through the marketing, distribution, and/or sale of generic pharmaceutical drugs in New Jersey including through, directly or indirectly, Hetero USA Inc.

ANSWER: Paragraph 26 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero Labs Limited Unit-V admits that it develops and manufactures high-quality generic pharmaceutical products that are ultimately used by consumers in the United States. Hetero does not contest personal jurisdiction in this Court for the limited purposes of this action only. Except as expressly admitted, Hetero denies the remaining allegations of Paragraph 26.

27. This Court has personal jurisdiction over Hetero USA Inc. because, *inter alia*, on information and belief, Hetero USA Inc. maintains a regular and established, physical place of business at 1035 Centennial Avenue, Piscataway, NJ 08854.

ANSWER: Hetero USA Inc. admits that it has a physical place of business at 1035 Centennial Avenue, Piscataway, NJ 08854. Hetero does not contest personal jurisdiction in this Court for the limited purposes of this action only. Except as expressly admitted, Hetero denies the remaining allegations of Paragraph 27.

28. On information and belief, Hetero USA Inc. 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. 0400362826.

ANSWER: Admitted.

29. On information and belief, Hetero USA Inc. will work in concert with Hetero Labs Limited Unit-V and/or Hetero Labs Ltd. toward the regulatory approval, manufacturing, use, importation, marketing, offer for sale, sale, and

distribution of generic pharmaceutical products, including Hetero's Proposed Product, throughout the United States, including in New Jersey and in this Judicial District, prior to the expiration of the patents-in-suit.

ANSWER: Paragraph 29 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero does not contest personal jurisdiction in this Court for the limited purposes of this action only. Except as expressly admitted, Hetero denies the remaining allegations of Paragraph 29.

30. Hetero has consented to personal jurisdiction in this Court in recent actions arising out of its ANDA submissions and has filed counterclaims in such cases. *See, e.g., Celgene Corporation v. Annora Pharma Private Limited, et al.*, C.A. No. 3-18-cv-11220 (MAS)(DEA) (D.N.J.) (Hetero USA Inc.); *Celgene Corporation v. Hetero Labs Limited, et al.*, Civil Action No. 2-19-cv-15449 (SDW)(LDW) (D.N.J.) (Hetero USA Inc., Hetero Labs Ltd., Hetero Labs Ltd. Unit-V); *Celgene Corporation v. Hetero Labs Limited, et al.*, Civil Action No. 2-19-cv-05797 (ES)(MAH) (D.N.J.) (Hetero USA Inc., Hetero Labs Ltd., Hetero Labs Ltd. Unit-V); *Celgene Corporation v. Hetero Labs Limited, et al.*, Civil Action No. 2-18-cv-17463 (SDW)(LDW) (D.N.J.) (Hetero USA Inc., Hetero Labs Ltd., Hetero Labs Ltd. Unit-V); *Celgene Corporation v. Hetero Labs Limited, et al.*, Civil Action No. 2-18-cv-14111 (ES)(MAH) (D.N.J.) (Hetero USA Inc., Hetero Labs Ltd., Hetero Labs Ltd. Unit-V); *Celgene Corporation v. Hetero Labs Limited, et al.*, Civil Action No. 2-17-cv-03387 (ES)(MAH) (D.N.J.) (Hetero USA Inc., Hetero Labs Ltd., Hetero Labs Ltd. Unit-V); *Otsuka Pharm. Co., Ltd. v. Hetero Drugs Limited, et al.*, Civil Action No. 1-15-cv-00161 (JBS)(KMW) (D.N.J.) (Hetero USA Inc., Hetero Labs Ltd.); *AstraZeneca AB, et al. v. Hetero USA Inc., et al.*, Civil Action No. 1-16-cv-02442 (RMB)(JS) (D.N.J.) (Hetero USA Inc., Hetero Labs Ltd.); and *BTG Int'l Ltd., et al. v. Actavis Lab'ys FL, Inc., et al.*, Civil Action No. 2-15-cv-05909 (KM)(JBC) (D.N.J.) (Hetero USA Inc., Hetero Labs Ltd., Hetero Labs Ltd. Unit-V). Hetero has purposefully availed itself of the rights, benefits, and privileges of New Jersey by asserting counterclaims in this Court.

ANSWER: Paragraph 30 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero does not contest personal jurisdiction in this Court for the limited purposes of this action only. Prior consent to personal jurisdiction in this Court has no bearing on this action. Except as expressly admitted, Hetero denies the remaining allegations of Paragraph 30.

31. Hetero did not contest personal jurisdiction in this Court in related actions *Axsome Malta Ltd., et al v. Alkem Laboratories Ltd., et al.*, Civil Action No. 23-

20354 (MCA)(LDW) (D.N.J.) and *Axsome Malta Ltd., et al. v. Hetero USA Inc., et al.*, Civil Action No. 24-196 (MCA)(LDW).

ANSWER: Paragraph 31 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero does not contest personal jurisdiction in this Court for the limited purposes of this action only. Prior consent to personal jurisdiction in this Court has no bearing on this action. Except as expressly admitted, Hetero denies the remaining allegations of Paragraph 31.

32. In the alternative, this Court has personal jurisdiction over Hetero Labs Ltd. because the requirements of Federal Rule of Civil Procedure 4(k)(2) are met as (a) Axsome's claims arise under federal law; (b) Hetero Labs Ltd. is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Hetero Labs Ltd. 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 Hetero Labs Ltd. satisfies due process.

ANSWER: Paragraph 32 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero does not contest personal jurisdiction in this Court for the limited purposes of this action only. Except as expressly admitted, Hetero denies the remaining allegations of Paragraph 32.

33. In the alternative, this Court has personal jurisdiction over Hetero Labs Limited Unit-V because the requirements of Federal Rule of Civil Procedure 4(k)(2) are met as (a) Axsome's claims arise under federal law; (b) Hetero Labs Limited Unit-V is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Hetero Labs Limited Unit-V 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 Hetero Labs Limited Unit-V satisfies due process.

ANSWER: Paragraph 33 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero does not contest personal jurisdiction in

this Court for the limited purposes of this action only. Except as expressly admitted, Hetero denies the remaining allegations of Paragraph 33.

34. At least because, on information and belief, Hetero Labs Ltd. and Hetero Labs Limited Unit-V are foreign companies, venue is proper in this Judicial District with respect to Hetero Labs Ltd. and Hetero Labs Limited Unit-V pursuant to 28 U.S.C. § 1391(c)(3) and 28 U.S.C. § 1400(b). Also, for at least the reasons set forth above in Paragraphs 22-31, venue is proper in this Judicial District as to Hetero USA Inc. pursuant to 28 U.S.C. § 1391(c)(3) and 28 U.S.C. § 1400(b).

ANSWER: Paragraph 34 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero does not contest venue in this Court for the limited purposes of this action only. Except as expressly admitted, Hetero denies the remaining allegations of Paragraph 34.

Acts Giving Rise To This Suit

35. Pursuant to Section 505 of the FFDCA, Hetero submitted ANDA No. 218654 seeking approval to engage in the commercial manufacture, use, sale, offer for sale, or importation of Hetero's Proposed Product, before certain patents-in-suit expire.

ANSWER: Hetero admits that it seeks regulatory approval from the FDA for ANDA No. 218654. The content of Hetero's ANDA speaks for itself. Except as expressly admitted, Hetero denies the remaining allegations of Paragraph 35.

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

ANSWER: Hetero's ANDA has not yet been tentatively or finally approved by FDA and the allegations of Paragraph 36 are wholly speculative. Except as expressly admitted, Hetero denies the remaining allegations of Paragraph 36.

37. On information and belief, in connection with the submission of its ANDA as described above, Hetero 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) ("Hetero's Paragraph IV Certifications"), alleging, inter alia, that the claims of United States Patent Nos. 8,440,715, 10,195,151, 10,512,609, 10,912,754, 10,940,133,

10,959,976, 11,160,779, 11,439,597, 11,560,354, 11,648,232, 11,771,666, 11,771,667, 11,779,554, 11,793,776, 11,839,598, 11,839,599, 11,850,226, 11,850,227, 11,850,228, 11,857,528, 11,865,098, 11,872,203, and 11,872,204 are invalid, unenforceable and/or will not be infringed by the activities described in Hetero's ANDA.

ANSWER: Hetero admits that it had provided Paragraph IV Certifications to the FDA in connection with the submission of its ANDA No. 218654. The content of Hetero's Paragraph IV Certifications speak for themselves. Except as expressly admitted, Hetero denies the remaining allegations of Paragraph 37.

38. No earlier than August 15, 2023, Hetero sent written notice of its first Paragraph IV Certification to Axsome ("Hetero's First Notice Letter"). Hetero'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, unenforceable and/or will not be infringed by the activities described in Hetero's ANDA. Hetero's First Notice Letter also informed Axsome that Hetero seeks approval to market Hetero'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: Hetero admits that it sent a notice letter to Axsome, which included notice that Hetero is seeking approval for Hetero's Proposed Product prior to 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. The content of the Hetero's Notice Letter speaks for itself. Except as expressly admitted, Hetero denies the remaining allegations of Paragraph 38.

39. No earlier than December 1, 2023, Hetero sent written notice of its second Paragraph IV Certification to Axsome ("Hetero's Second Notice Letter"). Hetero's Second Notice Letter alleged that the claims of United States Patent Nos. 11,771,666, 11,771,667, 11,779,554, and 11,793,776 are invalid, unenforceable, and/or will not be infringed by the activities described in Hetero's ANDA. Hetero's Second Notice Letter also informed Axsome that Hetero seeks approval to market Hetero's Proposed Product before the expiration of United States Patent Nos. 11,771,666, 11,771,667, 11,779,554, and 11,793,776.

ANSWER: Hetero admits that it sent a notice letter to Axsome, which included notice that Hetero is seeking approval for Hetero's Proposed Product prior to the expiration of United States Patent Nos. 11,771,666, 11,771,667, 11,779,554, and 11,793,776. The content of the Hetero's Notice Letter speaks for itself. Except as expressly admitted, Hetero denies the remaining allegations of Paragraph 39.

40. No earlier than March 11, 2024, Hetero sent written notice of its third Paragraph IV Certification to Axsome ("Hetero's Third Notice Letter"). Hetero's Third Notice Letter alleged that the claims of United States Patent Nos. 11,839,598, 11,839,599, 11,850,226, 11,850,227, 11,850,228, 11,857,528, 11,865,098, 11,872,203, and 11,872,204 are invalid, unenforceable, and/or will not be infringed by the activities described in Hetero's ANDA. Hetero's Third Notice Letter also informed Axsome that Hetero seeks approval to market Hetero's Proposed Product before the expiration of United States Patent Nos. 11,839,598, 11,839,599, 11,850,226, 11,850,227, 11,850,228, 11,857,528, 11,865,098, 11,872,203, and 11,872,204.

ANSWER: Hetero admits that it sent a notice letter to Axsome, which included notice that Hetero is seeking approval for Hetero's Proposed Product prior to the expiration of United States Patent Nos. 11,839,598, 11,839,599, 11,850,226, 11,850,227, 11,850,228, 11,857,528, 11,865,098, 11,872,203, and 11,872,204. The content of the Hetero's Notice Letter speaks for itself. Except as expressly admitted, Hetero denies the remaining allegations of Paragraph 40.

Count I: Infringement of the '598 Patent

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

ANSWER: Hetero repeats and realleges each of its responses to the preceding paragraphs as though fully set forth herein.

42. Hetero's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Hetero'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: Paragraph 42 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 42.

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

ANSWER: Paragraph 43 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 43.

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

ANSWER: Paragraph 44 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 44.

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

ANSWER: Paragraph 45 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 45.

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

ANSWER: Paragraph 46 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 46.

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

ANSWER: Paragraph 47 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 47.

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

ANSWER: Paragraph 48 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 48.

49. 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: Paragraph 49 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 49.

Count II: Infringement of the '599 Patent

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

ANSWER: Hetero repeats and realleges each of its responses to the preceding paragraphs as though fully set forth herein.

51. Hetero's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Hetero'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: Paragraph 51 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 51.

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

ANSWER: Paragraph 52 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 52.

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

ANSWER: Paragraph 53 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 53.

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

ANSWER: Paragraph 54 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 54.

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

ANSWER: Paragraph 55 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 55.

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

ANSWER: Paragraph 56 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 56.

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

ANSWER: Paragraph 57 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 57.

58. 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: Paragraph 58 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 58.

Count III: Infringement of the '226 Patent

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

ANSWER: Hetero repeats and realleges each of its responses to the preceding paragraphs as though fully set forth herein.

60. Hetero's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Hetero'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: Paragraph 60 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 60.

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

ANSWER: Paragraph 61 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 61.

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

ANSWER: Paragraph 62 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 62.

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

ANSWER: Paragraph 63 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 63.

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

ANSWER: Paragraph 64 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 64.

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

ANSWER: Paragraph 65 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 65.

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

ANSWER: Paragraph 66 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 66.

67. 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: Paragraph 67 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 67.

Count IV: Infringement of the '227 Patent

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

ANSWER: Hetero repeats and realleges each of its responses to the preceding paragraphs as though fully set forth herein.

69. Hetero's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Hetero'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: Paragraph 69 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 69.

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

ANSWER: Paragraph 70 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 70.

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

ANSWER: Paragraph 71 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 71.

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

ANSWER: Paragraph 72 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 72.

73. Unless enjoined by this Court, upon FDA approval of Hetero's ANDA, Hetero 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 Hetero's Proposed Product in the United States. On information and belief, Hetero knew and knows that Hetero's Proposed Product is designed for a use that infringes one or more claims of the '227 patent, and Hetero's Proposed Product lacks a substantial non-infringing use.

ANSWER: Paragraph 73 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 73.

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

ANSWER: Paragraph 74 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 74.

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

ANSWER: Paragraph 75 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 75.

76. 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: Paragraph 76 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 76.

Count V: Infringement of the '228 Patent

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

ANSWER: Hetero repeats and realleges each of its responses to the preceding paragraphs as though fully set forth herein.

78. Hetero's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Hetero'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: Paragraph 78 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 78.

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

ANSWER: Paragraph 79 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 79.

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

ANSWER: Paragraph 80 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 80.

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

ANSWER: Paragraph 81 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 81.

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

ANSWER: Paragraph 82 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 82.

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

ANSWER: Paragraph 83 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 83.

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

ANSWER: Paragraph 84 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 84.

85. 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: Paragraph 85 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 85.

Count VI: Infringement of the '528 Patent

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

ANSWER: Hetero repeats and realleges each of its responses to the preceding paragraphs as though fully set forth herein.

87. Hetero's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Hetero'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: Paragraph 87 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 87.

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

ANSWER: Paragraph 88 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 88.

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

ANSWER: Paragraph 89 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 89.

90. Unless enjoined by this Court, upon FDA approval of Hetero's ANDA, Hetero 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 Hetero's Proposed Product in the United States. On information and belief, upon FDA approval of Hetero's ANDA, Hetero will intentionally encourage acts of direct infringement with knowledge of the '528 patent and knowledge that its acts are encouraging infringement.

ANSWER: Paragraph 90 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 90.

91. Unless enjoined by this Court, upon FDA approval of Hetero's ANDA, Hetero 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 Hetero's Proposed Product in the United States. On information and belief, Hetero knew and knows that Hetero's Proposed Product is designed for a use that infringes one or more claims of the '528 patent, and Hetero's Proposed Product lacks a substantial non-infringing use.

ANSWER: Paragraph 91 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 91.

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

ANSWER: Paragraph 92 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 92.

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

ANSWER: Paragraph 93 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 93.

94. 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: Paragraph 94 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 94.

Count VII: Infringement of the '098 Patent

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

ANSWER: Hetero repeats and realleges each of its responses to the preceding paragraphs as though fully set forth herein.

96. Hetero's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Hetero'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: Paragraph 96 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 96.

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

ANSWER: Paragraph 97 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 97.

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

ANSWER: Paragraph 98 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 98.

99. Unless enjoined by this Court, upon FDA approval of Hetero's ANDA, Hetero 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 Hetero's Proposed Product in the United States. On information and belief, upon FDA approval of Hetero's ANDA, Hetero will intentionally encourage acts of direct infringement with knowledge of the '098 patent and knowledge that its acts are encouraging infringement.

ANSWER: Paragraph 99 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 99.

100. Unless enjoined by this Court, upon FDA approval of Hetero's ANDA, Hetero 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 Hetero's Proposed Product in the United States. On information and belief, Hetero knew and knows that Hetero's Proposed Product is designed for a use that infringes one or more claims of the '098 patent, and Hetero's Proposed Product lacks a substantial non-infringing use.

ANSWER: Paragraph 100 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 100.

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

ANSWER: Paragraph 101 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 101.

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

ANSWER: Paragraph 102 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 102.

103. 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: Paragraph 103 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 103.

Count VIII: Infringement of the '203 Patent

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

ANSWER: Hetero repeats and realleges each of its responses to the preceding paragraphs as though fully set forth herein.

105. Hetero's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Hetero'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: Paragraph 105 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 105.

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

ANSWER: Paragraph 106 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 106.

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

ANSWER: Paragraph 107 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 107.

108. Unless enjoined by this Court, upon FDA approval of Hetero's ANDA, Hetero 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 Hetero's Proposed Product in the United States. On information and belief, upon FDA approval of Hetero's ANDA, Hetero will intentionally encourage acts of direct infringement with knowledge of the '203 patent and knowledge that its acts are encouraging infringement.

ANSWER: Paragraph 108 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 108.

109. Unless enjoined by this Court, upon FDA approval of Hetero's ANDA, Hetero 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 Hetero's Proposed Product in the United States. On information and belief, Hetero knew and knows that Hetero's Proposed Product is designed for a use that infringes one or more claims of the '203 patent, and Hetero's Proposed Product lacks a substantial non-infringing use.

ANSWER: Paragraph 109 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 109.

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

ANSWER: Paragraph 110 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 110.

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

ANSWER: Paragraph 111 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 111.

112. 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: Paragraph 112 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 112.

Count IX: Infringement of the '204 Patent

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

ANSWER: Hetero repeats and realleges each of its responses to the preceding paragraphs as though fully set forth herein.

114. Hetero's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Hetero'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: Paragraph 114 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 114.

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

ANSWER: Paragraph 115 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 115.

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

ANSWER: Paragraph 116 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 116.

117. Unless enjoined by this Court, upon FDA approval of Hetero's ANDA, Hetero 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 Hetero's Proposed Product in the United States. On information and belief, upon FDA approval of Hetero's ANDA, Hetero will intentionally encourage acts of direct infringement with knowledge of the '204 patent and knowledge that its acts are encouraging infringement.

ANSWER: Paragraph 117 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 117.

118. Unless enjoined by this Court, upon FDA approval of Hetero's ANDA, Hetero 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 Hetero's Proposed Product in the United States. On information and belief, Hetero knew and knows that Hetero's Proposed Product is designed for a use that infringes one or more claims of the '204 patent, and Hetero's Proposed Product lacks a substantial non-infringing use.

ANSWER: Paragraph 118 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 118.

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

ANSWER: Paragraph 119 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 119.

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

ANSWER: Paragraph 120 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 120.

121. 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: Paragraph 121 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 121.

AXSOME'S PRAYER FOR RELIEF

All allegations in Axsome's Complaint that are not expressly admitted by Hetero are denied. Hetero denies that Axsome is entitled to any of the relief sought in its Prayer for Relief.

HETERO'S AFFIRMATIVE DEFENSES

Without prejudice to the denials in this Answer, and without admitting any allegations of the Complaint not expressly admitted, Hetero asserts the following Affirmative Defenses to Axsome's Complaint without assuming the burden of proof on any defense that would otherwise rest on Axsome. Hetero reserves the right to assert additional defenses, as warranted by facts learned through investigation and discovery.

FIRST DEFENSE

The manufacture, use, or sale, offer for sale, or importation of the products that are the subject of Hetero's ANDA No. 218654 has not infringed, does not infringe, and would not, if marketed, manufactured, used, sold, offered for sale, or imported into the United States, infringe any valid or enforceable claim of the patents-in-suit.

SECOND DEFENSE

Each of the claims of each of the patents-in-suit is invalid for failure to satisfy one or more of the conditions for patentability set forth in 35 U.S.C. §§ 101, 102, 103, and/or 112, or for failure to satisfy other judicially created bases for invalidation or unenforceability.

THIRD DEFENSE

Axsome's Complaint fails to state a claim for exceptional case under 35 U.S.C. § 285 and/or willful infringement. Hetero's actions in defending this case do not give rise to an exceptional case under 35 U.S.C. § 285.

RESERVATION OF DEFENSES

Hetero reserves any and all defenses available under the Federal Rules of Civil Procedure and the U.S. Patent Laws and any other defenses, at law or in equity, that may now exist or become available later as a result of discovery and further factual investigation during this litigation.

HETERO'S COUNTERCLAIMS

Defendants Hetero USA Inc., Hetero Labs Limited Unit-V, and Hetero Labs Ltd. (collectively, "Hetero"), by and through their undersigned counsel, plead the following counterclaims against Plaintiffs/Counterclaim Defendants Axsome Malta Ltd. and Axsome Therapeutics, Inc.'s (collectively, "Axsome" or "Plaintiffs"):

PARTIES

1. Hetero USA Inc. is a corporation organized and existing under the laws of Delaware, having a principal place of business at 1035 Centennial Avenue, Piscataway, NJ 08854.

2. Hetero Labs Limited Unit-V is a corporation organized and existing under the laws of India, having a principal place of business at Polepally, Jadcherla, Mahabubnagar – 509301, Andhra Pradesh, India.

3. Hetero Labs Ltd. is a corporation organized and existing under the laws of India, having a principal place of business at 7-2-A2, Hetero Corporate Industrial Estates, Sanath Nagar, Hyderabad 500 018, Andhra Pradesh, India.

4. 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.

5. 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.

JURISDICTION AND VENUE

6. This Court has subject matter jurisdiction over these Counterclaims for declaratory judgment pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202; based on an actual controversy between Hetero, on the one hand, and Axsome on the other hand, arising under the Patent Laws of the United States, 35 U.S.C. §§ 1 *et seq.*

7. This Court has personal jurisdiction over Axsome because, *inter alia*, Axsome subjected itself to the jurisdiction of this Court by filing its Complaint here.

8. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b), and/or by Axsome's choice of forum.

FACTUAL BACKGROUND

9. On information and belief, and based on the allegations in the Complaint, Axsome is the holder of New Drug Application ("NDA") No. 211230 for solriamfetol oral tablets, Eq. 75 mg base and Eq. 150 mg base, which is sold under trade name Sunosi®.

10. On information and belief, and based on the allegations in the Complaint, Axsome caused the Food and Drug Administration ("FDA") to list U.S. Patent Nos. 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 Asserted Patents") in the FDA's publication Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") in connection with NDA No. 211230.

11. The '598 patent lists the title as "Methods of Providing Solriamfetol Therapy to Subjects with Impaired Renal Function," and the issue date as December 12, 2023.

12. The '599 patent lists the title as "Methods of Providing Solriamfetol Therapy to Subjects with Impaired Renal Function," and the issue date as December 12, 2023.

13. The '226 patent lists the title as "Methods of Providing Solriamfetol Therapy to Subjects with Impaired Renal Function," and the issue date as December 26, 2023.

14. The '227 patent lists the title as "Methods of Providing Solriamfetol Therapy to Subjects with Impaired Renal Function," and the issue date as December 26, 2023.

15. The '228 patent lists the title as "Methods of Providing Solriamfetol Therapy to Subjects with Impaired Renal Function," and the issue date as December 26, 2023.

16. The '528 patent lists the title as "Methods of Providing Solriamfetol Therapy to Subjects with Impaired Renal Function," and the issue date as January 2, 2024.

17. The '098 patent lists the title as "Methods and Compositions for Treating Excessive Sleepiness," and the issue date as January 9, 2024.

18. The '203 patent lists the title as "Methods of Administering Solriamfetol to Lactating Women," and the issue date as January 16, 2024.

19. The '204 patent lists the title as "Methods of Administering Solriamfetol to Lactating Women," and the issue date as January 16, 2024.

20. Axsome purports and claims to be the owner of or exclusive licensee for, and to have the right to enforce, the Asserted Patents.

21. Hetero submitted Abbreviated New Drug Application ("ANDA") No. 218654 to the FDA under 21 U.S.C. § 355(j) seeking approval to engage in the commercial manufacture, use, importation, offer for sale or sale of Hetero's proposed drug product containing solriamfetol oral tablets, Eq. 75 mg base and Eq. 150 mg base ("Hetero's ANDA product"). For ANDA No. 218654, Hetero submitted a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) to the FDA with respect to the '598 patent, the '599 patent, the '226 patent, the '227 patent, the '228 patent, the '528 patent, the '098 patent, the '203 patent, and the '204 patent.

22. Hetero sent notice of this certification to Axsome on or about March 11, 2024 ("the Notice Letter"). On information and belief, and as Axsome alleges in its Complaint, Axsome received the Notice Letter.

23. On March 19, 2024, Axsome filed suit in this Judicial District against Hetero in connection with ANDA No. 218654 alleging infringement of the Asserted Patents.

24. In view of the foregoing, there has been, and is now, an actual, substantial, and continuing, justiciable controversy between Hetero and Axsome having sufficient immediacy and reality to warrant the issuance of a declaration of rights by the Court with respect to noninfringement and/or invalidity of the Asserted Patents, and as to Hetero's right to obtain FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of Hetero's ANDA product.

COUNT I
(Declaratory Judgment of Noninfringement of U.S. Patent No. 11,839,598)

25. Hetero incorporates by reference and re-alleges each of the foregoing paragraphs of Hetero's Answer and Affirmative Defenses to the Complaint and these Counterclaims as if fully set forth herein.

26. Hetero has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claims of the '598 patent.

27. A present, genuine, and justiciable controversy exists between Hetero, on the one hand, and Axsome, on the other hand, regarding, *inter alia*, the issue of whether the manufacture, use, sale, offer for sale and/or importation of Hetero's ANDA Product would infringe any valid or enforceable claim of the '598 patent.

28. The Court should declare that Hetero has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claims of the '598 patent.

COUNT II
(Declaratory Judgment of Invalidity of U.S. Patent No. 11,839,598)

29. Hetero incorporates by reference and re-alleges each of the foregoing paragraphs of Hetero's Answer and Affirmative Defenses to the Complaint and these Counterclaims as if fully set forth herein.

30. Upon information and belief, the claims of the '598 patent are invalid for failure to comply with one or more of the requirements of at least 35 U.S.C. §§ 101, 102, 103, 112, and/or 251 *et seq.*, and/or are invalid under the doctrine of obviousness-type double patenting, and/or for any other judicially created and/or non-statutory basis for invalidity or unenforceability.

31. There is a real, substantial, and justiciable controversy between Hetero and Axsome concerning whether the claims of the '598 patent are invalid and/or unenforceable for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, 251, and/or pursuant to common law and/or equitable doctrines.

32. The Court should declare that the claims of the '598 patent are invalid and/or unenforceable.

COUNT III
(Declaratory Judgment of Noninfringement of U.S. Patent No. 11,839,599)

33. Hetero incorporates by reference and re-alleges each of the foregoing paragraphs of Hetero's Answer and Affirmative Defenses to the Complaint and these Counterclaims as if fully set forth herein.

34. Hetero has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claims of the '599 patent.

35. A present, genuine, and justiciable controversy exists between Hetero, on the one hand, and Axsome, on the other hand, regarding, *inter alia*, the issue of whether the manufacture, use, sale, offer for sale and/or importation of Hetero's ANDA Product would infringe any valid or enforceable claim of the '599 patent.

36. The Court should declare that Hetero has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claims of the '599 patent.

COUNT IV
(Declaratory Judgment of Invalidity of U.S. Patent No. 11,839,599)

37. Hetero incorporates by reference and re-alleges each of the foregoing paragraphs of Hetero's Answer and Affirmative Defenses to the Complaint and these Counterclaims as if fully set forth herein.

38. Upon information and belief, the claims of the '599 patent are invalid for failure to comply with one or more of the requirements of at least 35 U.S.C. §§ 101, 102, 103, 112, and/or 251 *et seq.*, and/or are invalid under the doctrine of obviousness-type double patenting, and/or for any other judicially created and/or non-statutory basis for invalidity or unenforceability.

39. There is a real, substantial, and justiciable controversy between Hetero and Axsome concerning whether the claims of the '599 patent are invalid and/or unenforceable for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, 251, and/or pursuant to common law and/or equitable doctrines.

40. The Court should declare that the claims of the '599 patent are invalid and/or unenforceable.

COUNT V
(Declaratory Judgment of Noninfringement of U.S. Patent No. 11,850,226)

41. Hetero incorporates by reference and re-alleges each of the foregoing paragraphs of Hetero's Answer and Affirmative Defenses to the Complaint and these Counterclaims as if fully set forth herein.

42. Hetero has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claims of the '226 patent.

43. A present, genuine, and justiciable controversy exists between Hetero, on the one hand, and Axsome, on the other hand, regarding, *inter alia*, the issue of whether the manufacture, use, sale, offer for sale and/or importation of Hetero's ANDA Product would infringe any valid or enforceable claim of the '226 patent.

44. The Court should declare that Hetero has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claims of the '226 patent.

COUNT VI
(Declaratory Judgment of Invalidity of U.S. Patent No. 11,850,226)

45. Hetero incorporates by reference and re-alleges each of the foregoing paragraphs of Hetero's Answer and Affirmative Defenses to the Complaint and these Counterclaims as if fully set forth herein.

46. Upon information and belief, the claims of the '226 patent are invalid for failure to comply with one or more of the requirements of at least 35 U.S.C. §§ 101, 102, 103, 112, and/or 251 *et seq.*, and/or are invalid under the doctrine of obviousness-type double patenting, and/or for any other judicially created and/or non-statutory basis for invalidity or unenforceability.

47. There is a real, substantial, and justiciable controversy between Hetero and Axsome concerning whether the claims of the '226 patent are invalid and/or unenforceable for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, 251, and/or pursuant to common law and/or equitable doctrines.

48. The Court should declare that the claims of the '226 patent are invalid and/or unenforceable.

COUNT VII
(Declaratory Judgment of Noninfringement of U.S. Patent No. 11,850,227)

49. Hetero incorporates by reference and re-alleges each of the foregoing paragraphs of Hetero's Answer and Affirmative Defenses to the Complaint and these Counterclaims as if fully set forth herein.

50. Hetero has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claims of the '227 patent.

51. A present, genuine, and justiciable controversy exists between Hetero, on the one hand, and Axsome, on the other hand, regarding, *inter alia*, the issue of whether the manufacture, use, sale, offer for sale and/or importation of Hetero's ANDA Product would infringe any valid or enforceable claim of the '227 patent.

52. The Court should declare that Hetero has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claims of the '227 patent.

COUNT VIII
(Declaratory Judgment of Invalidity of U.S. Patent No. 11,850,227)

53. Hetero incorporates by reference and re-alleges each of the foregoing paragraphs of Hetero's Answer and Affirmative Defenses to the Complaint and these Counterclaims as if fully set forth herein.

54. Upon information and belief, the claims of the '227 patent are invalid for failure to comply with one or more of the requirements of at least 35 U.S.C. §§ 101, 102, 103, 112, and/or 251 *et seq.*, and/or are invalid under the doctrine of obviousness-type double patenting, and/or for any other judicially created and/or non-statutory basis for invalidity or unenforceability.

55. There is a real, substantial, and justiciable controversy between Hetero and Axsome concerning whether the claims of the '227 patent are invalid and/or unenforceable for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, 251, and/or pursuant to common law and/or equitable doctrines.

56. The Court should declare that the claims of the '227 patent are invalid and/or unenforceable.

COUNT IX
(Declaratory Judgment of Noninfringement of U.S. Patent No. 11,850,228)

57. Hetero incorporates by reference and re-alleges each of the foregoing paragraphs of Hetero's Answer and Affirmative Defenses to the Complaint and these Counterclaims as if fully set forth herein.

58. Hetero has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claims of the '228 patent.

59. A present, genuine, and justiciable controversy exists between Hetero, on the one hand, and Axsome, on the other hand, regarding, *inter alia*, the issue of whether the manufacture, use, sale, offer for sale and/or importation of Hetero's ANDA Product would infringe any valid or enforceable claim of the '228 patent.

60. The Court should declare that Hetero has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claims of the '228 patent.

COUNT X
(Declaratory Judgment of Invalidity of U.S. Patent No. 11,850,228)

61. Hetero incorporates by reference and re-alleges each of the foregoing paragraphs of Hetero's Answer and Affirmative Defenses to the Complaint and these Counterclaims as if fully set forth herein.

62. Upon information and belief, the claims of the '228 patent are invalid for failure to comply with one or more of the requirements of at least 35 U.S.C. §§ 101, 102, 103, 112, and/or 251 *et seq.*, and/or are invalid under the doctrine of obviousness-type double patenting, and/or for any other judicially created and/or non-statutory basis for invalidity or unenforceability.

63. There is a real, substantial, and justiciable controversy between Hetero and Axsome concerning whether the claims of the '228 patent are invalid and/or unenforceable for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, 251, and/or pursuant to common law and/or equitable doctrines.

64. The Court should declare that the claims of the '228 patent are invalid and/or unenforceable.

COUNT XI
(Declaratory Judgment of Noninfringement of U.S. Patent No. 11,857,528)

65. Hetero incorporates by reference and re-alleges each of the foregoing paragraphs of Hetero's Answer and Affirmative Defenses to the Complaint and these Counterclaims as if fully set forth herein.

66. Hetero has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claims of the '528 patent.

67. A present, genuine, and justiciable controversy exists between Hetero, on the one hand, and Axsome, on the other hand, regarding, *inter alia*, the issue of whether the manufacture, use, sale, offer for sale and/or importation of Hetero's ANDA Product would infringe any valid or enforceable claim of the '528 patent.

68. The Court should declare that Hetero has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claims of the '528 patent.

COUNT XII
(Declaratory Judgment of Invalidity of U.S. Patent No. 11,857,528)

69. Hetero incorporates by reference and re-alleges each of the foregoing paragraphs of Hetero's Answer and Affirmative Defenses to the Complaint and these Counterclaims as if fully set forth herein.

70. Upon information and belief, the claims of the '528 patent are invalid for failure to comply with one or more of the requirements of at least 35 U.S.C. §§ 101, 102, 103, 112, and/or 251 *et seq.*, and/or are invalid under the doctrine of obviousness-type double patenting, and/or for any other judicially created and/or non-statutory basis for invalidity or unenforceability.

71. There is a real, substantial, and justiciable controversy between Hetero and Axsome concerning whether the claims of the '528 patent are invalid and/or unenforceable for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, 251, and/or pursuant to common law and/or equitable doctrines.

72. The Court should declare that the claims of the '528 patent are invalid and/or unenforceable.

COUNT XIII
(Declaratory Judgment of Noninfringement of U.S. Patent No. 11,865,098)

73. Hetero incorporates by reference and re-alleges each of the foregoing paragraphs of Hetero's Answer and Affirmative Defenses to the Complaint and these Counterclaims as if fully set forth herein.

74. Hetero has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claims of the '098 patent.

75. A present, genuine, and justiciable controversy exists between Hetero, on the one hand, and Axsome, on the other hand, regarding, *inter alia*, the issue of whether the manufacture, use, sale, offer for sale and/or importation of Hetero's ANDA Product would infringe any valid or enforceable claim of the '098 patent.

76. The Court should declare that Hetero has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claims of the '098 patent.

COUNT XIV
(Declaratory Judgment of Invalidity of U.S. Patent No. 11,865,098)

77. Hetero incorporates by reference and re-alleges each of the foregoing paragraphs of Hetero's Answer and Affirmative Defenses to the Complaint and these Counterclaims as if fully set forth herein.

78. Upon information and belief, the claims of the '098 patent are invalid for failure to comply with one or more of the requirements of at least 35 U.S.C. §§ 101, 102, 103, 112, and/or 251 *et seq.*, and/or are invalid under the doctrine of obviousness-type double patenting, and/or for any other judicially created and/or non-statutory basis for invalidity or unenforceability.

79. There is a real, substantial, and justiciable controversy between Hetero and Axsome concerning whether the claims of the '098 patent are invalid and/or unenforceable for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, 251, and/or pursuant to common law and/or equitable doctrines.

80. The Court should declare that the claims of the '098 patent are invalid and/or unenforceable.

COUNT XV
(Declaratory Judgment of Noninfringement of U.S. Patent No. 11,872,203)

81. Hetero incorporates by reference and re-alleges each of the foregoing paragraphs of Hetero's Answer and Affirmative Defenses to the Complaint and these Counterclaims as if fully set forth herein.

82. Hetero has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claims of the '203 patent.

83. A present, genuine, and justiciable controversy exists between Hetero, on the one hand, and Axsome, on the other hand, regarding, *inter alia*, the issue of whether the manufacture, use, sale, offer for sale and/or importation of Hetero's ANDA Product would infringe any valid or enforceable claim of the '203 patent.

84. The Court should declare that Hetero has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claims of the '203 patent.

COUNT XVI
(Declaratory Judgment of Invalidity of U.S. Patent No. 11,872,203)

85. Hetero incorporates by reference and re-alleges each of the foregoing paragraphs of Hetero's Answer and Affirmative Defenses to the Complaint and these Counterclaims as if fully set forth herein.

86. Upon information and belief, the claims of the '203 patent are invalid for failure to comply with one or more of the requirements of at least 35 U.S.C. §§ 101, 102, 103, 112, and/or 251 *et seq.*, and/or are invalid under the doctrine of obviousness-type double patenting, and/or for any other judicially created and/or non-statutory basis for invalidity or unenforceability.

87. There is a real, substantial, and justiciable controversy between Hetero and Axsome concerning whether the claims of the '203 patent are invalid and/or unenforceable for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, 251, and/or pursuant to common law and/or equitable doctrines.

88. The Court should declare that the claims of the '203 patent are invalid and/or unenforceable.

COUNT XVII
(Declaratory Judgment of Noninfringement of U.S. Patent No. 11,872,204)

89. Hetero incorporates by reference and re-alleges each of the foregoing paragraphs of Hetero's Answer and Affirmative Defenses to the Complaint and these Counterclaims as if fully set forth herein.

90. Hetero has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claims of the '204 patent.

91. A present, genuine, and justiciable controversy exists between Hetero, on the one hand, and Axsome, on the other hand, regarding, *inter alia*, the issue of whether the manufacture, use, sale, offer for sale and/or importation of Hetero's ANDA Product would infringe any valid or enforceable claim of the '204 patent.

92. The Court should declare that Hetero has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claims of the '204 patent.

COUNT XVIII
(Declaratory Judgment of Invalidity of U.S. Patent No. 11,872,204)

93. Hetero incorporates by reference and re-alleges each of the foregoing paragraphs of Hetero's Answer and Affirmative Defenses to the Complaint and these Counterclaims as if fully set forth herein.

94. Upon information and belief, the claims of the '204 patent are invalid for failure to comply with one or more of the requirements of at least 35 U.S.C. §§ 101, 102, 103, 112, and/or 251 *et seq.*, and/or are invalid under the doctrine of obviousness-type double patenting, and/or for any other judicially created and/or non-statutory basis for invalidity or unenforceability.

95. There is a real, substantial, and justiciable controversy between Hetero and Axsome concerning whether the claims of the '204 patent are invalid and/or unenforceable for failure to comply with the requirements of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, 251, and/or pursuant to common law and/or equitable doctrines.

96. The Court should declare that the claims of the '204 patent are invalid and/or unenforceable.

PRAYER FOR RELIEF

WHEREFORE, Hetero prays that the Court enter judgment in its favor and against Axsome as follows:

- A. Declaring that the filing of Hetero's ANDA No. 218654 has not and does not directly or indirectly infringe any valid claim of any of the Asserted Patents;
- B. Declaring that the commercial manufacture, use, offer to sell, sale within the United States, and/or importation into the United States of Hetero's solriamfetol oral tablets, Eq. 75 mg base and Eq. 150 mg base product described in ANDA No. 218654 does not, and would not, if marketed, directly or indirectly infringe any valid claim of any of the Asserted Patents;
- C. Declaring that the claims of the Asserted Patents are invalid;
- D. Ordering that judgment be entered in favor of Hetero and that Axsome's Complaint be dismissed with prejudice;
- E. Declaring this case exceptional and awarding Hetero its reasonable attorney fees and costs of defending this action and prosecuting their counterclaims under 35 U.S.C. § 285; and
- F. Awarding Hetero such other and further relief as this Court deems just and proper.

Dated: April 26, 2024

Respectfully submitted,

Of Counsel:

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Hetero Labs Ltd.*

CERTIFICATION PURSUANT TO LOCAL CIVIL RULES 11.2 AND 40.1

Pursuant to Local Civil Rules 11.2 and 40.1, I hereby certify that, to the best of my knowledge, the matter in controversy is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding.

Dated: April 26, 2024

s/ Kaan Ekiner

Kaan Ekiner

CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 201.1

Pursuant to Local Civil Rule 201.1, Defendants/Counterclaimants Hetero USA Inc., Hetero Labs Limited Unit-V, and Hetero Labs Ltd., by its undersigned counsel, hereby certify that this action seeks declaratory and injunctive relief and therefore, this action is not appropriate for compulsory arbitration.

Dated: April 26, 2024

s/ Kaan Ekiner

Kaan Ekiner

CERTIFICATE OF SERVICE

I, Kaan Ekiner, hereby certify that on April 26, 2024, a true and correct copy of the foregoing **DEFENDANTS HETERO USA INC., HETERO LABS LIMITED UNIT-V, AND HETERO LABS LTD.'S ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS TO PLAINTIFFS' COMPLAINT** was filed electronically with the Clerk of Court using the CM/ECF system, which will send notification of such filing to all counsel of record.

Dated: April 26, 2024

s/ Kaan Ekiner

Kaan Ekiner