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

AXSOME MALTA LTD. and AXSOME THERAPEUTICS, INC., Plaintiffs, v. HETERO USA INC., HETERO LABS LIMITED UNIT-V, and HETERO LABS LTD., Defendants.	Civil Action No. 2:24-cv-00196-MCA-LDW

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 their respective 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. 11,771,666 ("'666 patent"), 11,771,667 ("'667 patent"), 11,779,554 ("'554 patent"), and 11,793,776 ("'776 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. 11,771,666 ("'666 patent"), 11,771,667 ("'667 patent"), 11,779,554 ("'554 patent"), and 11,793,776 ("'776 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 October 3, 2023, the USPTO duly and lawfully issued the ’666 patent, entitled, “Methods of Administering Solriamfetol to Lactating Women.” The face of the ’666 patent identifies Herriot Tabuteau as the inventor. A copy of the ’666 patent is attached hereto as Exhibit A.

ANSWER: Hetero admits that the ’666 patent is titled “Methods of Administering Solriamfetol to Lactating Women.” Hetero admits that the face of the ’666 patent identifies Herriot Tabuteau as the inventor, and that the ’666 patent was issued by the USPTO on or about October 3, 2023. What appears to be an uncertified copy of the ’666 patent was attached to Plaintiffs’ Complaint as Exhibit A. Hetero denies the remaining allegations in Paragraph 9.

> 10. On October 3, 2023, the USPTO duly and lawfully issued the ’667 patent, entitled, “Methods of Administering Solriamfetol to Lactating Women.” The face of the ’667 patent identifies Herriot Tabuteau as the inventor. A copy of the ’667 patent is attached hereto as Exhibit B.

ANSWER: Hetero admits that the ’667 patent is titled “Methods of Administering Solriamfetol to Lactating Women.” Hetero admits that the face of the ’667 patent identifies Herriot Tabuteau as the inventor, and that the ’667 patent was issued by the USPTO on or about October 3, 2023. What appears to be an uncertified copy of the ’667 patent was attached to Plaintiffs’ Complaint as Exhibit B. Hetero denies the remaining allegations in Paragraph 10.

> 11. On October 10, 2023, the USPTO duly and lawfully issued the ’554 patent, entitled, “Methods of Administering Solriamfetol to Lactating Women.” The face of the ’554 patent identifies Herriot Tabuteau as the inventor. A copy of the ’554 patent is attached hereto as Exhibit C.

ANSWER: Hetero admits that the ’554 patent is titled “Methods of Administering Solriamfetol to Lactating Women.” Hetero admits that the face of the ’554 patent identifies Herriot Tabuteau as the inventor, and that the ’554 patent was issued by the USPTO on or about October 10, 2023. What appears to be an uncertified copy of the ’554 patent was attached to Plaintiffs’ Complaint as Exhibit C. Hetero denies the remaining allegations in Paragraph 11.

> 12. On October 24, 2023, the USPTO duly and lawfully issued the ’776 patent, entitled, “Methods of Administering Solriamfetol to Lactating Women.” The face of the ’776 patent identifies Herriot Tabuteau as the inventor. A copy of the ’776 patent is attached hereto as Exhibit D.

ANSWER: Hetero admits that the '776 patent is titled "Methods of Administering Solriamfetol to Lactating Women." Hetero admits that the face of the '776 patent identifies Herriot Tabuteau as the inventor, and that the '776 patent was issued by the USPTO on or about October 24, 2023. What appears to be an uncertified copy of the '776 patent was attached to Plaintiffs' Complaint as Exhibit D. Hetero denies the remaining allegations in Paragraph 12.

The Sunosi® Drug Product

13. 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 13 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 13, and on that basis denies these allegations.

14. 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 14, and on that basis denies these allegations.

Jurisdiction and Venue

15. 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 15 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 15.

16. 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 16 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 16.

17. 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 17.

18. 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 18.

19. 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 19.

20. 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 20 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 20.

21. 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 21 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 21.

22. 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 22.

23. 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.

24. 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 24 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 24.

> 25. 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 (D.N.J.) (MAS)(DEA) (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 Labs. 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 25 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 25.

> 26. 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 26 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 26.

27. 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 27 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 27.

28. 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 16-27, 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 28 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 28.

Acts Giving Rise To This Suit

29. 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 29.

30. 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 30 are wholly speculative. Except as expressly admitted, Hetero denies the remaining allegations of Paragraph 30.

31. 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. 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, and 11,793,776 are invalid, unenforceable and/or will not be infringed by the activities described in Hetero's ANDA.

ANSWER: Hetero admits that it had provided a Paragraph IV Certification to the FDA in connection with the submission of its ANDA No. 218654. The content of Hetero's Paragraph IV Certification speaks for itself. Except as expressly admitted, Hetero denies the remaining allegations of Paragraph 31.

32. 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 32.

33. 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 33.

Count I: Infringement of the '666 Patent

34. 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.

35. 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 '666 patent, constitutes

infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

ANSWER: Paragraph 35 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 35.

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

ANSWER: Paragraph 36 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 36.

37. Unless enjoined by this Court, upon FDA approval of Hetero's ANDA, Hetero will infringe one or more claims of the '666 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Hetero's Proposed Product in the United States.

ANSWER: Paragraph 37 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 37.

38. Unless enjoined by this Court, upon FDA approval of Hetero's ANDA, Hetero will induce infringement of one or more claims of the '666 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing 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 '666 patent and knowledge that its acts are encouraging infringement.

ANSWER: Paragraph 38 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 38.

39. Unless enjoined by this Court, upon FDA approval of Hetero's ANDA, Hetero will contributorily infringe one or more claims of the '666 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing 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 '666 patent, and Hetero's Proposed Product lacks a substantial non-infringing use.

ANSWER: Paragraph 39 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 39.

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

ANSWER: Paragraph 40 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 40.

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

ANSWER: Paragraph 41 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 41.

42. 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 42 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 42.

Count II: Infringement of the '667 Patent

43. 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.

44. 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 '667 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

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

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

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 of Paragraph 45.

46. Unless enjoined by this Court, upon FDA approval of Hetero's ANDA, Hetero will infringe one or more claims of the '667 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Hetero's Proposed Product in the United States.

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. Unless enjoined by this Court, upon FDA approval of Hetero's ANDA, Hetero will induce infringement of one or more claims of the '667 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing 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 '667 patent and knowledge that its acts are encouraging infringement.

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. Unless enjoined by this Court, upon FDA approval of Hetero's ANDA, Hetero will contributorily infringe one or more claims of the '667 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing 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 '667 patent, and Hetero's Proposed Product lacks a substantial non-infringing use.

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

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.

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

ANSWER: Paragraph 50 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 50.

51. 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 51 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 51.

Count III: Infringement of the '554 Patent

52. 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.

53. 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 '554 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

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

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

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 of Paragraph 54.

55. Unless enjoined by this Court, upon FDA approval of Hetero's ANDA, Hetero will infringe one or more claims of the '554 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Hetero's Proposed Product in the United States.

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. Unless enjoined by this Court, upon FDA approval of Hetero's ANDA, Hetero will induce infringement of one or more claims of the '554 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing 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 '554 patent and knowledge that its acts are encouraging infringement.

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. Unless enjoined by this Court, upon FDA approval of Hetero's ANDA, Hetero will contributorily infringe one or more claims of the '554 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing 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 '554 patent, and Hetero's Proposed Product lacks a substantial non-infringing use.

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

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.

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

ANSWER: Paragraph 59 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 59.

60. 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 60 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 60.

Count IV: Infringement of the '776 Patent

61. 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.

62. 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 '776 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

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

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

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 of Paragraph 63.

64. Unless enjoined by this Court, upon FDA approval of Hetero's ANDA, Hetero will infringe one or more claims of the '776 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Hetero's Proposed Product in the United States.

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. Unless enjoined by this Court, upon FDA approval of Hetero's ANDA, Hetero will induce infringement of one or more claims of the '776 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing 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 '776 patent and knowledge that its acts are encouraging infringement.

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. Unless enjoined by this Court, upon FDA approval of Hetero's ANDA, Hetero will contributorily infringe one or more claims of the '776 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing 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 '776 patent, and Hetero's Proposed Product lacks a substantial non-infringing use.

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

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.

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

ANSWER: Paragraph 68 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 68.

69. 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 69 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Hetero denies the allegations in Paragraph 69.

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. 11,771,666 ("'666 patent"), 11,771,667 ("'667 patent"), 11,779,554 ("'554 patent"), and 11,793,776 ("'776 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 '666 patent lists the title as "Methods of Administering Solriamfetol to Lactating Women," and the issue date as October 3, 2023.

12. The '667 patent lists the title as "Methods of Administering Solriamfetol to Lactating Women," and the issue date as October 3, 2023.

13. The '554 patent lists the title as "Methods of Administering Solriamfetol to Lactating Women," and the issue date as October 10, 2023.

14. The '776 patent lists the title as "Methods of Administering Solriamfetol to Lactating Women," and the issue date as October 24, 2023.

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

16. 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 ’666 patent, the ’667 patent, the ’554 patent, and the ’776 patent.

17. Hetero sent notice of this certification to Axsome on or about December 1, 2023 (“the Notice Letter”). On information and belief, and as Axsome alleges in its Complaint, Axsome received the Notice Letter.

18. On January 11, 2024, Axsome filed suit in this Judicial District against Hetero in connection with ANDA No. 218654 alleging infringement of the Asserted Patents.

19. 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. 11,771,666)

20. 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.

21. 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 ’666 patent.

22. 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 '666 patent.

23. 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 '666 patent.

COUNT II
(Declaratory Judgment of Invalidity of U.S. Patent No. 11,771,666)

24. 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.

25. Upon information and belief, the claims of the '666 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.

26. There is a real, substantial, and justiciable controversy between Hetero and Axsome concerning whether the claims of the '666 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.

27. The Court should declare that the claims of the '666 patent are invalid and/or unenforceable.

COUNT III
(Declaratory Judgment of Noninfringement of U.S. Patent No. 11,771,667)

28. 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.

29. 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 '667 patent.

30. 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 '667 patent.

31. 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 '667 patent.

COUNT IV
(Declaratory Judgment of Invalidity of U.S. Patent No. 11,771,667)

32. 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.

33. Upon information and belief, the claims of the '667 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.

34. There is a real, substantial, and justiciable controversy between Hetero and Axsome concerning whether the claims of the '667 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.

35. The Court should declare that the claims of the '667 patent are invalid and/or unenforceable.

COUNT V
(Declaratory Judgment of Noninfringement of U.S. Patent No. 11,779,554)

36. 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.

37. 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 '554 patent.

38. 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 '554 patent.

39. 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 '554 patent.

COUNT VI
(Declaratory Judgment of Invalidity of U.S. Patent No. 11,779,554)

40. 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.

41. Upon information and belief, the claims of the '554 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.

42. There is a real, substantial, and justiciable controversy between Hetero and Axsome concerning whether the claims of the '554 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.

43. The Court should declare that the claims of the '554 patent are invalid and/or unenforceable.

COUNT VII
(Declaratory Judgment of Noninfringement of U.S. Patent No. 11,793,776)

44. 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.

45. 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 '776 patent.

46. 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 '776 patent.

47. 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 '776 patent.

COUNT VIII
(Declaratory Judgment of Invalidity of U.S. Patent No. 11,793,776)

48. 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.

49. Upon information and belief, the claims of the '776 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.

50. There is a real, substantial, and justiciable controversy between Hetero and Axsome concerning whether the claims of the '776 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.

51. The Court should declare that the claims of the '776 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: March 12, 2024

Respectfully submitted,

s/ Kaan Ekiner

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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: March 12, 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: March 12, 2024

s/ Kaan Ekiner
Kaan Ekiner

CERTIFICATE OF SERVICE

I, Kaan Ekiner, hereby certify that on March 12, 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: March 12, 2024

s/ Kaan Ekiner
Kaan Ekiner