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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

AXSOME MALTA LTD., and AXSOME THERAPEUTICS, INC.,	Honorable Madeline C. Arleo, U.S.D.J.
Plaintiffs,	Civil Action No. 24 CV 10620 (MCA)(LDW)
v.	
HIKMA PHARMACEUTICALS USA INC.,	**DEFENDANT HIKMA PHARMACEUTICALS USA INC.'S ANSWER, SEPARATE DEFENSES, AND COUNTERCLAIMS**
Defendant.	

Defendant Hikma Pharmaceuticals USA Inc. ("Hikma"), by and through its undersigned counsel, provide the following answers, separate defenses, and counterclaims to the Complaint for Patent Infringement ("Complaint") (D.I. 1) of Plaintiffs Axsome Malta Ltd. and Axsome Therapeutics, Inc., (collectively, "Axsome" or "Plaintiffs"). This pleading is based upon Hikma's knowledge as to its own activities, and upon information and belief as to other matters. Pursuant to Fed. R. Civ. P. 8(b)(3), Hikma denies all allegations in Plaintiffs' Complaint except those admitted specifically 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 Hikma's submission of Abbreviated New Drug Application ("ANDA") No. 218016 ("Hikma's ANDA"), with the United States Food and Drug Administration ("FDA") seeking approval to commercially market generic versions of Axsome's

solriamfetol oral tablets drug products prior to the expiration of one or more of United States Patent Nos. 12,090,126 ("the '126 patent") and 12,102,609 ("the '609 patent"), (together, "the patents-in-suit"). Axsome is the owner of the patents-in-suit.

ANSWER: Hikma admits that Hikma submitted ANDA No. 218016 ("Hikma's ANDA") to the FDA seeking approval to commercially market a generic version of solriamfetol oral tablets ("Hikma's Proposed Product") prior to the expiration of the patents-in-suit. Hikma further admits that Plaintiffs' Complaint purports to bring an action for patent infringement under the patent laws of the United States, 35 U.S.C. § 100 et seq., but denies that Plaintiff is entitled to any relief. Hikma lacks knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of Paragraph 1, and therefore, denies the same.

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: Hikma admits that the product labeling available on the FDA's website states that Sunosi® "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 (OSA)." Hikma lacks knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of this paragraph, and therefore denies the same.

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: Hikma lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of this paragraph, and therefore denies the same.

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: Hikma lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of this paragraph, and therefore denies the same.

5. On information and belief, Defendant Hikma is a corporation organized and existing under the laws of Delaware, having a principal place of business at 200 Connell Drive, 4th Floor, Berkeley Heights, New Jersey 07922.

ANSWER: Hikma admits that Hikma is a corporation organized and existing under the laws of Delaware, having a place of business at 200 Connell Drive, 4th Floor, Berkeley Heights, New Jersey 07922.

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

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma admits that it markets and sells generic pharmaceutical products throughout the United States. Hikma lacks information or knowledge sufficient to form a belief as to the truth or falsity of the remaining allegations of this paragraph, and therefore denies the same.

The Patents-in-Suit

7. On September 17, 2024, the USPTO duly and lawfully issued the '126 patent, entitled, "Methods of Administering Solriamfetol to Lactating Women." The face of the '126 patent identifies Herriot Tabuteau as the inventor. A copy of the '126 patent is attached hereto as Exhibit A.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma admits that on its face, the '126 patent was issued on September 17, 2024, is entitled "Methods of administering solriamfetol to lactating women," and identifies Herriot Tabuteau as the inventor. Hikma admits that purported copy of the '126 patent is attached to the Complaint as Exhibit A. Hikma specifically denies that the '126 patent was duly

and lawfully issued. Hikma lacks information or knowledge sufficient to form a belief as to the truth or falsity of the remaining allegations of this paragraph, and therefore denies the same.

8. On October 1, 2024, the USPTO duly and lawfully issued the '609 patent, entitled, "Methods of Administering Solriamfetol to Lactating Women." The face of the '609 patent identifies Herriot Tabuteau as the inventor. A copy of the '609 patent is attached hereto as Exhibit B.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma admits that on its face, the '609 patent was issued on October 1, 2024, is entitled "Methods of administering solriamfetol to lactating women," and identifies Herriot Tabuteau as the inventor. Hikma admits that purported copy of the '609 patent is attached to the Complaint as Exhibit B. Hikma specifically denies that the '609 patent was duly and lawfully issued. Hikma lacks information or knowledge sufficient to form a belief as to the truth or falsity of the remaining allegations of this paragraph, and therefore denies the same.

The Sunosi® Drug Product

9. Axsome holds an approved New Drug Application ("NDA") under Section 505(a) of the Federal Food Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 355(a), for solriamfetol oral tablets, Eq. 75 mg base and Eq. 150 mg base ("NDA No. 211230"), which is sold under the trademark Sunosi®. Sunosi® is a DNRI indicated to improve wakefulness in adult patients with excessive daytime sleepiness associated with narcolepsy or obstructive sleep apnea. The claims of the patents-in-suit cover, *inter alia*, methods of using Sunosi® to improve wakefulness in adult patients with excessive daytime sleepiness associated with narcolepsy or obstructive sleep apnea.

ANSWER: Hikma admits that the FDA's website indicates that Axsome Malta Ltd. is the holder of New Drug Application ("NDA") No. 211230 for Sunosi® (solriamfetol) oral tablets, EQ 75b mg base and EQ 150 mg base. Hikma admits that the Sunosi® label available on the FDA's website states that Sunosi® 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 (OSA)." Hikma denies the remaining allegations of this paragraph.

10. 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: Hikma admits that the patents-in-suit are listed in the FDA's Orange Book in connection with Sunosi®. Hikma lacks information or knowledge sufficient to form a belief as to the truth or falsity of the remaining allegations of this paragraph, and therefore denies the same.

Jurisdiction and Venue: Hikma

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

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma does not contest subject matter jurisdiction for the purposes of this action only, and expressly reserves the right to contest subject matter jurisdiction in any other case as to any party. Hikma otherwise denies the remaining allegations of this Paragraph.

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

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma does not contest personal jurisdiction for the purposes of this action only, and expressly reserves the right to contest personal jurisdiction in any other case as to any party. Hikma otherwise denies the remaining allegations of this Paragraph.

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

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma does not contest personal jurisdiction for the purposes of this action only, and expressly reserves the right to contest personal jurisdiction in any other case as to any party. Hikma otherwise denies the remaining allegations of this Paragraph.

14. On information and belief, Hikma 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: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma does not contest personal jurisdiction for the purposes of this action only, and expressly reserves the right to contest personal jurisdiction in any other case as to any party. Hikma otherwise denies the remaining allegations of this Paragraph.

15. 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 Hikma seeks FDA approval to manufacture, market, import, offer for sale, and/or sell pursuant to ANDA No. 218016 ("Hikma's Proposed Product").

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma does not contest personal jurisdiction for the purposes of this action only, and expressly reserves the right to contest personal jurisdiction in any other case as to any party. Hikma otherwise denies the remaining allegations of this Paragraph.

16. On information and belief, Hikma 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. 0100487525 and is registered as manufacturer and wholesaler with the New Jersey Department of Health under Registration No. 5002130.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma does not contest personal jurisdiction for the purposes of this action only, and expressly reserves the right to contest personal jurisdiction in any other case as to any party. Hikma admits that Hikma is registered under Business ID No. 0100487525 with the State of New Jersey and Registration No. 5002130 with the New Jersey Department of Health. Hikma otherwise denies the remaining allegations of this Paragraph.

17. This Court has personal jurisdiction over Hikma because, *inter alia*, on information and belief, Hikma maintains a regular and established, physical place of business at 200 Connell Drive, 4th Floor, Berkeley Heights, New Jersey 07922.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To

the extent a response is required, Hikma's website speaks for itself. Hikma does not contest personal jurisdiction for the purposes of this action only, and expressly reserves the right to contest personal jurisdiction in any other case as to any party. Hikma otherwise denies the remaining allegations of this Paragraph.

18. Hikma has consented to personal jurisdiction in this Court in numerous recent actions arising out of its ANDA submissions and has filed counterclaims in such cases. *See, e.g., Celgene Corp. v. West-Ward Pharma Int'l Ltd., et al.*, Civil Action No. 2:18-cv-13477 (D.N.J.); *Celgene Corporation v. Hikma Pharmaceuticals USA Inc.*, Civil Action No. 21- 20459 (SDW)(LDW) (D.N.J.); *Celgene Corporation v. Hikma Pharmaceuticals USA, Inc.*, Civil Action No. 21-10398 (SDW)(LDW) (D.N.J.). Hikma has purposefully availed itself of the rights, benefits, and privileges of New Jersey by asserting counterclaims in this Court.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma admits that Hikma was a party to the lawsuits identified in Paragraph 18. Hikma does not contest personal jurisdiction for the purposes of this action only, and expressly reserves the right to contest personal jurisdiction in any other case as to any party. Hikma otherwise denies the remaining allegations of this Paragraph.

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

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma admits that Hikma was a party to the lawsuits identified in Paragraph 19. Hikma does not contest personal jurisdiction for the purposes of this action only, and expressly reserves the right to contest personal jurisdiction in any other case as to any party. Hikma otherwise denies the remaining allegations of this Paragraph.

20. For at least the reasons set forth above in Paragraphs 13-19, venue is proper in this Judicial District with respect to Hikma pursuant to 28 U.S.C. § 1391(c)(3) and 28 U.S.C. § 1400(b).

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma does not contest venue for the purposes of this action

only, and expressly reserves the right to contest venue in any other case as to any party. Hikma otherwise denies the remaining allegations of this Paragraph.

Acts Giving Rise To This Suit

21. Pursuant to Section 505 of the FFDCA, Hikma submitted ANDA No. 218016 seeking approval to engage in the commercial manufacture, use, sale, offer for sale, or importation of Hikma's Proposed Product, before the patents-in-suit expire.

ANSWER: Hikma admits that it filed ANDA No. 218016 seeking approval to engage in the commercial manufacture, use, or sale of Hikma's Proposed Product prior to the expiration of the patents-in-suit. Hikma otherwise denies the remaining allegations of Paragraph 21.

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

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma admits that it filed ANDA No. 218016 seeking approval to engage in the commercial manufacture, use, or sale of Hikma's Proposed Product. Hikma otherwise denies the remaining allegations of Paragraph 22.

23. On information and belief, in connection with the submission of its ANDA as described above, Hikma 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) ("Hikma'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, 11,872,204, 11,969,404, 11,986,454, 11,986,455, 11,998,639, 12,005,036, 12,036,194, 12,064,411, 12,090,126, and 12,102,609 are invalid and/or will not be infringed by the activities described in Hikma's ANDA.

ANSWER: Hikma admits that ANDA No. 218016 includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), and seeks approval to engage in the commercial manufacture, use, or sale of Hikma's Proposed Product before the expiration of the '715 patent, the '151 patent, the '609 patent, the '754 patent, the '133 patent, the '976 patent, the '779 patent, the '597 patent, the '354 patent, the '232 patent, the '666 patent, the '667 patent, the '554 patent, '776 patent, the '598

patent, the ’599 patent, the ’226 patent, the ’227 patent, the ’228 patent, the ’528 patent, the ’098 patent, the ’203 patent, the ’204 patent, the ’639 patent, the ’404 patent, the ’454 patent, the ’455 patent, the ’036 patent, the ’194 patent, the ’411 patent, the ’126 patent, and the ’609 patent. Hikma denies the remaining allegations of Paragraph 23.

24. No earlier than August 1, 2023, Hikma sent written notice of a Paragraph IV Certification (“Hikma’s First Notice Letter”) to Axsome. According to Hikma’s First Notice Letter, Hikma submitted an ANDA pursuant to Section 505 of the FFDCA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Hikma’s Proposed Product before expiration of certain patents listed in the Orange Book with respect to Sunosi®.

ANSWER: Hikma admits that on August 1, 2023, Hikma sent Hikma’s First Notice Letter. Hikma further admits that Hikma’s First Notice Letter informed Plaintiffs that Hikma filed ANDA No. 218016 seeking approval to engage in the commercial manufacture, use, or sale of Hikma’s Proposed Product before the expiration of the ’715 patent, the ’151 patent, the ’609 patent, the ’754 patent, the ’133 patent, the ’976 patent, the ’779 patent, the ’597 patent, the ’354 patent, and the ’232 patent. Hikma denies the remaining allegations of Paragraph 24.

25. No earlier than March 18, 2024, Hikma sent written notice of a Paragraph IV Certification (“Hikma’s Second Notice Letter”) to Axsome. According to Hikma’s Second Notice Letter, Hikma submitted an ANDA pursuant to Section 505 of the FFDCA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Hikma’s Proposed Product before expiration of certain patents listed in the Orange Book with respect to Sunosi®.

ANSWER: Hikma admits that on March 18, 2024, Hikma sent Hikma’s Second Notice Letter. Hikma further admits that Hikma’s Second Notice Letter informed Plaintiffs that Hikma filed ANDA No. 218016 seeking approval to engage in the commercial manufacture, use, or sale of Hikma’s Proposed Product before the expiration of the ’666 patent, the ’667 patent, the ’554 patent, ’776 patent, 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. Hikma denies the remaining allegations of Paragraph 25.

26. No earlier than August 22, 2024, Hikma sent written notice of a Paragraph IV Certification ("Hikma's Third Notice Letter") to Axsome. According to Hikma's Third Notice Letter, Hikma submitted an ANDA pursuant to Section 505 of the FFDCA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Hikma's Proposed Product before expiration of certain patents listed in the Orange Book with respect to Sunosi®.

ANSWER: Hikma admits that on August 23, 2024, Hikma sent Hikma's Third Notice Letter. Hikma further admits that Hikma's Third Notice Letter informed Plaintiffs that Hikma filed ANDA No. 218016 seeking approval to engage in the commercial manufacture, use, or sale of Hikma's Proposed Product before the expiration of the '639 patent, '404 patent, '454 patent, '455 patent, '036 patent, and '194 patent. Hikma denies the remaining allegations of Paragraph 26.

27. No earlier than September 3, 2024, Hikma sent written notice of a Paragraph IV Certification ("Hikma's Fourth Notice Letter") to Axsome. According to Hikma's Fourth Notice Letter, Hikma submitted an ANDA pursuant to Section 505 of the FFDCA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Hikma's Proposed Product before expiration of certain patents listed in the Orange Book with respect to Sunosi®.

ANSWER: Hikma admits that on August 29, 2024, Hikma sent Hikma's Fourth Notice Letter. Hikma further admits that Hikma's Fourth Notice Letter informed Plaintiffs that Hikma filed ANDA No. 218016 seeking approval to engage in the commercial manufacture, use, or sale of Hikma's Proposed Product before the expiration of the '411 patent. Hikma denies the remaining allegations of Paragraph 27.

28. No earlier than October 16, 2024, Hikma sent written notice of Hikma's fifth Paragraph IV Certification to Axsome ("Hikma's Fifth Notice Letter"). Hikma's Fifth Notice Letter alleged, inter alia, that the claims of the '126 patent are invalid and/or will not be infringed by the activities described in Hikma's ANDA. Hikma's Fifth Notice Letter also informed Axsome that Hikma seeks approval to market Hikma's Proposed Product before the expiration of the '126 patent.

ANSWER: Hikma admits that on October 16, 2024, Hikma sent Hikma's Fifth Notice Letter. Hikma further admits that Hikma's Fifth Notice Letter informed Plaintiffs that Hikma filed ANDA No. 218016 seeking approval to engage in the commercial manufacture, use, or sale of

Hikma's Proposed Product before the expiration of the '126 patent. Hikma denies the remaining allegations of Paragraph 28.

29. No earlier than October 18, 2024, Hikma sent written notice of Hikma's sixth Paragraph IV Certification to Axsome ("Hikma's Sixth Notice Letter"). Hikma's Sixth Notice Letter alleged, inter alia, that the claims of the '609 patent are invalid and/or will not be infringed by the activities described in Hikma's ANDA. Hikma's Sixth Notice Letter also informed Axsome that Hikma seeks approval to market Hikma's Proposed Product before the expiration of the '609 patent.

ANSWER: Hikma admits that on October 18, 2024, Hikma sent Hikma's Sixth Notice Letter. Hikma further admits that Hikma's Sixth Notice Letter informed Plaintiffs that Hikma filed ANDA No. 218016 seeking approval to engage in the commercial manufacture, use, or sale of Hikma's Proposed Product before the expiration of the '609 patent. Hikma denies the remaining allegations of Paragraph 29.

Count I: Infringement of the '126 Patent

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

ANSWER: To the extent an answer to Paragraph 30 is required, Hikma incorporates by reference its answers to the foregoing paragraphs as if fully set forth herein.

31. Hikma's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Hikma's Proposed Product, prior to the expiration of the '126 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: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma denies the allegations of Paragraph 31.

32. A justiciable controversy exists between Axsome and Hikma as to the infringement of the '126 patent.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma denies the allegations of Paragraph 32.

33. Unless enjoined by this Court, upon FDA approval of Hikma's ANDA, Hikma will

infringe one or more claims of the '126 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Hikma's Proposed Product in the United States.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma denies the allegations of Paragraph 33.

34. Unless enjoined by this Court, upon FDA approval of Hikma's ANDA, Hikma will induce infringement of one or more claims of the '126 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Hikma's Proposed Product in the United States. On information and belief, upon FDA approval of Hikma's ANDA, Hikma will intentionally encourage acts of direct infringement with knowledge of the '126 patent and knowledge that its acts are encouraging infringement.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma denies the allegations of Paragraph 34.

35. Unless enjoined by this Court, upon FDA approval of Hikma's ANDA, Hikma will contributorily infringe one or more claims of the '126 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Hikma's Proposed Product in the United States. On information and belief, Hikma knew and knows that Hikma's Proposed Product is designed for a use that infringes one or more claims of the '126 patent, and Hikma's Proposed Product lacks a substantial non-infringing use.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma denies the allegations of Paragraph 35.

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

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma denies the allegations of Paragraph 36.

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

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma denies the allegations of Paragraph 37.

38. 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: This paragraph contains legal conclusions to which no answer is required. To

the extent a response is required, Hikma denies the allegations of Paragraph 38.

Count II: Infringement of the '609 Patent

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

ANSWER: To the extent an answer to Paragraph 39 is required, Hikma incorporates by reference its answers to the foregoing paragraphs as if fully set forth herein.

40. Hikma's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Hikma's Proposed Product, prior to the expiration of the '609 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: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma denies the allegations of Paragraph 40.

41. A justiciable controversy exists between Axsome and Hikma as to the infringement of the '609 patent.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma denies the allegations of Paragraph 41.

42. Unless enjoined by this Court, upon FDA approval of Hikma's ANDA, Hikma will infringe one or more claims of the '609 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Hikma's Proposed Product in the United States.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma denies the allegations of Paragraph 42.

43. Unless enjoined by this Court, upon FDA approval of Hikma's ANDA, Hikma will induce infringement of one or more claims of the '609 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Hikma's Proposed Product in the United States. On information and belief, upon FDA approval of Hikma's ANDA, Hikma will intentionally encourage acts of direct infringement with knowledge of the '609 patent and knowledge that its acts are encouraging infringement.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma denies the allegations of Paragraph 43.

44. Unless enjoined by this Court, upon FDA approval of Hikma's ANDA, Hikma will contributorily infringe one or more claims of the '609 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Hikma's Proposed Product in the United States. On information and belief, Hikma knew and knows that Hikma's Proposed Product is designed for a use that infringes one or more claims of the '609 patent, and Hikma's Proposed Product lacks a substantial non-infringing use.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma denies the allegations of Paragraph 44.

45. Failure to enjoin Hikma's infringement of the '609 patent will substantially and irreparably damage and harm Axsome.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma denies the allegations of Paragraph 45.

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

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma denies the allegations of Paragraph 46.

47. 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: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Hikma denies the allegations of Paragraph 47.

RESPONSE TO PRAYER FOR RELIEF

The remainder of Plaintiffs' Complaint recites a prayer for relief for which no response is required. To the extent a response is required, Hikma denies that Plaintiff is entitled to any remedy or relief.

SEPARATE DEFENSES

Hikma asserts the following defenses without prejudice to the denials in this Answer, and without admitting any allegations of the Complaint not otherwise admitted. Hikma does not assume the burden of proof on any such defenses, except as required by applicable law with respect

to the particular defense asserted. Hikma reserves the right to assert other defenses and/or to otherwise supplement this Answer upon discovery of facts or evidence rendering such action appropriate.

FIRST DEFENSE

Each purported claim in the Complaint, in whole or in part, is barred for failure to state a claim upon which relief can be granted.

SECOND DEFENSE

The claims of the patents-in-suit are invalid for failure to comply with the statutory provisions of Title 35 of the United States Code, including without limitation sections 101, 102, 103, and/or 112, or other judicially created bases for invalidity.

THIRD DEFENSE

Hikma does not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the patents-in-suit. If the products that are the subject of ANDA No. 218016 were marketed, Hikma would not infringe any valid and enforceable claim of the patents-in-suit.

FOURTH DEFENSE

Hikma has not, does not, and will not induce the infringement of, or contribute to the infringement of, any valid and enforceable claim of the patents-in-suit. If the products that are the subject of ANDA No. 218016 were marketed, Hikma would not induce the infringement of, or contribute to the infringement of, any valid and enforceable claim of the patents-in-suit.

FIFTH DEFENSE

The claims of the patents-in-suit are barred in whole or in part by the doctrine of prosecution history estoppel, judicial estoppel, and/or other equitable doctrines.

SIXTH DEFENSE

Hikma's actions in defending this case do not give rise to an exceptional case under 35 U.S.C. § 285.

SEVENTH DEFENSE

Any additional defenses or counterclaims that discovery may reveal.

COUNTERCLAIMS

For its Counterclaims against Axsome Malta Ltd., and Axsome Therapeutics, Inc., (together "Axsome" or "Counterclaim Defendants/Plaintiffs"), Counterclaim Plaintiff/Defendant Hikma Pharmaceuticals USA Inc. ("Hikma" or "Counterclaim Plaintiff/Defendant"), states as follows:

THE PARTIES

1. On information and belief Axsome Malta Ltd. is a corporation organized and existing under the laws of the Republic of Malta, having a principal place of business at 78 Mill Street, Zone 5, Central Business District, Qormi, CBD 5090, Malta.

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

3. Hikma is a corporation organized and existing under the laws of Delaware, having a place of business at 200 Connell Drive, 4th Floor, Berkeley Heights, New Jersey 07922.

JURISDICTION AND VENUE

4. These counterclaims arise under the patent laws of the United States and the Declaratory Judgment Act. This Court has subject matter jurisdiction over these counterclaims pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

5. This Court has personal jurisdiction over Counterclaim Defendants/Plaintiffs on the basis of, *inter alia*, its contacts with New Jersey relating to the subject matter of this action, including having filed suit.

6. Venue is proper under 28 U.S.C. §§ 1391 and 1400.

BACKGROUND

7. Upon information and belief, Axsome holds approved New Drug Application ("NDA") No. 211230 for Sunosi® brand solriamfetol tablets.

8. An NDA must include, among other things, the number of any patent that claims the "drug" or a "method of using [the] drug" for which the NDA was submitted and for which a claim of patent infringement could reasonably be asserted against an authorized party. *See* 21 U.S.C. § 355(b)(1), (c)(2); 21 C.F.R. § 314.53(b), (c)(2).

9. Upon approval of the NDA, the U.S. Food and Drug Administration ("FDA") publishes patent information for the approved drug in the "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the "Orange Book." *See* 21 U.S.C. § 355(j)(7)(A)(iii).

10. U.S. Patent 12,090,126 (the "'126 patent"), titled "Methods of administering solriamfetol to lactating women," issued on September 17, 2024.

11. U.S. Patent 12,102,609 (the "'609 patent"), titled "Methods of administering solriamfetol to lactating women," issued on October 1, 2024.

12. Upon information and belief, Axsome Malta Ltd is the assignee of the '126 and '609 patents.

13. Upon information and belief, Counterclaim Defendants/Plaintiffs caused the '126 and '609 patents to be listed in the Orange Book as a patent that claims such a drug for which Axsome submitted NDA No. 211230.

14. Hikma submitted Abbreviated New Drug Application ("ANDA") No. 218016 ("Hikma's ANDA") to obtain FDA approval to market a generic version of solriamfetol oral tablets ("Hikma's ANDA Product") prior to the expiration of '126 and '609 patents.

15. By letter dated October 16, 2024 (the "Hikma Fifth Notice Letter"), pursuant to 21 U.S.C. § 355(j)(2)(B), Hikma notified Counterclaim Defendants/Plaintiffs that ANDA No. 215242 includes a Paragraph IV Certification with respect to the '126 patent. The Hikma Fifth Notice Letter, which is incorporated herein by reference, contained a detailed statement of the factual and legal bases for Hikma Paragraph IV Certification that the claims of the '126 patent are invalid, not infringed, and/or unenforceable.

16. By letter dated October 18, 2024 (the "Hikma Sixth Notice Letter"), pursuant to 21 U.S.C. § 355(j)(2)(B), Hikma notified Counterclaim Defendants/Plaintiffs that ANDA No. 215242 includes a Paragraph IV Certification with respect to the '609 patent. The Hikma Sixth Notice Letter, which is incorporated herein by reference, contained a detailed statement of the factual and legal bases for Hikma Paragraph IV Certification that the claims of the '609 patent are invalid, not infringed, and/or unenforceable.

17. On November 20, 2024, Counterclaim Defendants/Plaintiffs filed this instant lawsuit alleging infringement of the '126 and '609 patents.

COUNT I
(Declaratory Judgment of Non-Infringement of the '126 Patent)

18. Hikma re-alleges and incorporates by reference the allegations in Paragraphs 1 through 17 of its Counterclaims as though fully set forth herein.

19. Counterclaim Defendants/Plaintiffs allege ownership of the '126 patent and have brought claims against Hikma alleging infringement of the '126 patent.

20. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Hikma's ANDA and/or the commercial marketing of Hikma's ANDA Product infringe, have infringed, and/or will infringe a valid and enforceable claim of the '126 patent.

21. Hikma has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '126 patent and is not liable for such infringement.

22. Hikma is entitled to a declaration that the manufacture, use, or sale of Hikma's ANDA Product would not infringe any valid or enforceable claim of the '126 patent.

COUNT II
(Declaratory Judgment of Invalidity or Unenforceability of the '126 Patent)

23. Hikma re-alleges and incorporates by reference the allegations in Paragraphs 1 through 22 of its Counterclaims as though fully set forth herein.

24. Counterclaim Defendants/Plaintiffs allege ownership of the '126 patent and have brought claims against Hikma alleging infringement of the '126 patent.

25. One or more claims of the '126 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially-created bases for invalidity.

26. The '126 patent describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

27. The alleged invention of the '126 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over

the prior art set forth in the '126 patent is not more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the '126 patent and would have had a reasonable expectation of success in doing so.

28. The subject matter claimed in the '126 patent fails to comply with 35 U.S.C. § 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

29. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Hikma's ANDA and/or the commercial marketing of Hikma's ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the '126 patent.

30. Hikma is entitled to a declaration that all claims of the '126 patent are invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially-created bases for invalidity.

COUNT III
(Declaratory Judgment of Non-Infringement of the '609 Patent)

31. Hikma re-alleges and incorporates by reference the allegations in Paragraphs 1 through 30 of its Counterclaims as though fully set forth herein.

32. Counterclaim Defendants/Plaintiffs allege ownership of the '609 patent and have brought claims against Hikma alleging infringement of the '609 patent.

33. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Hikma's ANDA and/or the commercial marketing of Hikma's

ANDA Product infringe, have infringed, and/or will infringe a valid and enforceable claim of the '609 patent.

34. Hikma has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '609 patent and is not liable for such infringement.

35. Hikma is entitled to a declaration that the manufacture, use, or sale of Hikma's ANDA Product would not infringe any valid or enforceable claim of the '609 patent.

COUNT IV
(Declaratory Judgment of Invalidity or Unenforceability of the '609 Patent)

36. Hikma re-alleges and incorporates by reference the allegations in Paragraphs 1 through 35 of its Counterclaims as though fully set forth herein.

37. Counterclaim Defendants/Plaintiffs allege ownership of the '609 patent and have brought claims against Hikma alleging infringement of the '609 patent.

38. One or more claims of the '609 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially-created bases for invalidity.

39. The '609 patent describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

40. The alleged invention of the '609 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the '609 patent is not more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the '609 patent and would have had a reasonable expectation of success in doing so.

41. The subject matter claimed in the '609 patent fails to comply with 35 U.S.C. § 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

42. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Hikma's ANDA and/or the commercial marketing of Hikma's ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the '609 patent.

43. Hikma is entitled to a declaration that all claims of the '609 patent are invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially-created bases for invalidity.

PRAYER FOR RELIEF

WHEREFORE, Hikma respectfully requests judgment in its favor and against Counterclaim Defendants/Plaintiffs as follows:

a. Declaring that the filing of Hikma's ANDA No. 218016 has not infringed and does not infringe any valid and enforceable claim of the '126 patent;

b. Declaring that the manufacture, use, offer to sell, sale, and/or importation into the United States of Hikma's ANDA Product does not, and would not, if marketed, infringe any valid and enforceable claim of the '126 patent;

c. Declaring that the filing of Hikma's ANDA No. 218016 has not infringed and does not infringe any valid and enforceable claim of the '609 patent;

d. Declaring that the manufacture, use, offer to sell, sale, and/or importation into the United States of Hikma's ANDA Product does not, and would not, if marketed, infringe any valid and enforceable claim of the '609 patent;

e. Declaring this an exceptional case in favor of Hikma and awarding its attorneys' fees pursuant to 35 U.S.C. § 285 and/or under all applicable statutes and rules in common law that would be appropriate;

f. Awarding costs and expenses under all applicable statutes and rules in common law that would be appropriate; and

g. Awarding any and all such other relief as the Court determines to be just and proper.

MIDLIGE RICHTER LLC
Attorneys for Defendant,
Hikma Pharmaceuticals USA Inc

By: s/ James S. Richter
James S. Richter
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Dated: February 3, 2025

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LOCAL CIVIL RULE 11.2 CERTIFICATION

Pursuant to Local Civil Rule 11.2 and 40.1, I hereby certify, to the best of my knowledge, this matter is related to the following actions, which are currently pending in this Court: *Axsome Malta Ltd. et al. v. Alkem Laboratories Ltd. et al.,* Civil Action No. 23-cv-20354 (MCA)(LDW) (Consolidated)*; Axsome Malta Ltd. et al v. Alkem Laboratories Ltd.*, No. 24-cv-10617 (MCA)(LDW); *Axsome Malta Ltd. et al v. Hetero USA Inc. et al.*, No. 24-cv-10618 (MCA)(LDW); *Axsome Malta Ltd. et al v. Aurobindo Pharma USA, Inc. et al.*, No. 24-cv-10619 (MCA)(LDW).

Hikma is not aware of any other action pending in any court or any pending arbitration or administrative proceeding related to this matter.

s/ James S. Richter
James S. Richter

Dated: February 3, 2025

LOCAL CIVIL RULE 201.1 CERTIFICATION

I hereby certify that the above-captioned matter is not subject to compulsory arbitration in that the parties seek, *inter alia*, declaratory relief in their respective pleadings.

I hereby certify under penalty of perjury that the foregoing is true and correct.

s/ James S. Richter
James S. Richter

Dated: February 3, 2025

CERTIFICATE OF SERVICE

The undersigned attorney certifies that a copy of Hikma's foregoing Answer, Separate Defenses, and Counterclaims was filed via ECF and served on all counsel of record by electronic mail on February 3, 2025.

s/ James S. Richter
James S. Richter

Dated: February 3, 2025