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

AXSOME MALTA LTD., and AXSOME THERAPEUTICS, INC. Plaintiffs, v. AUROBINDO PHARMA USA, INC., and AUROBINDO PHARMA LIMITED, Defendants.	)	Civil Action No. 24-07511-MCA-LDW

DEFENDANTS' ANSWER, AFFIRMATIVE DEFENSES AND COUNTERCLAIMS

Defendants, Aurobindo Pharma USA, Inc. and Aurobindo Pharma Limited ("Aurobindo" or "Defendants"), by way of Answer to Plaintiffs' Complaint, state as follows:

Defendants deny each and every allegation contained in the Complaint, except as specifically admitted or explained herein. To the extent that the headings or any other non-numbered statements in the Complaint contain any allegations, Defendants deny each and every such allegation.

Nature of the Action

1. This complaint is an action for patent infringement under the patent laws of the United States, 35 U.S.C. §100, *et seq.*, arising from Defendants' submission of Abbreviated New Drug Application ("ANDA") No. 218725 ("Aurobindo'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 United States Patent No. 11,969,404 ("the '404 patent"). Axsome is the owner of the '404 patent.

ANSWER:

Admitted that the Complaint purports to bring an action for infringement of U.S. Patent No. 11,969,404 ("the '404 patent") ("the patent-in-suit") under the patent laws of the United

States, 35 U.S.C. § 100, et seq. Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 1.

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:

Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 2 and, therefore, deny them.

3. Axsome Malta Ltd. is a corporation organized and existing under the laws of the Republic of Malta, having its principal place of business at Pinto Business Centre, Level 4, Office 4, Mill Street, Qormi, Triq il-Mithna Hal, Malta, QRM 3104.

ANSWER:

Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 3 and, therefore, deny them.

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

ANSWER:

Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 4 and, therefore, deny them.

5. On information and belief, Defendant Aurobindo Pharma USA, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 279 Princeton Hightstown Road, East Windsor, New Jersey 08520.

ANSWER:

Admitted.

6. On information and belief, Defendant Aurobindo Pharma Limited is a corporation organized and existing under the laws of India, having a principal place of business at Galaxy Floors: 22-24, Plot No. 1, Survey No. 83/1, Hyderabad Knowledge City, Raidurg Pamkaktha, Ranga Reddy District, Hyderabad, Telangana, India, 500032.

ANSWER:

Admitted.

7. On information and belief, Defendants are 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:

Admitted.

The '404 Patent

8. On April 30, 2024, the USPTO duly and lawfully issued the '404 patent, entitled, "Methods of Providing Solriamfetol Therapy to Subjects with Impaired Renal Function." The face of the '404 patent identifies Katayoun Zomorodi as the inventor. A copy of the '404 patent is attached hereto as Exhibit A.

ANSWER:

Admitted that on April 30, 2024 the '404 patent issued; is titled "Methods of Providing Solriamfetol Therapy to Subjects with Impaired Renal Function;" the face of the '404 patent identifies Katayoun Zomorodi as the inventor; and a copy of the '404 patent was attached to the complaint as Exhibit A. Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 8 and, therefore, deny them.

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 '404 patent 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:

Admitted that the online version of the FDA's "Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations" lists Axsome Malta Ltd. as the holder of NDA No. N211230 for SUNOSI® (solriamfetol HCl) oral tablets (eq. 75 mg base and eq. 150 mg base). Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 9 and, therefore, deny them.

10. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the '404 patent is listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to Sunosi®.

ANSWER:

Admitted.

Jurisdiction and Venue

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:

Admitted that subject matter jurisdiction is appropriate only for claims under 35 U.S.C. § 271(e)(2)(A), and except as so expressly admitted, deny the allegations of Paragraph 11.

12. As set forth below, the Court has personal jurisdiction over both Aurobindo Pharma USA, Inc. and Aurobindo Pharma Limited by virtue of, *inter alia*, their systematic and continuous contacts with the State of New Jersey.

ANSWER:

For the limited purposes of this action only, Aurobindo Pharma USA, Inc. and Aurobindo Pharma Limited consent to personal jurisdiction of this Court and, except as so expressly admitted, deny the allegations of Paragraph 12.

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

ANSWER:

For the limited purposes of this action only, Aurobindo consents to personal jurisdiction of this Court and, except as so expressly admitted, denies the allegations of Paragraph 13.

14. On information and belief, Aurobindo 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:

For the limited purposes of this action only, Aurobindo consents to personal jurisdiction of this Court and, except as so expressly admitted, denies the allegations of Paragraph 14.

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 Aurobindo seeks FDA approval to manufacture, market, import, offer for sale, and/or sell pursuant to ANDA No. 218725 ("Aurobindo's Proposed Product").

ANSWER:

For the limited purposes of this action only, Aurobindo consents to personal jurisdiction of this Court and, except as so expressly admitted, denies the allegations of Paragraph 15.

16. This Court has personal jurisdiction over Aurobindo Pharma Limited 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, Aurobindo Pharma 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, Aurobindo Pharma USA, Inc.

ANSWER:

For the limited purposes of this action only, Aurobindo consents to personal jurisdiction of this Court.

17. This Court has personal jurisdiction over Aurobindo Pharma USA, Inc. because, *inter alia*, on information and belief, Aurobindo maintains a regular and established, physical place of business at 279 Princeton Hightstown Road, East Windsor, New Jersey 08520.

ANSWER:

For the limited purposes of this action only, Aurobindo consents to personal jurisdiction of this Court.

18. On information and belief, Aurobindo Pharma 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. 0100921223.

ANSWER:

For the limited purposes of this action only, Aurobindo consents to personal jurisdiction of this Court.

19. On information and belief, Aurobindo Pharma USA, Inc. will work in concert with Aurobindo Pharma Limited toward the regulatory approval, manufacturing, use, importation, marketing, offer for sale, sale, and distribution of generic pharmaceutical products, including Aurobindo's Proposed Product, throughout the United States, including in New Jersey and in this Judicial District, prior to the expiration of the '404 patent.

ANSWER:

For the limited purposes of this action only, Aurobindo consents to personal jurisdiction of this Court and, except as so expressly admitted, denies the allegations of Paragraph 19.

20. Aurobindo 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.*, *Theravance Biopharma R&D IP, LLC, et al. v. Eugia Pharma Specialities Limited et al.*, Civil Action No. 1:23-cv-00926 (Aurobindo Pharma USA, Inc., Aurobindo Pharma Limited); *Forest Lab'ys, LLC, et al. v. Aurobindo Pharma USA, Inc., et al.*, Civil Action No. 2:17-cv-11679 (Aurobindo Pharma USA, Inc., Aurobindo Pharma Limited); *Boehringer Ingelheim Pharms., Inc.,*

et al. v. Aurobindo Pharma USA, Inc., et al., Civil Action No. 3:17-cv-07887 (Aurobindo Pharma USA, Inc.); *Mitsubishi Tanabe Pharma Corp., et al. v. Aurobindo Pharma USA, Inc., et al.*, Civil Action No. 1:17-cv-05005 (Aurobindo Pharma USA, Inc.). Aurobindo has purposefully availed itself of the rights, benefits, and privileges of New Jersey by asserting counterclaims in this Court..

ANSWER:

For the limited purposes of this action only, Aurobindo consents to personal jurisdiction of this Court and, except as so expressly admitted, denies the allegations of Paragraph 20.

21. Aurobindo consented to 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:

For the limited purposes of this action only, Aurobindo consents to personal jurisdiction of this Court and, except as so expressly admitted, denies the allegations of Paragraph 21.

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

ANSWER:

For the limited purposes of this action only, Aurobindo consents to personal jurisdiction of this Court and, except as so expressly admitted, denies the allegations of Paragraph 22.

23. At least because, on information and belief, Aurobindo Pharma Limited is a foreign company, venue is proper in this Judicial District with respect to Aurobindo Pharma

Limited 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 13-21, venue is proper in this Judicial District with respect to Aurobindo Pharma USA, Inc. pursuant to 28 U.S.C. § 1391(c)(3) and 28 U.S.C. § 1400(b).

ANSWER:

For the limited purposes of this action only, Aurobindo consents to personal jurisdiction of this Court and, except as so expressly admitted, denies the allegations of Paragraph 23.

Acts Giving Rise To This Suit

24. Pursuant to Section 505 of the FFDCA, Aurobindo submitted ANDA No. 218725 seeking approval to engage in the commercial manufacture, use, sale, offer for sale, or importation of Aurobindo's Proposed Product, before the '404 patent expires.

ANSWER:

Admitted that Aurobindo submitted ANDA No. 218725 to the FDA with a written certification according to Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV) to the '404 patent. Paragraph 24 states a legal conclusion to which no response is required, and except as so expressly admitted, denies the allegations of Paragraph 24.

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

ANSWER:

Admitted that Aurobindo's ANDA contains a Paragraph IV Certification with respect to the '404 patent, and except as so expressly admitted, denies the allegations of Paragraph 25.

26. On information and belief, in connection with the submission of its ANDA as described above, Aurobindo provided a written certification to the FDA, as called for by Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Aurobindo's Paragraph IV Certifications"), alleging, *inter alia*, that the claims of United States Patent Nos. 8,440,715, 10,195,151, 10,512,609, 10,959,976, 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, 11,850,226, 11,850,227, 11,850,228, 11,857,528, 11,865,098, 11,872,203, 11,872,204, and 11,969,404 are invalid and/or will not be infringed by the activities described in Aurobindo's ANDA.

ANSWER:

Admitted that by letter dated August 10, 2023, Aurobindo notified Axsome that it had filed a written certification according to Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to certain claims of the '715 patent, the '151 patent, the '609 patent, the '597 patent, the '976 patent, the '779 patent, the '354 patent, and the '232 patent. Admitted that by letter dated December 8, 2023, Aurobindo notified Axsome that it had filed a written certification according to Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to certain claims of the '666 patent, the '667 patent, the '554 patent, and the '776 patent. Admitted that by letter dated February 13, 2024, Aurobindo notified Axsome that it had filed a written certification according to Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to certain claims of the '598 patent, the '226 patent, the '227 patent, the '228 patent, the '528 patent, the '203 patent, and the '204 patent. Admitted that by letter dated February 27, 2024, Aurobindo notified Axsome that it had filed a written certification according to Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to certain claims of the '098 patent. Admitted that by letter dated May 21, 2024, Aurobindo notified Axsome that it had filed a written certification according to Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to certain claims of the '404 patent.

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

8,440,715, 10,195,151, 10,512,609, 10,959,976, 11,160,779, 11,439,597, 11,560,354, and 11,648,232.

ANSWER:

Admitted that by letter dated August 10, 2023, Aurobindo notified Axsome that it had filed a written certification according to Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to certain claims of the '715 patent, the '151 patent, the '609 patent, the '976 patent, the '779 patent, the '597 patent, the '354 patent, and the '232 patent.

28. No earlier than December 8, 2023, Aurobindo Pharma Limited sent written notice of Aurobindo's second Paragraph IV Certification to Axsome ("Aurobindo's Second Notice Letter"). Aurobindo'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 and/or will not be infringed by the activities described in Aurobindo's ANDA. Aurobindo's Second Notice Letter also informed Axsome that Aurobindo seeks approval to market Aurobindo'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:

Admitted that by letter dated December 8, 2023, Aurobindo notified Axsome that it had filed a written certification according to Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to certain claims of the '666 patent, the '667 patent, the '554 patent, and the '776 patent.

29. No earlier than February 13, 2024, Aurobindo Pharma Limited sent written notice of Aurobindo's third Paragraph IV Certification to Axsome ("Aurobindo's Third Notice Letter"). Aurobindo's Third Notice Letter alleged that the claims of United States Patent Nos. 11,839,598, 11,850,226, 11,850,227, 11,850,228, 11,857,528, 11,872,203, and 11,872,204 are invalid and/or will not be infringed by the activities described in Aurobindo's ANDA. Aurobindo's Third Notice Letter also informed Axsome that Aurobindo seeks approval to market Aurobindo's Proposed Product before the expiration of United States Patent Nos. 11,839,598, 11,850,226, 11,850,227, 11,850,228, 11,857,528, 11,872,203, and 11,872,204.

ANSWER:

Admitted that by letter dated February 13, 2024, Aurobindo notified Axsome that it had filed a written certification according to Section 505 of the FFDCA, 21 U.S.C. §

355(j)(2)(A)(vii)(IV) with respect to certain claims of the '598 patent, the '226 patent, the '227 patent, the '228 patent, the '528 patent, the '203 patent, and the '204 patent.

30. No earlier than February 27, 2024, Aurobindo Pharma Limited sent written notice of Aurobindo's fourth Paragraph IV Certification to Axsome ("Aurobindo's Fourth Notice Letter"). Aurobindo's Fourth Notice Letter alleged that the claims of United States Patent No. 11,865,098 are invalid and/or will not be infringed by the activities described in Aurobindo's ANDA. Aurobindo's Fourth Notice Letter also informed Axsome that Aurobindo seeks approval to market Aurobindo's Proposed Product before the expiration of United States Patent Nos. 11,865,098.

ANSWER:

Admitted that by letter dated February 27, 2024, Aurobindo notified Axsome that it had filed a written certification according to Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to certain claims of the '098 patent.

31. No earlier than May 21, 2024, Aurobindo Pharma Limited sent written notice of Aurobindo's fifth Paragraph IV Certification to Axsome ("Aurobindo's Fifth Notice Letter"). Aurobindo's Fifth Notice Letter alleged that the claims of the '404 patent are invalid and/or will not be infringed by the activities described in Aurobindo's ANDA. Aurobindo's Fifth Notice Letter also informed Axsome that Aurobindo seeks approval to market Aurobindo's Proposed Product before the expiration of the '404 patent.

ANSWER:

Admitted that by letter dated May 21, 2024, Aurobindo notified Axsome that it had filed a written certification according to Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to certain claims of the '404 patent.

Count I: Infringement of the '404 Patent

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

ANSWER:

Defendant realleges the answers to the preceding paragraphs as if fully set forth herein.

33. Aurobindo's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Aurobindo's Proposed Product, prior to the expiration of the '404 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 33 states a legal conclusion to which no response is required. Defendant denies that it has infringed the '404 patent. Admitted that Defendant filed Defendant's ANDA for approval by FDA of the matters recited therein. Defendant denies the remaining allegations in Paragraph 33 of the Complaint.

34. A justiciable controversy exists between Axsome and Aurobindo as to the infringement of the '404 patent.

ANSWER:

Paragraph 34 states a legal conclusion to which no response is required. Defendant denies that it has or will infringe the '404 patent.

35. Unless enjoined by this Court, upon FDA approval of Aurobindo's ANDA, Aurobindo will infringe one or more claims of the '404 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Aurobindo's Proposed Product in the United States.

ANSWER:

Paragraph 35 states legal conclusions to which no response is required. Defendant denies that it will infringe the '404 patent and denies the remaining allegations of this paragraph.

36. Unless enjoined by this Court, upon FDA approval of Aurobindo's ANDA, Aurobindo will induce infringement of one or more claims of the '404 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Aurobindo's Proposed Product in the United States. On information and belief, upon FDA approval of Aurobindo's ANDA, Aurobindo will intentionally encourage acts of direct infringement with knowledge of the '404 patent and knowledge that its acts are encouraging infringement.

ANSWER:

Paragraph 36 states legal conclusions to which no response is required. Defendant denies that it will infringe the '404 patent and denies the remaining allegations of this paragraph.

37. Unless enjoined by this Court, upon FDA approval of Aurobindo's ANDA, Aurobindo will contributorily infringe one or more claims of the '404 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Aurobindo's Proposed Product in the United States. On information and belief, Aurobindo knew and knows that Aurobindo's Proposed Product is designed for a use that infringes one or more claims of the '404 patent, and Aurobindo's Proposed Product lacks a substantial non-infringing use.

ANSWER:

Paragraph 37 states legal conclusions to which no response is required. Defendant denies that it will infringe the '404 patent and denies the remaining allegations of this paragraph.

38. Failure to enjoin Aurobindo's infringement of the '404 patent will substantially and irreparably damage and harm Axsome.

ANSWER:

Denied.

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

ANSWER:

Denied.

40. This case is an exceptional one, and Axsome is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

ANSWER:

Denied.

Response to Plaintiff's Prayer for Relief

Defendant denies that Plaintiff is entitled to the judgment or any of the relief sought in paragraphs (A) through (K) under the heading "PRAYER FOR RELIEF."

AFFIRMATIVE DEFENSES

Aurobindo alleges and asserts the following affirmative defenses in response to the allegations in the complaint. Aurobindo reserves the right to seek leave to assert additional defenses based on the Court's claim construction and as it learns more information through discovery.

FIRST AFFIRMATIVE DEFENSE

The manufacture, use or sale of the product that is the subject of ANDA No. 218725 has not infringed, is not infringing, and would not, if marketed, infringe, either directly or indirectly, any valid and enforceable claim of the '404 patent, either literally or under the doctrine of equivalents.

SECOND AFFIRMATIVE DEFENSE

The claims of the '404 patent are invalid for failure to comply with one or more conditions for patentability as set forth in one or more provisions of 35 U.S.C. §§ 101, 102, 103 and/or 112, or under other judicially-created bases for invalidation.

THIRD AFFIRMATIVE DEFENSE

Plaintiffs are estopped and/or precluded from asserting that the product described in ANDA No. 218725 infringes the '404 patent by reason of actions taken and statements made by the applicant for that patent to the PTO during prosecution of the application that lead to the '404 patent.

FOURTH AFFIRMATIVE DEFENSE

Plaintiffs' Complaint fails to state a proper claim for willful infringement or for this being an exceptional case justifying an award of attorney's fees.

FIFTH AFFIRMATIVE DEFENSE

The Complaint fails to state a claim upon which relief can be granted.

RESERVATION OF ADDITIONAL AFFIRMATIVE DEFENSE

Aurobindo reserves the right to assert additional affirmative defenses that may be developed through discovery, or otherwise, in this action.

COUNTERCLAIMS

For its Counterclaims against Plaintiff, Defendant/Counterclaim-Plaintiff Aurobindo Pharma U.S.A., Inc. ("Aurobindo" or "Counterclaim-Plaintiff") states as follows, without admitting any allegations of the Complaint not expressly admitted and without assuming the burden when such burden would otherwise be on Plaintiff/Counterclaim-Defendant.

PARTIES

1. Aurobindo Pharma USA, Inc. is a company organized and existing under the laws of the State of Delaware, having a principal place of business at 279 Princeton Hightstown Road, East Windsor, New Jersey 08520.

2. Aurobindo Pharma Limited is a corporation organized and existing under the laws of India, having a principal place of business at Galaxy Floors: 22-24, Plot No. 1, Survey No. 83/1, Hyderabad Knowledge City, Raidurg Pamkaktha, Ranga Reddy District, Hyderabad, Telangana, India, 500032.

3. Upon information and belief, Plaintiff 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.

4. Upon information and belief, Plaintiff 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

5. These counterclaims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and under the patent laws of the United States, Title 35 of the United States Code.

6. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 1367, 2201, and 2202.

7. Plaintiff/Counterclaim-Defendant Axsome Malta Ltd. and Axsome Therapeutics, Inc. (collectively, "Axsome") are subject to personal jurisdiction in this Judicial District because Plaintiff subjected itself to the jurisdiction of this Court by filing the Complaint here. Plaintiff Axsome is also subject to personal jurisdiction in this Judicial District because Axsome sells products here, regularly practices business here, and purposefully availed itself of the benefits of jurisdiction in the State of New Jersey.

8. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b) and by Counterclaim-Defendant's choice of forum in filing its Complaint against Aurobindo here.

9. As a consequence of Plaintiff/Counterclaim-Defendant's complaint against Aurobindo, there is now an actual, substantial, continuing and justiciable controversy between the parties as to the infringement, validity, and enforceability of the '404 patent.

THE CONTROVERSY

10. On April 30, 2024, the United States Patent and Trademark Office ("USPTO") issued the '404 patent, entitled, "Methods of Providing Solriamfetol Therapy to Subjects with Impaired Renal Function." The face of the '404 patent identifies Katayoun Zomorodi as the inventor.

11. Plaintiff Axsome Malta Ltd. purports to be the holder of the New Drug Application ("NDA") No. 211230 for the manufacture and sale of (solriamfetol HCl eq 75 mg base and eq 150 mg base) Oral Tablets, under the registered trademark SUNOSI® in the United States.

12. The Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. § 301 et seq., as amended by the Hatch-Waxman Amendments, sets forth the rules that the Food and Drug Administration ("FDA") must follow when determining whether to approve for marketing brand and generic drugs.

13. Under the FFDCA, an applicant seeking to market a new brand drug must prepare a NDA for review by the FDA. See 21 U.S.C. § 355.

14. An NDA may include the patent 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).

15. An NDA holder is required to submit to the FDA the patent number of each patent relevant to the drug for which the NDA was submitted to the FDA. The FDA automatically lists the NDA holder's disclosed patents pursuant to 21 U.S.C. §§ 355(b)(1) and (c)(2) in the Orange Book.

16. Upon information and belief, Plaintiffs caused the '404 patent to be listed in the Orange Book in connection with NDA No. 211230.

17. Aurobindo submitted ANDA No. 218725 ("Aurobindo's ANDA") to the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Aurobindo's ANDA Product within the United States at some time after approval

by the FDA and referenced NDA No. 211230. As part of Aurobindo's ANDA, Aurobindo submitted a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV), commonly called a "paragraph IV certification," that the '404 patent is invalid, unenforceable and/or will not be infringed by the commercial manufacture, use, or sale of Aurobindo's ANDA Product.

18. On August 10, 2023, Aurobindo sent Axsome written notice that Aurobindo had filed ANDA No. 218725 seeking approval to market Aurobindo's ANDA Product prior to the expiration of the '715 patent, the '151 patent, the '609 patent, the '597 patent, the '976 patent, the '779 patent, the '354 patent and the '232 patent, pursuant to FFD&C Act, 21 U.S.C. § 355(j)(2)(B) (the "August Paragraph IV notice letter"). The August Paragraph IV notice letter included Aurobindo's allegations that the patents are invalid and/or not infringed by Aurobindo's ANDA Product.

19. On or about September 18, 2023, Plaintiff/Counterclaim-Defendant Axsome sued Aurobindo, alleging infringement of the '715 patent, the '151 patent, the '609 patent, the '597 patent, the '976 patent, the '779 patent, the '354 patent and the '232 patent. There has been and is now an actual and justiciable controversy between Aurobindo and Axsome as to whether the drug products described in ANDA No. 218725 infringe, induce infringement, or contribute to the infringement of any valid, enforceable claims of the '715 patent, the '151 patent, the '609 patent, the '597 patent, the '976 patent, the '779 patent, the '354 patent and the '232 patent.

20. On December 8, 2023, Aurobindo sent Axsome written notice that Aurobindo had amended its ANDA No. 218725 to seek approval to market Aurobindo's ANDA Product prior to the expiration of the '666 patent, the '667 patent, the '554 patent and the '776 patent, pursuant to FFD&C Act, 21 U.S.C. § 355(j)(2)(B) (the "December Paragraph IV notice

letter"). The December Paragraph IV notice letter included Aurobindo's allegations that the patents are invalid and/or not infringed by Aurobindo's ANDA Product.

21. On or about January 18, 2024, Plaintiff/Counterclaim-Defendant Axsome sued Aurobindo, alleging infringement of the '666 patent, the '667 patent, the '554 patent and the '776 patent. There has been and is now an actual and justiciable controversy between Aurobindo and Axsome as to whether the drug products described in ANDA No. 218725 infringe, induce infringement, or contribute to the infringement of any valid, enforceable claims of the '666 patent, the '667 patent, the '554 patent and the '776 patent.

22. On February 13, 2024, Aurobindo sent Axsome written notice that Aurobindo had amended its ANDA No. 218725 to seek approval to market Aurobindo's ANDA Product prior to the expiration of the '598 patent, the '226 patent, the '227 patent, the '228 patent, the '528 patent, the '203 patent and the '204 patent, pursuant to FFD&C Act, 21 U.S.C. § 355(j)(2)(B) (the "February 13 Paragraph IV notice letter"). The February 13 Paragraph IV notice letter included Aurobindo's allegations that the patents are invalid and/or not infringed by Aurobindo's ANDA Product.

23. On February 27, 2024, Aurobindo sent Axsome written notice that Aurobindo had amended its ANDA No. 218725 to seek approval to market Aurobindo's ANDA Product prior to the expiration of the '098 patent, pursuant to FFD&C Act, 21 U.S.C. § 355(j)(2)(B) (the "February 27 Paragraph IV notice letter"). The February 27 Paragraph IV notice letter included Aurobindo's allegations that the '098 patent is invalid and/or not infringed by Aurobindo's ANDA Product.

24. On or about March 19, 2024, Plaintiff/Counterclaim-Defendant Axsome sued Aurobindo, alleging infringement of the '598 patent, the '226 patent, the '227 patent, the '228

patent, the ’528 patent, the ’203 patent, the ’204 patent and the ’098 patent. There has been and is now an actual and justiciable controversy between Aurobindo and Axsome as to whether the drug products described in ANDA No. 218725 infringe, induce infringement, or contribute to the infringement of any valid, enforceable claims of the patents-in-suit.

25. On May 21, 2024, Aurobindo sent Axsome written notice that Aurobindo had amended its ANDA No. 218725 to seek approval to market Aurobindo’s ANDA Product prior to the expiration of the ’404 patent, pursuant to FFD&C Act, 21 U.S.C. § 355(j)(2)(B) (the “May 21 Paragraph IV notice letter”). The May 21 Paragraph IV notice letter included Aurobindo’s allegations that the ’404 patent is invalid and/or not infringed by Aurobindo’s ANDA Product.

26. Aurobindo and Plaintiff/Counterclaim-Defendant Axsome have adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment with respect to the ’404 patent. The ’404 patent effectively delays FDA approval of the drug products described in ANDA No. 218725.

COUNT I

(Declaratory Judgment of Non-Infringement of the ’404 Patent by Aurobindo’s ANDA Product and Declaratory Judgment of Invalidity of the ’404 Patent)

27. Aurobindo repeats and incorporates by reference Paragraphs 1-26 of its Counterclaims as if fully set forth herein.

28. This counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 et seq. and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and seeks a declaration that no valid claim of the ’404 patent will be infringed by the manufacture, use, sale, offer for sale, or importation into the United States of Aurobindo’s ANDA Product described by ANDA No. 218725 and that all claims of the ’404 patent are invalid for failure to comply with the

statutory prerequisites of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, and/or 112, or other judicially-created bases for invalidation and unenforceability.

29. In Aurobindo's May 21 Paragraph IV notice letter, Aurobindo provided reasons sufficient to show that Aurobindo's ANDA Product described by ANDA No. 218725 does not infringe any valid claim of the '404 patent.

30. There is an actual, substantial, and continuing justiciable case or controversy between the parties having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment concerning whether the manufacture, use, sale, offering for sale, or importation of Aurobindo's ANDA Product described by ANDA No. 218725 will infringe any valid and enforceable claim of the '404 patent.

31. Aurobindo is entitled to a judicial declaration that the manufacture, use, sale, offering for sale, or importation of Aurobindo's ANDA Product described by ANDA No. 218725 will not infringe, directly or indirectly, any valid claim of the '404 patent.

PRAYER FOR RELIEF

WHEREFORE, Aurobindo respectfully requests the Court enter a Judgment and Order in its favor and against Counterclaim-Defendant to include:

(a) A declaration that Aurobindo's submission of ANDA No. 218725 seeking FDA approval to market its ANDA Product described therein prior to the expiration of the '404 patent does not, and will not, infringe, any valid and enforceable claim of the '404 patent;

(b) A declaration that Aurobindo's commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Aurobindo's ANDA Product described by ANDA No. 218725 does not, and will not, infringe any valid and enforceable claim of the '404 patent;

(c) A declaration that the claims of the ’404 patent are invalid;

(d) A declaration that Counterclaim-Defendant is entitled to no damages, interest, costs, or other relief from or against Aurobindo;

(e) A declaration that this case is exceptional in favor of Aurobindo and awarding attorneys’ fees pursuant to 35 U.S.C. § 285, other statutes or rules, or the inherent power of the Court;

(f) An award of costs and expenses;

(g) A declaration that Counterclaim-Defendant is not entitled to injunctive relief; and

(h) Such other and further relief as the Court may deem just and proper.

Respectfully submitted,

McNeely, Hare & War, LLP

/s/ William D. Hare

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Counsel for Defendants Aurobindo Pharma USA, Inc. and Aurobindo Pharma Limited.

Dated: August 19, 2024

CERTIFICATION PURSUANT TO L.CIV.R. 11.2 & 40.1

Pursuant to Local Civil Rules 11.2 and 40.1, I hereby certify that the matters captioned *Axsome Malta Ltd., et al. v. Alkem Lab'ys Ltd., et al.*, Civil Action No. 23-20354 (MCA)(JBC) (D.N.J.); *Axsome Malta Ltd., et al. v. Aurobindo Pharma USA, Inc. et al.*, Civil Action No. 24-00309 (MCA)(JBC) (D.N.J.); and *Axsome Malta Ltd., et al. v. Aurobindo Pharma USA, Inc. et al.*, Civil Action No. 24-04002 (MCA)(LDW) (D.N.J.), are related to the matter in controversy because the matter in controversy involves the same plaintiffs and Defendants Aurobindo Pharma USA, Inc. and Aurobindo Pharma Limited, and relate to the same generic version of the same pharmaceutical product.

Dated: August 19, 2024

Respectfully submitted,

McNeely, Hare & War, LLP

/s/ William D. Hare

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CERTIFICATE OF SERVICE

I hereby certify that on the 19th day of August, 2024, I served a true and correct copy of the foregoing DEFENDANTS' ANSWER, AFFIRMATIVE DEFENSES AND COUNTERCLAIMS on the counsel of record for Plaintiffs listed below via electronic mail:

/s/ William D. Hare

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