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UNITED STATES DISTRICT COURT
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. _____** **COMPLAINT FOR PATENT INFRINGEMENT** **(Filed Electronically)**

Plaintiffs Axsome Malta Ltd. and Axsome Therapeutics, Inc. (together, "Axsome"), by their undersigned attorneys, for their Complaint against defendants Aurobindo Pharma USA, Inc. and Aurobindo Pharma Limited (together, "Defendants" or "Aurobindo"), allege as follows:

Nature of the Action

1. This complaint is an action for patent infringement under the patent laws of the United States, 35 U.S.C. §100, *et seq.*, arising from 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 one or more of United

States Patent Nos. 11,839,598 ("the '598 patent"), 11,850,226 ("the '226 patent"), 11,850,227 ("the '227 patent"), 11,850,228 ("the '228 patent"), 11,857,528 ("the '528 patent"), 11,865,098 ("the '098 patent"), 11,872,203 ("the '203 patent"), and 11,872,204 ("the '204 patent") (collectively, "the patents-in-suit"). Axsome is the owner of the patents-in-suit.

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.

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.

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.

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 its principal place of business at 279 Princeton Hightstown Road, East Windsor, New Jersey 08520.

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.

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.

The Patents-in-Suit

8. On December 12, 2023, the USPTO duly and lawfully issued the '598 patent, entitled, "Methods of Providing Solriamfetol Therapy to Subjects with Impaired Renal Function." The face of the '598 patent identifies Katayoun Zomorodi as the inventor. A copy of the '598 patent is attached hereto as Exhibit A.

9. On December 26, 2023, the USPTO duly and lawfully issued the '226 patent, entitled, "Methods of Providing Solriamfetol Therapy to Subjects with Impaired Renal Function." The face of the '226 patent identifies Katayoun Zomorodi as the inventor. A copy of the '226 patent is attached hereto as Exhibit B.

10. On December 26, 2023, the USPTO duly and lawfully issued the '227 patent, entitled, "Methods of Providing Solriamfetol Therapy to Subjects with Impaired Renal Function." The face of the '227 patent identifies Katayoun Zomorodi as the inventor. A copy of the '227 patent is attached hereto as Exhibit C.

11. On December 26, 2023, the USPTO duly and lawfully issued the '228 patent, entitled, "Methods of Providing Solriamfetol Therapy to Subjects with Impaired Renal Function." The face of the '228 patent identifies Katayoun Zomorodi as the inventor. A copy of the '228 patent is attached hereto as Exhibit D.

12. On January 2, 2024, the USPTO duly and lawfully issued the '528 patent, entitled, "Methods of Providing Solriamfetol Therapy to Subjects with Impaired Renal Function." The face of the '528 patent identifies Katayoun Zomorodi as the inventor. A copy of the '528 patent is attached hereto as Exhibit E.

13. On January 9, 2024, the USPTO duly and lawfully issued the '098 patent, entitled, "Methods and Compositions for Treating Excessive Sleepiness." The face of the '098 patent identifies Lawrence Patrick Carter, Yuan Lu, and Katayoun Zomorodi as the inventors. A copy of the '098 patent is attached hereto as Exhibit F.

14. On January 16, 2024, the USPTO duly and lawfully issued the '203 patent, entitled, "Methods of Administering Solriamfetol to Lactating Women." The face of the '203 patent identifies Herriot Tabuteau as the inventor. A copy of the '203 patent is attached hereto as Exhibit G.

15. On January 16, 2024, the USPTO duly and lawfully issued the '204 patent, entitled, "Methods of Administering Solriamfetol to Lactating Women." The face of the '204 patent identifies Herriot Tabuteau as the inventor. A copy of the '204 patent is attached hereto as Exhibit H.

The Sunosi® Drug Product

16. Axsome holds an approved New Drug Application ("NDA") under Section 505(a) of the Federal Food Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 355(a), for solriamfetol oral tablets, Eq. 75 mg base and Eq. 150 mg base ("NDA No. 211230"), which is sold under the 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.

17. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the patents-in-suit are listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to Sunosi®.

Jurisdiction and Venue

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

19. 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.

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

21. 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.

22. On information and belief, this Judicial District will be a destination for the generic version of Axsome's solriamfetol oral tablets drug products for which Aurobindo seeks FDA approval to manufacture, market, import, offer for sale, and/or sell pursuant to ANDA No. 218725 ("Aurobindo's Proposed Product").

23. 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.

24. 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.

25. 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.

26. 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 patents-in-suit.

27. 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.

28. 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.).

29. 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.

30. 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 20-28, 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).

Acts Giving Rise To This Suit

31. 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 patents-in-suit expire.

32. 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.

33. On information and belief, in connection with the submission of its ANDA as described above, Aurobindo 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) ("Aurobindo'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, 10,959,976, 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, and 11,872,204 are invalid and/or will not be infringed by the activities described in Aurobindo's ANDA.

34. 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.

35. 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.

36. 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.

37. 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 No. 11,865,098.

Count I: Infringement of the '598 Patent

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

39. 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 '598 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

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

41. Unless enjoined by this Court, upon FDA approval of Aurobindo's ANDA, Aurobindo will infringe one or more claims of the '598 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Aurobindo's Proposed Product in the United States.

42. Unless enjoined by this Court, upon FDA approval of Aurobindo's ANDA, Aurobindo will induce infringement of one or more claims of the '598 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing 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 '598 patent and knowledge that its acts are encouraging infringement.

43. Unless enjoined by this Court, upon FDA approval of Aurobindo's ANDA, Aurobindo will contributorily infringe one or more claims of the '598 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing 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 '598 patent, and Aurobindo's Proposed Product lacks a substantial non-infringing use.

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

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

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

Count II: Infringement of the '226 Patent

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

48. 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 '226 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

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

50. Unless enjoined by this Court, upon FDA approval of Aurobindo's ANDA, Aurobindo will infringe one or more claims of the '226 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Aurobindo's Proposed Product in the United States.

51. Unless enjoined by this Court, upon FDA approval of Aurobindo's ANDA, Aurobindo will induce infringement of one or more claims of the '226 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing 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 ’226 patent and knowledge that its acts are encouraging infringement.

52. Unless enjoined by this Court, upon FDA approval of Aurobindo’s ANDA, Aurobindo will contributorily infringe one or more claims of the ’226 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing 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 ’226 patent, and Aurobindo’s Proposed Product lacks a substantial non-infringing use.

53. Failure to enjoin Aurobindo’s infringement of the ’226 patent will substantially and irreparably damage and harm Axsome.

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

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

Count III: Infringement of the ’227 Patent

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

57. 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 ’227 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

58. A justiciable controversy exists between Axsome and Aurobindo as to the infringement of the ’227 patent.

59. Unless enjoined by this Court, upon FDA approval of Aurobindo's ANDA, Aurobindo will infringe one or more claims of the '227 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Aurobindo's Proposed Product in the United States.

60. Unless enjoined by this Court, upon FDA approval of Aurobindo's ANDA, Aurobindo will induce infringement of one or more claims of the '227 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing 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 '227 patent and knowledge that its acts are encouraging infringement.

61. Unless enjoined by this Court, upon FDA approval of Aurobindo's ANDA, Aurobindo will contributorily infringe one or more claims of the '227 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing 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 '227 patent, and Aurobindo's Proposed Product lacks a substantial non-infringing use.

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

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

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

Count IV: Infringement of the '228 Patent

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

66. 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 '228 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

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

68. Unless enjoined by this Court, upon FDA approval of Aurobindo's ANDA, Aurobindo will infringe one or more claims of the '228 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Aurobindo's Proposed Product in the United States.

69. Unless enjoined by this Court, upon FDA approval of Aurobindo's ANDA, Aurobindo will induce infringement of one or more claims of the '228 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing 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 '228 patent and knowledge that its acts are encouraging infringement.

70. Unless enjoined by this Court, upon FDA approval of Aurobindo's ANDA, Aurobindo will contributorily infringe one or more claims of the '228 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing

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 '228 patent, and Aurobindo's Proposed Product lacks a substantial non-infringing use.

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

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

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

Count V: Infringement of the '528 Patent

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

75. 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 '528 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

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

77. Unless enjoined by this Court, upon FDA approval of Aurobindo's ANDA, Aurobindo will infringe one or more claims of the '528 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Aurobindo's Proposed Product in the United States.

78. Unless enjoined by this Court, upon FDA approval of Aurobindo's ANDA, Aurobindo will induce infringement of one or more claims of the '528 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing 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 '528 patent and knowledge that its acts are encouraging infringement.

79. Unless enjoined by this Court, upon FDA approval of Aurobindo's ANDA, Aurobindo will contributorily infringe one or more claims of the '528 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing 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 '528 patent, and Aurobindo's Proposed Product lacks a substantial non-infringing use.

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

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

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

Count VI: Infringement of the '098 Patent

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

84. 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 '098 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

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

86. Unless enjoined by this Court, upon FDA approval of Aurobindo's ANDA, Aurobindo will infringe one or more claims of the '098 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Aurobindo's Proposed Product in the United States.

87. Unless enjoined by this Court, upon FDA approval of Aurobindo's ANDA, Aurobindo will induce infringement of one or more claims of the '098 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing 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 '098 patent and knowledge that its acts are encouraging infringement.

88. Unless enjoined by this Court, upon FDA approval of Aurobindo's ANDA, Aurobindo will contributorily infringe one or more claims of the '098 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing 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 ’098 patent, and Aurobindo’s Proposed Product lacks a substantial non-infringing use.

89. Failure to enjoin Aurobindo’s infringement of the ’098 patent will substantially and irreparably damage and harm Axsome.

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

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

Count VII: Infringement of the ’203 Patent

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

93. 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 ’203 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

94. A justiciable controversy exists between Axsome and Aurobindo as to the infringement of the ’203 patent.

95. Unless enjoined by this Court, upon FDA approval of Aurobindo’s ANDA, Aurobindo will infringe one or more claims of the ’203 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Aurobindo’s Proposed Product in the United States.

96. Unless enjoined by this Court, upon FDA approval of Aurobindo’s ANDA, Aurobindo will induce infringement of one or more claims of the ’203 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing

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 '203 patent and knowledge that its acts are encouraging infringement.

97. Unless enjoined by this Court, upon FDA approval of Aurobindo's ANDA, Aurobindo will contributorily infringe one or more claims of the '203 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing 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 '203 patent, and Aurobindo's Proposed Product lacks a substantial non-infringing use.

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

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

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

Count VIII: Infringement of the '204 Patent

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

102. 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 '204 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

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

104. Unless enjoined by this Court, upon FDA approval of Aurobindo's ANDA, Aurobindo will infringe one or more claims of the '204 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Aurobindo's Proposed Product in the United States.

105. Unless enjoined by this Court, upon FDA approval of Aurobindo's ANDA, Aurobindo will induce infringement of one or more claims of the '204 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing 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 '204 patent and knowledge that its acts are encouraging infringement.

106. Unless enjoined by this Court, upon FDA approval of Aurobindo's ANDA, Aurobindo will contributorily infringe one or more claims of the '204 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing 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 '204 patent, and Aurobindo's Proposed Product lacks a substantial non-infringing use.

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

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

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

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Axsome respectfully requests the following relief:

(A) A Judgment that Aurobindo infringed one or more claims of each of the patents-in-suit asserted against Aurobindo by submitting ANDA No. 218725;

(B) A Judgment that Aurobindo has infringed, and that Aurobindo's making, using, offering to sell, selling, or importing Aurobindo's Proposed Product will infringe one or more claims of each of the patents-in-suit asserted against Aurobindo;

(C) An Order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of FDA approval of ANDA No. 218725 be a date no earlier than the later of the expiration of each patent-in-suit asserted against Aurobindo, or any later expiration of exclusivity to which Axsome is or becomes entitled;

(D) Preliminary and permanent injunctions enjoining Aurobindo and its officers, agents, attorneys and employees, and those acting in privity and/or concert with them, from making, using, offering to sell, selling, or importing Aurobindo's Proposed Product until after the expiration of each of the patents-in-suit asserted against Aurobindo, or any later expiration of exclusivity to which Axsome is or becomes entitled;

(E) A permanent injunction, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Aurobindo, its officers, agents, attorneys and employees, and those acting in privity and/or concert with them, from practicing any method claimed in the patents-in-suit asserted against Aurobindo, or from actively inducing or contributing to the infringement of any claim of the patents-in-suit asserted against Aurobindo, until after the expiration of each such patent-in-suit, or any later expiration of exclusivity to which Axsome is or becomes entitled;

(F) A Judgment that the commercial manufacture, use, importation into the United States, offer for sale, and/or sale of Aurobindo's Proposed Product will directly infringe, induce and/or contribute to infringement of one or more claims of each of the patents-in-suit asserted against Aurobindo;

(G) To the extent that Aurobindo has committed any acts with respect to the methods claimed in the patents-in-suit asserted against Aurobindo, other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), a Judgment awarding Axsome damages for such acts;

(H) If Aurobindo engages in the commercial manufacture, use, importation into the United States, offer for sale, and/or sale of Aurobindo's Proposed Product prior to the expiration of the patents-in-suit asserted against Aurobindo, a Judgment awarding damages to Axsome resulting from such infringement, together with interest;

(I) A Judgment declaring that each patent-in-suit asserted against Aurobindo remains valid and enforceable;

(J) A Judgment that this is an exceptional case pursuant to 35 U.S.C. § 285 and awarding Axsome its attorneys' fees, costs, and expenses incurred in this action; and

(K) Such further and other relief as this Court may deem just and proper.

Dated: March 19, 2024

By: s/ Charles M. Lizza

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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)(LDW) (D.N.J.), *Axsome Malta Ltd., et al. v. Unichem Lab'ys Ltd., et al.*, Civil Action No. 23-23255 (MCA)(LDW), *Axsome Malta Ltd., et al. v. Hetero USA Inc., et al.*, Civil Action No. 24-196 (MCA)(LDW), *Axsome Malta Ltd., et al. v. Aurobindo Pharma USA, Inc., et al.*, Civil Action No. 24-309 (MCA)(LDW), and *Axsome Malta Ltd., et al. v. Sandoz Inc.*, Civil Action No. 24-860 (MCA)(LDW) are related to the matter in controversy because the matter in controversy involves the same plaintiffs, some of the same patents, and some of the same defendants, and because Defendants are seeking FDA approval to market a generic version of the same pharmaceutical product.

Dated: March 19, 2024

By: s/ Charles M. Lizza

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