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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

AXSOME MALTA LTD. and AXSOME THERAPEUTICS, INC., **Plaintiffs,** **v.** **ALKEM LABORATORIES LTD., HIKMA PHARMACEUTICALS USA INC., SANDOZ INC., and UNICHEM LABORATORIES LTD.,** **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 Alkem Laboratories Ltd. ("Alkem"), Hikma Pharmaceuticals USA Inc. ("Hikma"), Sandoz Inc. ("Sandoz"), and Unichem Laboratories Ltd. ("Unichem") (Alkem, Hikma, Sandoz, and Unichem, collectively, "Defendants"), 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 their respective

Abbreviated New Drug Application ("ANDA") Nos. 218722 ("Alkem's ANDA"), 218016 ("Hikma's ANDA"), 218610 ("Sandoz's ANDA"), and 218761 ("Unichem's ANDA"), with the United States Food and Drug Administration ("FDA") seeking approval to commercially market generic versions of Axsome's solriamfetol oral tablets drug products prior to the expiration of one or more of United States Patent Nos. 11,771,666 ("the '666 patent"), 11,771,667 ("the '667 patent"), 11,779,554 ("the '554 patent"), 11,793,776 ("the '776 patent"), 11,839,598 ("the '598 patent"), 11,839,599 ("the '599 patent"), 11,850,226 ("the '226 patent"), 11,850,227 ("the '227 patent"), 11,850,228 ("the '228 patent"), 11,857,528 ("the '528 patent"), 11,865,098 ("the '098 patent"), 11,872,203 ("the '203 patent"), and 11,872,204 ("the '204 patent") (collectively, "the patents-in-suit"). Axsome is the owner of the patents-in-suit.

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 a 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 Delaware, having a principal place of business at One World Trade Center, 22nd Floor, New York, New York 10007.

5. On information and belief, Defendant Alkem is a corporation organized and existing under the laws of India, having a principal place of business at Devashish Building, Alkem House, Senapati Bapat Road, Lower Parel, Mumbai, 400 013, Maharashtra, India.

6. 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.

7. On information and belief, Defendant Sandoz is a corporation organized and existing under the laws of the State of Colorado, having its principal place of business at 100 College Road West, Princeton, New Jersey 08540.

8. On information and belief, Defendant Unichem is a corporation organized and existing under the laws of India, having its principal place of business at Centre of Excellence, Plot No. 12 to 14, Pilerne Industrial Estate, Pilerne, Bardez, Goa 403 511, India.

9. On information and belief, Defendants are all pharmaceutical companies that formulate, manufacture, package, and market generic drug products for distribution in the District of New Jersey and throughout the United States.

The Patents-in-Suit

10. On October 3, 2023, the USPTO duly and lawfully issued the ’666 patent, entitled, “Methods of Administering Solriamfetol to Lactating Women.” The face of the ’666 patent identifies Herriot Tabuteau as the inventor. A copy of the ’666 patent is attached hereto as Exhibit A.

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

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

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

14. 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 E.

15. On December 12, 2023, the USPTO duly and lawfully issued the '599 patent, entitled, "Methods of Providing Solriamfetol Therapy to Subjects with Impaired Renal Function." The face of the '599 patent identifies Katayoun Zomorodi as the inventor. A copy of the '599 patent is attached hereto as Exhibit F.

16. 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 G.

17. 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 H.

18. 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 I.

19. 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 J.

20. 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 K.

21. 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 L.

22. 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 M.

The Sunosi® Drug Product

23. 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.

24. 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: Alkem

25. This Court has jurisdiction over the subject matter of Counts I through XIII against Alkem pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

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

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

28. On information and belief, Alkem 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.

29. 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 Alkem seeks

FDA approval to manufacture, market, import, offer for sale, and/or sell pursuant to ANDA No. 218722 ("Alkem's Proposed Product").

30. On information and belief, Alkem 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. 0400132325.

31. Alkem 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.*, *Azurity Pharm., Inc. v. Alkem Labs. Ltd.*, Civil Action No. 22-cv-0143 (D.N.J.); *Celgene Corp. v. Alkem Labs. Ltd*., Civil Action No. 18-cv-11265 (D.N.J.); *Valeant Pharm. N. Am. LLC v. Alkem Labs. Ltd*., Civil Action No. 18-cv-13905 (D.N.J.); *Sumitomo Dainippon Pharma Co. v. Alkem Labs. Ltd*., Civil Action No. 18- cv-14787 (D.N.J.). Alkem has purposefully availed itself of the rights, benefits, and privileges of New Jersey by asserting counterclaims in this Court.

32. Alkem 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.).

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

34. At least because, on information and belief, Alkem is a foreign company, venue is proper in this Judicial District with respect to Alkem pursuant to 28 U.S.C. § 1391(c)(3) and 28 U.S.C. § 1400(b).

Jurisdiction and Venue: Hikma

35. This Court has jurisdiction over the subject matter of Counts XIV through XXVI against Hikma pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

36. 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.

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

38. 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.

39. 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").

40. 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.

41. 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.

42. 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.

43. 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.).

44. For at least the reasons set forth above in Paragraphs 37-43, 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).

Jurisdiction and Venue: Sandoz

45. This Court has jurisdiction over the subject matter of Counts XXVII through XXX against Sandoz pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

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

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

48. On information and belief, Sandoz 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.

49. 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 Sandoz seeks FDA approval to manufacture, market, import, offer for sale, and/or sell pursuant to ANDA No. 218610 ("Sandoz's Proposed Product").

50. This Court has personal jurisdiction over Sandoz because, *inter alia*, on information and belief, Sandoz maintains a regular and established, physical place of business at 100 College Road West, Princeton, New Jersey 08540.

51. On information and belief, Sandoz 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. 0100097265.

52. Sandoz 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.*, *Teva Pharmaceuticals USA, Inc., et al. v. Sandoz Inc., et al.*, Civil Action No. 17-275 (FLW)(DEA) (D.N.J.); *Amgen, Inc. v. Sandoz Inc., et al.*, Civil Action No. 18-11026 (MAS)(DEA) (D.N.J.); *Immunex Corp., et al. v. Sandoz Inc., et al.*, Civil Action No. 16-1118 (CCC) (D.N.J.). Sandoz has purposefully availed itself of the rights, benefits, and privileges of New Jersey by asserting counterclaims in this Court.

53. Sandoz 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.).

54. For at least the reasons set forth above in Paragraphs 47-53, venue is proper in this Judicial District with respect to Sandoz pursuant to 28 U.S.C. § 1391(c)(3) and 28 U.S.C. § 1400(b).

Jurisdiction and Venue: Unichem

55. This Court has jurisdiction over the subject matter of Counts XXXI through XXXIX against Unichem pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

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

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

58. On information and belief, Unichem 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.

59. 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 Unichem seeks FDA approval to manufacture, market, import, offer for sale, and/or sell pursuant to ANDA No. 218761 ("Unichem's Proposed Product").

60. Unichem 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.*, *AstraZeneca AB, et al. v. Unichem Inc., et al.*, Civil Action No. 22-7472 (KMW)(EAP)

(D.N.J.); *Bayer Intellectual Property GmbH, et al. v. Unichem Inc. a/k/a Unichem Laboratories, Ltd., et al.*, Civil Action No. 20-05439 (MCA)(MAH) (D.N.J.); and *Celgene Corporation v. Unichem Laboratories, Ltd.*, Civil Action No. 18-11268 (MAS)(DEA) (D.N.J.). Unichem has purposefully availed itself of the rights, benefits, and privileges of New Jersey by asserting counterclaims in this Court.

61. Unichem did not challenge 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.).

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

63. At least because, on information and belief, Unichem is a foreign company, venue is proper in this Judicial District with respect to Unichem pursuant to 28 U.S.C. § 1391(c)(3) and 28 U.S.C. § 1400(b).

Acts Giving Rise To Counts I-XIII Against Alkem

64. Pursuant to Section 505 of the FFDCA, Alkem submitted ANDA No. 218722 seeking approval to engage in the commercial manufacture, use, sale, offer for sale, or importation of Alkem's Proposed Product, before the patents-in-suit expire.

65. No earlier than August 11, 2023, Alkem sent written notice of a Paragraph IV Certification ("Alkem's Notice Letter") to Axsome. According to Alkem's Notice Letter, Alkem 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 Alkem's Proposed Product before expiration of certain patents listed in the Orange Book with respect to Sunosi®.

66. No earlier than March 29, 2024, Alkem sent written notice of a Paragraph IV Certification ("Alkem's Second Notice Letter") to Axsome. According to Alkem's Second Notice Letter, Alkem 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 Alkem's Proposed Product before expiration of certain patents listed in the Orange Book with respect to Sunosi®.

67. On information and belief, in connection with the filing of its ANDA as described above, Alkem 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), indicating that it seeks to obtain approval of its ANDA to engage in the commercial manufacture, use, or sale of Alkem's Proposed Product before the expiration of the Orange Book patents with respect to Sunosi®, including the patents-in-suit.

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

Acts Giving Rise To Counts XIV-XXVI Against Hikma

69. 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.

70. 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®.

71. 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®.

72. On information and belief, in connection with the filing of its ANDA as described above, Hikma 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), indicating that it seeks to obtain approval of its ANDA to engage in the commercial manufacture, use, or sale of Hikma's Proposed Product before the expiration of the Orange Book patents with respect to Sunosi®, including the patents-in-suit.

73. 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.

Acts Giving Rise to Counts XXVII-XXX Against Sandoz

74. Pursuant to Section 505 of the FFDCA, Sandoz submitted ANDA No. 218610 seeking approval to engage in the commercial manufacture, use, sale, offer for sale, or importation of Sandoz's Proposed Product, before the patents-in-suit expire.

75. No earlier than August 15, 2023, Sandoz sent written notice of a Paragraph IV Certification ("Sandoz's First Notice Letter") to Axsome. According to Sandoz's First Notice Letter, Sandoz 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 Sandoz's Proposed Product before expiration of certain patents listed in the Orange Book with respect to Sunosi®.

76. No earlier than January 12, 2024, Sandoz sent written notice of a Paragraph IV Certification ("Sandoz's Second Notice Letter") to Axsome. According to Sandoz's Second Notice Letter, Sandoz 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 Sandoz's Proposed Product before expiration of certain patents listed in the Orange Book with respect to Sunosi®.

77. On information and belief, in connection with the filing of its ANDA as described above, Sandoz 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), indicating that it seeks to obtain approval of its ANDA to engage in the commercial manufacture, use, or sale of Sandoz's Proposed Product

before the expiration of the Orange Book patents with respect to Sunosi®, including the '528 patent, the '098 patent, the '203 patent, and the '204 patent.

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

Acts Giving Rise to Counts XXXI-XXXIX Against Unichem

79. Pursuant to Section 505 of the FFDCA, Unichem submitted ANDA No. 218761 seeking approval to engage in the commercial manufacture, use, sale, offer for sale, or importation of Unichem's Proposed Product, before the patents-in-suit expire.

80. No earlier than August 9, 2023, Unichem sent written notice of a Paragraph IV Certification ("Unichem's First Notice Letter") to Axsome. According to Unichem's First Notice Letter, Unichem 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 Unichem's Proposed Product before expiration of certain patents listed in the Orange Book with respect to Sunosi®.

81. No earlier than November 7, 2023, Unichem sent written notice of a Paragraph IV Certification ("Unichem's Second Notice Letter") to Axsome. According to Unichem's Second Notice Letter, Unichem 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 Unichem's Proposed Product before expiration of certain patents listed in the Orange Book with respect to Sunosi®.

82. On information and belief, in connection with the filing of its ANDA as described above, Unichem 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), indicating that it seeks to obtain approval of its

ANDA to engage in the commercial manufacture, use, or sale of Unichem's Proposed Product before the expiration of the Orange Book patents with respect to Sunosi®, including 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.

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

Count I: Infringement of the '666 Patent by Alkem

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

85. Alkem's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Alkem's Proposed Product, prior to the expiration of the '666 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

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

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

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

Proposed Product in the United States. On information and belief, upon FDA approval of Alkem's ANDA, Alkem will intentionally encourage acts of direct infringement with knowledge of the '666 patent and knowledge that its acts are encouraging infringement.

89. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem will contributorily infringe one or more claims of the '666 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Alkem's Proposed Product in the United States. On information and belief, Alkem knew and knows that Alkem's Proposed Product is designed for a use that infringes one or more claims of the '666 patent, and Alkem's Proposed Product lacks a substantial non-infringing use.

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

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

92. 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 '667 Patent by Alkem

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

94. Alkem's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Alkem's Proposed Product, prior to the expiration of the '667 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

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

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

97. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem will induce infringement of one or more claims of the '667 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Alkem's Proposed Product in the United States. On information and belief, upon FDA approval of Alkem's ANDA, Alkem will intentionally encourage acts of direct infringement with knowledge of the '667 patent and knowledge that its acts are encouraging infringement.

98. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem will contributorily infringe one or more claims of the '667 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Alkem's Proposed Product in the United States. On information and belief, Alkem knew and knows that Alkem's Proposed Product is designed for a use that infringes one or more claims of the '667 patent, and Alkem's Proposed Product lacks a substantial non-infringing use.

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

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

101. 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 '554 Patent by Alkem

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

103. Alkem's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Alkem's Proposed Product, prior to the expiration of the '554 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

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

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

106. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem will induce infringement of one or more claims of the '554 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Alkem's Proposed Product in the United States. On information and belief, upon FDA approval of Alkem's ANDA, Alkem will intentionally encourage acts of direct infringement with knowledge of the '554 patent and knowledge that its acts are encouraging infringement.

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

that Alkem's Proposed Product is designed for a use that infringes one or more claims of the '554 patent, and Alkem's Proposed Product lacks a substantial non-infringing use.

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

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

110. 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 '776 Patent by Alkem

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

112. Alkem's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Alkem's Proposed Product, prior to the expiration of the '776 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

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

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

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

Proposed Product in the United States. On information and belief, upon FDA approval of Alkem's ANDA, Alkem will intentionally encourage acts of direct infringement with knowledge of the '776 patent and knowledge that its acts are encouraging infringement.

116. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem will contributorily infringe one or more claims of the '776 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Alkem's Proposed Product in the United States. On information and belief, Alkem knew and knows that Alkem's Proposed Product is designed for a use that infringes one or more claims of the '776 patent, and Alkem's Proposed Product lacks a substantial non-infringing use.

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

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

119. 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 '598 Patent by Alkem

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

121. Alkem's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Alkem'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.

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

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

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

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

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

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

128. 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 '599 Patent by Alkem

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

130. Alkem's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Alkem's Proposed Product, prior to the expiration of the '599 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

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

132. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem will infringe one or more claims of the '599 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Alkem's Proposed Product in the United States.

133. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem will induce infringement of one or more claims of the '599 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Alkem's Proposed Product in the United States. On information and belief, upon FDA approval of Alkem's ANDA, Alkem will intentionally encourage acts of direct infringement with knowledge of the '599 patent and knowledge that its acts are encouraging infringement.

134. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem will contributorily infringe one or more claims of the '599 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Alkem's Proposed Product in the United States. On information and belief, Alkem knew and knows

that Alkem's Proposed Product is designed for a use that infringes one or more claims of the '599 patent, and Alkem's Proposed Product lacks a substantial non-infringing use.

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

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

137. 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 '226 Patent by Alkem

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

139. Alkem's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Alkem'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.

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

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

142. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem 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 Alkem's

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

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

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

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

146. 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 '227 Patent by Alkem

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

148. Alkem's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Alkem'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.

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

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

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

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

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

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

155. 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 IX: Infringement of the ’228 Patent by Alkem

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

157. Alkem’s submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Alkem’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.

158. A justiciable controversy exists between Axsome and Alkem as to the infringement of the ’228 patent.

159. Unless enjoined by this Court, upon FDA approval of Alkem’s ANDA, Alkem 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 Alkem’s Proposed Product in the United States.

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

161. Unless enjoined by this Court, upon FDA approval of Alkem’s ANDA, Alkem 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 Alkem’s Proposed Product in the United States. On information and belief, Alkem knew and knows

that Alkem's Proposed Product is designed for a use that infringes one or more claims of the '228 patent, and Alkem's Proposed Product lacks a substantial non-infringing use.

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

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

164. 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 X: Infringement of the '528 Patent by Alkem

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

166. Alkem's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Alkem'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.

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

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

169. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem 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 Alkem's

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

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

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

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

173. 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 XI: Infringement of the '098 Patent by Alkem

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

175. Alkem's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Alkem'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.

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

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

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

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

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

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

182. 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 XII: Infringement of the '203 Patent by Alkem

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

184. Alkem's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Alkem'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.

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

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

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

188. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem 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 Alkem's Proposed Product in the United States. On information and belief, Alkem knew and knows

that Alkem's Proposed Product is designed for a use that infringes one or more claims of the '203 patent, and Alkem's Proposed Product lacks a substantial non-infringing use.

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

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

191. 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 XIII: Infringement of the '204 Patent by Alkem

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

193. Alkem's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Alkem'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.

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

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

196. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem 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 Alkem's

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

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

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

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

200. 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 XIV: Infringement of the '666 Patent by Hikma

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

202. 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 '666 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

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

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

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

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

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

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

209. 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 XV: Infringement of the '667 Patent by Hikma

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

211. 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 '667 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

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

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

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

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

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

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

218. 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 XVI: Infringement of the '554 Patent by Hikma

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

220. 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 '554 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

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

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

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

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

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

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

227. 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 XVII: Infringement of the '776 Patent by Hikma

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

229. 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 '776 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

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

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

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

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

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

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

236. 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 XVIII: Infringement of the '598 Patent by Hikma

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

238. 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 '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.

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

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

241. Unless enjoined by this Court, upon FDA approval of Hikma's ANDA, Hikma 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 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 '598 patent and knowledge that its acts are encouraging infringement.

242. Unless enjoined by this Court, upon FDA approval of Hikma's ANDA, Hikma 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 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 '598 patent, and Hikma's Proposed Product lacks a substantial non-infringing use.

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

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

245. 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 XIX: Infringement of the '599 Patent by Hikma

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

247. 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 '599 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

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

249. Unless enjoined by this Court, upon FDA approval of Hikma's ANDA, Hikma will infringe one or more claims of the '599 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Hikma's Proposed Product in the United States.

250. Unless enjoined by this Court, upon FDA approval of Hikma's ANDA, Hikma will induce infringement of one or more claims of the '599 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing 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 '599 patent and knowledge that its acts are encouraging infringement.

251. Unless enjoined by this Court, upon FDA approval of Hikma's ANDA, Hikma will contributorily infringe one or more claims of the '599 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing 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 '599 patent, and Hikma's Proposed Product lacks a substantial non-infringing use.

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

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

254. 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 XX: Infringement of the '226 Patent by Hikma

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

256. 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 '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.

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

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

259. Unless enjoined by this Court, upon FDA approval of Hikma's ANDA, Hikma 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 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 '226 patent and knowledge that its acts are encouraging infringement.

260. Unless enjoined by this Court, upon FDA approval of Hikma's ANDA, Hikma 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 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 '226 patent, and Hikma's Proposed Product lacks a substantial non-infringing use.

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

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

263. 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 XXI: Infringement of the '227 Patent by Hikma

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

265. 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 '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.

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

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

268. Unless enjoined by this Court, upon FDA approval of Hikma's ANDA, Hikma 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 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 '227 patent and knowledge that its acts are encouraging infringement.

269. Unless enjoined by this Court, upon FDA approval of Hikma's ANDA, Hikma 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 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 '227 patent, and Hikma's Proposed Product lacks a substantial non-infringing use.

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

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

272. 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 XXII: Infringement of the '228 Patent by Hikma

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

274. 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 '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.

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

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

277. Unless enjoined by this Court, upon FDA approval of Hikma's ANDA, Hikma 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 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 '228 patent and knowledge that its acts are encouraging infringement.

278. Unless enjoined by this Court, upon FDA approval of Hikma's ANDA, Hikma 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 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 '228 patent, and Hikma's Proposed Product lacks a substantial non-infringing use.

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

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

281. 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 XXIII: Infringement of the '528 Patent by Hikma

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

283. 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 '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.

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

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

286. Unless enjoined by this Court, upon FDA approval of Hikma's ANDA, Hikma 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 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 '528 patent and knowledge that its acts are encouraging infringement.

287. Unless enjoined by this Court, upon FDA approval of Hikma's ANDA, Hikma 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 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 '528 patent, and Hikma's Proposed Product lacks a substantial non-infringing use.

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

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

290. 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 XXIV: Infringement of the '098 Patent by Hikma

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

292. 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 '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.

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

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

295. Unless enjoined by this Court, upon FDA approval of Hikma's ANDA, Hikma 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 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 '098 patent and knowledge that its acts are encouraging infringement.

296. Unless enjoined by this Court, upon FDA approval of Hikma's ANDA, Hikma 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 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 '098 patent, and Hikma's Proposed Product lacks a substantial non-infringing use.

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

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

299. 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 XXV: Infringement of the '203 Patent by Hikma

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

301. 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 '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.

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

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

304. Unless enjoined by this Court, upon FDA approval of Hikma's ANDA, Hikma 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 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 '203 patent and knowledge that its acts are encouraging infringement.

305. Unless enjoined by this Court, upon FDA approval of Hikma's ANDA, Hikma 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 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 '203 patent, and Hikma's Proposed Product lacks a substantial non-infringing use.

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

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

308. 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 XXVI: Infringement of the '204 Patent by Hikma

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

310. 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 '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.

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

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

313. Unless enjoined by this Court, upon FDA approval of Hikma's ANDA, Hikma 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 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 '204 patent and knowledge that its acts are encouraging infringement.

314. Unless enjoined by this Court, upon FDA approval of Hikma's ANDA, Hikma 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 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 '204 patent, and Hikma's Proposed Product lacks a substantial non-infringing use.

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

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

317. 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 XXVII: Infringement of the '528 Patent by Sandoz

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

319. Sandoz's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Sandoz'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.

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

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

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

323. Unless enjoined by this Court, upon FDA approval of Sandoz's ANDA, Sandoz 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 Sandoz's Proposed Product in the United States. On information and belief, Sandoz knew and knows

that Sandoz's Proposed Product is designed for a use that infringes one or more claims of the '528 patent, and Sandoz's Proposed Product lacks a substantial non-infringing use.

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

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

326. 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 XXVIII: Infringement of the '098 Patent by Sandoz

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

328. Sandoz's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Sandoz'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.

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

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

331. Unless enjoined by this Court, upon FDA approval of Sandoz's ANDA, Sandoz 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 Sandoz's

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

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

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

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

335. 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 XXIX: Infringement of the '203 Patent by Sandoz

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

337. Sandoz's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Sandoz'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.

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

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

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

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

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

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

344. 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 XXX: Infringement of the '204 Patent by Sandoz

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

346. Sandoz's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Sandoz'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.

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

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

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

350. Unless enjoined by this Court, upon FDA approval of Sandoz's ANDA, Sandoz 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 Sandoz's Proposed Product in the United States. On information and belief, Sandoz knew and knows

that Sandoz's Proposed Product is designed for a use that infringes one or more claims of the '204 patent, and Sandoz's Proposed Product lacks a substantial non-infringing use.

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

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

353. 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 XXXI: Infringement of the '598 Patent by Unichem

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

355. Unichem's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Unichem'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.

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

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

358. Unless enjoined by this Court, upon FDA approval of Unichem's ANDA, Unichem 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

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

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

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

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

362. 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 XXXII: Infringement of the '599 Patent by Unichem

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

364. Unichem's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Unichem's Proposed Product, prior to the expiration of the '599 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

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

366. Unless enjoined by this Court, upon FDA approval of Unichem's ANDA, Unichem will infringe one or more claims of the '599 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Unichem's Proposed Product in the United States.

367. Unless enjoined by this Court, upon FDA approval of Unichem's ANDA, Unichem will induce infringement of one or more claims of the '599 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Unichem's Proposed Product in the United States. On information and belief, upon FDA approval of Unichem's ANDA, Unichem will intentionally encourage acts of direct infringement with knowledge of the '599 patent and knowledge that its acts are encouraging infringement.

368. Unless enjoined by this Court, upon FDA approval of Unichem's ANDA, Unichem will contributorily infringe one or more claims of the '599 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Unichem's Proposed Product in the United States. On information and belief, Unichem knew and knows that Unichem's Proposed Product is designed for a use that infringes one or more claims of the '599 patent, and Unichem's Proposed Product lacks a substantial non-infringing use.

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

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

371. 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 XXXIII: Infringement of the '226 Patent by Unichem

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

373. Unichem's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Unichem'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.

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

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

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

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

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

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

380. 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 XXXIV: Infringement of the '227 Patent by Unichem

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

382. Unichem's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Unichem'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.

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

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

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

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

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

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

389. 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 XXXV: Infringement of the '228 Patent by Unichem

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

391. Unichem's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Unichem'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.

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

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

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

395. Unless enjoined by this Court, upon FDA approval of Unichem's ANDA, Unichem 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

Unichem's Proposed Product in the United States. On information and belief, Unichem knew and knows that Unichem's Proposed Product is designed for a use that infringes one or more claims of the '228 patent, and Unichem's Proposed Product lacks a substantial non-infringing use.

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

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

398. 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 XXXVI: Infringement of the '528 Patent by Unichem

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

400. Unichem's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Unichem'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.

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

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

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

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

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

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

407. 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 XXXVII: Infringement of the '098 Patent by Unichem

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

409. Unichem's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Unichem'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.

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

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

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

413. Unless enjoined by this Court, upon FDA approval of Unichem's ANDA, Unichem 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 Unichem's Proposed Product in the United States. On information and belief, Unichem knew and knows that Unichem's Proposed Product is designed for a use that infringes one or more

claims of the ’098 patent, and Unichem’s Proposed Product lacks a substantial non-infringing use.

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

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

416. 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 XXXVIII: Infringement of the ’203 Patent by Unichem

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

418. Unichem’s submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Unichem’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.

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

420. Unless enjoined by this Court, upon FDA approval of Unichem’s ANDA, Unichem 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 Unichem’s Proposed Product in the United States.

421. Unless enjoined by this Court, upon FDA approval of Unichem’s ANDA, Unichem 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

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

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

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

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

425. 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 XXXIX: Infringement of the '204 Patent by Unichem

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

427. Unichem's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Unichem'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.

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

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

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

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

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

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

434. 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 AGAINST ALKEM

WHEREFORE, Plaintiff Axsome respectfully requests the following relief:

(A) A Judgment that Alkem infringed one or more claims of each of the patents-in-suit asserted against Alkem by submitting ANDA No. 218722;

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

(C) An Order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of FDA approval of ANDA No. 218722 be a date no earlier than the later of the expiration of each patent-in-suit asserted against Alkem, or any later expiration of exclusivity to which Axsome is or becomes entitled;

(D) Preliminary and permanent injunctions enjoining Alkem 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 Alkem's Proposed Product until after the expiration of each of the patents-in-suit asserted against Alkem, 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 Alkem, 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 Alkem, or from actively inducing or contributing to the infringement of any claim of the patents-in-suit asserted against Alkem, 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 Alkem'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 Alkem;

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

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

(I) A Judgment declaring that each patent-in-suit asserted against Alkem 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.

PRAYER FOR RELIEF AGAINST HIKMA

WHEREFORE, Plaintiff Axsome respectfully requests the following relief:

(A) A Judgment that Hikma infringed one or more claims of each of the patents-in-suit asserted against Hikma by submitting ANDA No. 218016;

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

(C) An Order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of FDA approval of ANDA No. 218016 be a date no earlier than the later of the expiration of each patent-in-suit asserted against Hikma, or any later expiration of exclusivity to which Axsome is or becomes entitled;

(D) Preliminary and permanent injunctions enjoining Hikma 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 Hikma's Proposed Product until after the expiration of each of the patents-in-suit asserted against Hikma, 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 Hikma, 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 Hikma, or from actively inducing or contributing to the infringement of any claim of the patents-in-suit asserted against Hikma, 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 Hikma'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 Hikma;

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

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

(I) A Judgment declaring that each patent-in-suit asserted against Hikma 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.

PRAYER FOR RELIEF AGAINST SANDOZ

WHEREFORE, Plaintiff Axsome respectfully requests the following relief:

(A) A Judgment that Sandoz infringed one or more claims of each of the patents-in-suit asserted against Sandoz by submitting ANDA No. 218610;

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

(C) An Order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of FDA approval of ANDA No. 218610 be a date no earlier than the later of the expiration of each patent-in-suit asserted against Sandoz, or any later expiration of exclusivity to which Axsome is or becomes entitled;

(D) Preliminary and permanent injunctions enjoining Sandoz 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 Sandoz's Proposed Product until after the expiration

of each of the patents-in-suit asserted against Sandoz, 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 Sandoz, 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 Sandoz, or from actively inducing or contributing to the infringement of any claim of the patents-in-suit asserted against Sandoz, 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 Sandoz'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 Sandoz;

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

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

(I) A Judgment declaring that each patent-in-suit asserted against Sandoz 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.

PRAYER FOR RELIEF AGAINST UNICHEM

WHEREFORE, Plaintiff Axsome respectfully requests the following relief:

(A) A Judgment that Unichem infringed one or more claims of each of the patents-in-suit asserted against Unichem by submitting ANDA No. 218761;

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

(C) An Order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of FDA approval of ANDA No. 218761 be a date no earlier than the later of the expiration of each patent-in-suit asserted against Unichem, or any later expiration of exclusivity to which Axsome is or becomes entitled;

(D) Preliminary and permanent injunctions enjoining Unichem 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 Unichem's Proposed Product until after the expiration of each of the patents-in-suit asserted against Unichem, 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 Unichem, 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 Unichem, or from actively inducing or contributing to the infringement of any claim of the patents-in-suit asserted against Unichem, 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 Unichem'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 Unichem;

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

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

(I) A Judgment declaring that each patent-in-suit asserted against Unichem 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: April 5, 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), *Axsome Malta Ltd., et al. v. Sandoz Inc.*, Civil Action No. 24-860 (MCA)(LDW), *Axsome Malta Ltd., et al. v. Hetero USA Inc., et al.*, Civil Action No. 24-3999 (MCA)(LDW), *Axsome Malta Ltd., et al. v. Aurobindo Pharma USA, Inc., et al.*, Civil Action No. 24-4002 (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: April 5, 2024

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