Charles M. Lizza
William C. Baton
Sarah A. Sullivan
Alexander L. Callo
SAUL EWING LLP
One Riverfront Plaza, Suite 1520
Newark, NJ 07102-5426
(973) 286-6700
clizza@saul.com

Attorneys for Plaintiffs Axsome Malta Ltd.
and Axsome Therapeutics, Inc.

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

AXSOME MALTA LTD., and AXSOME THERAPEUTICS, INC., **Plaintiffs,** **v.** **ALKEM LABORATORIES LTD., AUROBINDO PHARMA USA, INC., HETERO USA INC., HETERO LABS LIMITED UNIT-V, HETERO LABS 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"), Aurobindo Pharma USA, Inc. ("Aurobindo"), Hetero USA Inc., Hetero Labs Limited Unit-V, and Hetero Labs Ltd. (collectively, "Hetero"), Hikma Pharmaceuticals USA Inc. ("Hikma"), Sandoz Inc. ("Sandoz"), and Unichem Laboratories Ltd. ("Unichem") (Alkem,

Aurobindo, Hetero, 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"), 218725 ("Aurobindo's ANDA"), 218654 ("Hetero'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. 8,440,715 ('the '715 patent"), 8,877,806 ("the '806 patent"), 9,604,917 ("the '917 patent"), 10,351,517 ("the '517 patent"), 10,195,151 ("the '151 patent"), 10,512,609 ("the '609 patent"), 11,439,597 ("the '597 patent"), 10,912,754 ("the '754 patent"), 10,959,976 ("the '976 patent"), 11,160,779 ("the '779 patent"), 10,940,133 ("the '133 patent"), 11,560,354 ("the '354 patent"), and 11,648,232 ("the '232 patent") (collectively, "the patents-in-suit"). Axsome is the owner of or exclusive licensee for all substantial rights in 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 78 Mill Street, Zone 5, Central Business District, Qormi, CBD 5090, Malta.

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 Aurobindo is a corporation organized and existing under the laws of Delaware, having a principal place of business at 279 Princeton Hightstown Road, East Windsor, New Jersey 08520.

7. On information and belief, Defendant Hetero USA Inc. is a corporation organized and existing under the laws of Delaware, having a principal place of business at 1035 Centennial Avenue, Piscataway, NJ 08854.

8. On information and belief, Defendant Hetero Labs Limited Unit-V is a corporation organized and existing under the laws of India, having a principal place of business at Polepally, Jadcherla, Mahabubnagar – 509301, Andhra Pradesh, India.

9. On information and belief, Defendant Hetero Labs Ltd. is a corporation organized and existing under the laws of India, having a principal place of business at 7-2-A2, Hetero Corporate Industrial Estates, Sanath Nagar, Hyderabad 500 018, Andhra Pradesh, India.

10. 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.

11. 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 506 Carnegie Center, Suite 400, Princeton, New Jersey 08540.

12. 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.

13. 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

14. On May 14, 2013, the United States Patent and Trademark Office ("USPTO") duly and lawfully issued the '715 patent, entitled, "Treatment of Sleep-wake Disorders." The face of the '715 patent identifies Abdallah Ahnaou, Wilhelmus H. L. M. Drinkenburg, Joseph Palumbo, and Jonathan Sporn as the inventors. A copy of the '715 patent is attached hereto as Exhibit A.

15. On November 4, 2014, the USPTO duly and lawfully issued the '806 patent, entitled, "Treatment of Sleep-wake Disorders." The face of the '806 patent identifies Abdallah Ahnaou, Wilhelmus H. L. M. Drinkenburg, Joseph Palumbo, and Jonathan Sporn as the inventors. A copy of the '806 patent is attached hereto as Exhibit B.

16. On March 28, 2017, the USPTO duly and lawfully issued the '917 patent, entitled, "Treatment of Sleep-wake Disorders." The face of the '917 patent identifies Abdallah

Ahnaou, Wilhelmus H. L. M. Drinkenburg, Joseph Palumbo, and Jonathan Sporn as the inventors. A copy of the ’917 patent is attached hereto as Exhibit C.

17. On July 16, 2019, the USPTO duly and lawfully issued the ’517 patent, entitled, “Treatment of Sleep-wake Disorders.” The face of the ’517 patent identifies Abdallah Ahnaou, Wilhelmus H. L. M. Drinkenburg, Joseph Palumbo, and Jonathan Sporn as the inventors. A copy of the ’517 patent is attached hereto as Exhibit D.

18. On February 5, 2019, the USPTO duly and lawfully issued the ’151 patent, entitled, “Formulations of (R)-2-amino-3-phenylpropyl carbamate.” The face of the ’151 patent identifies Clark Patrick Allphin and Edwin Gerard Walsh as the inventors. A copy of the ’151 patent is attached hereto as Exhibit E.

19. On December 24, 2019, the USPTO duly and lawfully issued the ’609 patent, entitled, “Formulations of (R)-2-amino-3-phenylpropyl carbamate.” The face of the ’609 patent identifies Clark Patrick Allphin and Edwin Gerard Walsh as the inventors. A copy of the ’609 patent is attached hereto as Exhibit F.

20. On September 13, 2022, the USPTO duly and lawfully issued the ’597 patent, entitled, “Formulations of (R)-2-amino-3-phenylpropyl carbamate.” The face of the ’597 patent identifies Clark Patrick Allphin and Edwin Gerard Walsh as the inventors. A copy of the ’597 patent is attached hereto as Exhibit G.

21. On February 9, 2021, the USPTO duly and lawfully issued the ’754 patent, entitled, “Methods and Compositions for Treating Excessive Sleepiness.” The face of the ’754 patent identifies Lawrence Patrick Carter, Yuan Lu, and Katayoun Zomorodi as the inventors. A copy of the ’754 patent is attached hereto as Exhibit H.

22. On March 30, 2021, the USPTO duly and lawfully issued the ’976 patent, entitled, “Methods and Compositions for Treating Excessive Sleepiness.” The face of the ’976 patent identifies Lawrence Patrick Carter, Yuan Lu, and Katayoun Zomorodi as the inventors. A copy of the ’976 patent is attached hereto as Exhibit I.

23. On November 2, 2021, the USPTO duly and lawfully issued the ’779 patent, entitled, “Methods of Providing Solriamfetol Therapy to Subjects with Impaired Renal Function.” The face of the ’779 patent identifies Katayoun Zomorodi as the inventor. A copy of the ’779 patent is attached hereto as Exhibit J.

24. On March 9, 2021, the USPTO duly and lawfully issued the ’133 patent, entitled, “Methods of Providing Solriamfetol Therapy to Subjects with Impaired Renal Function.” The face of the ’133 patent identifies Katayoun Zomorodi as the inventor. A copy of the ’133 patent is attached hereto as Exhibit K.

25. On January 24, 2023, the USPTO duly and lawfully issued the ’354 patent, entitled, “Compositions comprising (R)-2-amino-3-phenylpropyl carbamate and uses thereof.” The face of the ’354 patent identifies Fionn Hurley as the inventor. A copy of the ’354 patent is attached hereto as Exhibit L.

26. On May 16, 2023, the USPTO duly and lawfully issued the ’232 patent, entitled, “Methods and Compositions for Treating Excessive Sleepiness.” The face of the ’232 patent identifies Lawrence Patrick Carter, Yuan Lu, and Katayoun Zomorodi as the inventors. A copy of the ’232 patent is attached hereto as Exhibit M.

The Sunosi® Drug Product

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

trade name Sunosi®. Sunosi® is a DNRI indicated to improve wakefulness in adult patients with excessive daytime sleepiness associated with narcolepsy or obstructive sleep apnea. The claims of the patents-in-suit cover, *inter alia*, solriamfetol pharmaceutical compositions and methods of using Sunosi® to improve wakefulness in adult patients with excessive daytime sleepiness associated with narcolepsy or obstructive sleep apnea.

28. 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

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

30. 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.

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

32. 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.

33. 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").

34. 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.

35. 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.

36. 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.

37. 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: Aurobindo

38. This Court has jurisdiction over the subject matter of Counts XI through XVIII against Aurobindo pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

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

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

41. On information and belief, Aurobindo is in the business of, among other things, manufacturing, marketing, importing, offering for sale, and selling pharmaceutical products, including generic drug products, throughout the United States, including in this Judicial District.

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

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

44. On information and belief, Aurobindo is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business ID No. 0100921223.

45. Aurobindo has consented to personal jurisdiction in this Court in numerous recent actions arising out of its ANDA submissions and has filed counterclaims in such cases. *See, e.g.*, *Forest Labs., LLC, et al* v. *Aurobindo Pharma USA, Inc., et al*, Civil Action No. 2:17-cv-11679 (D.N.J. filed Nov. 15, 2017); *Boehringer Ingelheim Pharma., Inc., et al* v. *Aurobindo Pharma USA, Inc., et al*, Civil Action No. 3:17-cv-07887 (D.N.J. filed Nov. 27, 2017); *Mitsubishi Tanabe Pharma Corp., et al* v. *Aurobindo Pharma USA, Inc., et al*, Civil Action No. 3:17-cv-05005

(D.N.J. filed July 7, 2017). Aurobindo has purposefully availed itself of the rights, benefits, and privileges of New Jersey by asserting counterclaims in this Court.

46. For at least the reasons set forth above in Paragraphs 40-45, venue is proper in this Judicial District with respect to Aurobindo pursuant to 28 U.S.C. § 1391(c)(3) and 28 U.S.C. § 1400(b).

Jurisdiction and Venue: Hetero

47. This Court has jurisdiction over the subject matter of Counts XIX through XXVIII against Hetero pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

48. As set forth below, the Court has personal jurisdiction over each of Hetero USA Inc., Hetero Labs Limited Unit-V, and Hetero Labs Ltd. by virtue of, *inter alia*, their systematic and continuous contacts with the State of New Jersey.

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

50. On information and belief, Hetero is in the business of, among other things, manufacturing, marketing, importing, offering for sale, and selling pharmaceutical products, including generic drug products, throughout the United States, including in this Judicial District.

51. On information and belief, this Judicial District will be a destination for the generic version of Axsome's solriamfetol oral tablets drug products for which Hetero seeks FDA approval to manufacture, market, import, offer for sale, and/or sell pursuant to ANDA No. 218654 ("Hetero's Proposed Product").

52. This Court has personal jurisdiction over Hetero Labs Ltd. because, *inter alia*, it: (1) has purposefully availed itself of the privilege of doing business in the State of New Jersey, including directly or indirectly through its subsidiary, agent, and/or alter ego, Hetero USA Inc., a company with a regular and established physical place of business in New Jersey; and (2)

maintains extensive and systematic contacts with the State of New Jersey, including through the marketing, distribution, and/or sale of generic pharmaceutical drugs in New Jersey including through, directly or indirectly, Hetero USA Inc.

53. This Court has personal jurisdiction over Hetero Labs Limited Unit-V because, *inter alia*, it: (1) has purposefully availed itself of the privilege of doing business in the State of New Jersey, including directly or indirectly through its subsidiary, agent, and/or alter ego, Hetero USA Inc., a company with a regular and established physical place of business in New Jersey; and (2) maintains extensive and systematic contacts with the State of New Jersey, including through the marketing, distribution, and/or sale of generic pharmaceutical drugs in New Jersey including through, directly or indirectly, Hetero USA Inc.

54. This Court has personal jurisdiction over Hetero USA Inc. because, *inter alia*, on information and belief, Hetero USA Inc. maintains a regular and established, physical place of business at 1035 Centennial Avenue, Piscataway, NJ 08854.

55. On information and belief, Hetero USA Inc. is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business ID No. 0400362826.

56. On information and belief, Hetero USA Inc. will work in concert with Hetero Labs Limited Unit-V and/or Hetero Labs Ltd. toward the regulatory approval, manufacturing, use, importation, marketing, offer for sale, sale, and distribution of generic pharmaceutical products, including Hetero's Proposed Product, throughout the United States, including in New Jersey and in this Judicial District, prior to the expiration of the patents-in-suit.

57. Hetero has consented to personal jurisdiction in this Court in recent actions arising out of its ANDA submissions and has filed counterclaims in such cases. *See, e.g.,*

Celgene Corporation v. Annora Pharma Private Limited, et al., C.A. No. 3-18-cv-11220 (D.N.J.) (Hetero USA Inc.); *Celgene Corporation v. Hetero Labs Limited, et al.,* Civil Action No. 2-19-cv-15449 (SDW)(LDW) (D.N.J.) (Hetero USA Inc., Hetero Labs Ltd., Hetero Labs Ltd. Unit-V); *Celgene Corporation v. Hetero Labs Limited, et al.,* Civil Action No. 2-19-cv-05797 (ES)(MAH) (D.N.J.) (Hetero USA Inc., Hetero Labs Ltd., Hetero Labs Ltd. Unit-V); *Celgene Corporation v. Hetero Labs Limited, et al.,* Civil Action No. 2-18-cv-17463 (SDW)(LDW) (D.N.J.) (Hetero USA Inc., Hetero Labs Ltd., Hetero Labs Ltd. Unit-V); *Celgene Corporation v. Hetero Labs Limited, et al.,* Civil Action No. 2-18-cv-14111 (ES)(MAH) (D.N.J.) (Hetero USA Inc., Hetero Labs Ltd., Hetero Labs Ltd. Unit-V); *Celgene Corporation v. Hetero Labs Limited, et al.,* Civil Action No. 2-17-cv-03387 (ES)(MAH) (D.N.J.) (Hetero USA Inc., Hetero Labs Ltd., Hetero Labs Ltd. Unit-V); *Otsuka Pharm. Co., Ltd. v. Hetero Drugs Ltd., et al.,* Civil Action No. 1-15-cv-00161 (JBS)(KMW) (D.N.J.) (Hetero USA Inc., Hetero Labs Ltd.); *AstraZeneca AB, et al. v. Hetero USA Inc., et al.,* Civil Action No. 1-16-cv-02442 (RMB)(JS) (D.N.J.) (Hetero USA Inc., Hetero Labs Ltd.); and *BTG Int'l Ltd., et al. v. Actavis Labs. FL, Inc., et al.,* Civil Action No. 2-15-cv-05909 (KM)(JBC) (D.N.J.) (Hetero USA Inc., Hetero Labs Ltd., Hetero Labs Ltd. Unit-V). Hetero has purposefully availed itself of the rights, benefits, and privileges of New Jersey by asserting counterclaims in this Court.

58. In the alternative, this Court has personal jurisdiction over Hetero Labs Ltd. because the requirements of Federal Rule of Civil Procedure 4(k)(2) are met as (a) Axsome's claims arise under federal law; (b) Hetero Labs Ltd. is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Hetero Labs Ltd. has sufficient contacts with the United States as a whole, including, but not limited to, preparing and submitting ANDAs to the FDA and/or manufacturing, importing, offering to sell, or selling pharmaceutical

products that are distributed throughout the United States, such that this Court's exercise of jurisdiction over Hetero Labs Ltd. satisfies due process.

59. In the alternative, this Court has personal jurisdiction over Hetero Labs Limited Unit-V because the requirements of Federal Rule of Civil Procedure 4(k)(2) are met as (a) Axsome's claims arise under federal law; (b) Hetero Labs Limited Unit-V is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Hetero Labs Limited Unit-V has sufficient contacts with the United States as a whole, including, but not limited to, preparing and submitting ANDAs to the FDA and/or manufacturing, importing, offering to sell, or selling pharmaceutical products that are distributed throughout the United States, such that this Court's exercise of jurisdiction over Hetero Labs Limited Unit-V satisfies due process.

60. At least because, on information and belief, Hetero Labs Ltd. and Hetero Labs Limited Unit-V are foreign companies, venue is proper in this Judicial District with respect to Hetero Labs Ltd. and Hetero Labs Limited Unit-V pursuant to 28 U.S.C. § 1391(c)(3) and 28 U.S.C. § 1400(b). Also, for at least the reasons set forth above in Paragraphs 49-57, venue is proper in this Judicial District as to Hetero USA Inc. pursuant to 28 U.S.C. § 1391(c)(3) and 28 U.S.C. § 1400(b).

Jurisdiction and Venue: Hikma

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

62. 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.

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

64. 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.

65. 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").

66. 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.

67. 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.

68. 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.

69. For at least the reasons set forth above in Paragraphs 63-68, 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

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

71. 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.

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

73. 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.

74. 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").

75. 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 506 Carnegie Center, Suite 400, Princeton, New Jersey 08540.

76. 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.

77. 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 Neuroscience, Inc. v. Sandoz Inc., et al.,* Civil Action No. 17-275 (FLW)(DEA) (D.N.J.); *Amgen, Inc. v. Sandoz Inc.,* Civil Action No. 18-11026 (MAS)(DEA) (D.N.J.); *Immunex Corp. v. Sandoz Inc.,* 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.

78. For at least the reasons set forth above in Paragraphs 72-78, 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

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

80. 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.

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

82. 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.

83. 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").

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

85. 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.

86. 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-X Against Alkem

87. 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 certain patents-in-suit expire.

88. 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®.

89. Alkem's Notice Letter alleges that the claims of certain patents-in-suit are invalid and/or will not be infringed by the activities described in Alkem's ANDA.

90. On information and belief, in connection with the submission 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) ("Alkem's Paragraph IV Certification"), alleging that the claims of the '715 patent, the '151 patent, the '609 patent, the '597 patent, the '754 patent, the '976 patent, the '779 patent, the '133 patent, the '354 patent, and the '232 patent are invalid and/or will not be infringed by the activities described in Alkem's ANDA.

91. 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 XI-XVIII Against Aurobindo

92. Pursuant to Section 505 of the FFDCA, Aurobindo submitted ANDA No. 218725 seeking approval to engage in the commercial manufacture, use, sale, offer for sale, or importation of Aurobindo's Proposed Product, before certain patents-in-suit expire.

93. No earlier than August 10, 2023, Aurobindo sent written notice of a Paragraph IV Certification ("Aurobindo's Notice Letter") to Axsome. According to Aurobindo's Notice Letter, Aurobindo 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 Aurobindo's Proposed Product before expiration of certain patents listed in the Orange Book with respect to Sunosi®.

94. Aurobindo's Notice Letter alleges that the claims of certain patents-in-suit are invalid and/or will not be infringed by the activities described in Aurobindo's ANDA.

95. On information and belief, in connection with the submission of its ANDA as described above, Aurobindo provided a written certification to the FDA, as called for by Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Aurobindo's Paragraph IV Certification"), alleging that the claims of the '715 patent, the '151 patent, the '609 patent, the '597 patent, the '976 patent, the '779 patent, the '354 patent, and the '232 patent are invalid and/or will not be infringed by the activities described in Aurobindo's ANDA.

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

Acts Giving Rise To Counts XIX-XXVIII Against Hetero

97. Pursuant to Section 505 of the FFDCA, Hetero submitted ANDA No. 218654 seeking approval to engage in the commercial manufacture, use, sale, offer for sale, or importation of Hetero's Proposed Product, before certain patents-in-suit expire.

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

99. Hetero's Notice Letter alleges that the claims of certain patents-in-suit are invalid, unenforceable, and/or will not be infringed by the activities described in Hetero's ANDA.

100. On information and belief, in connection with the submission of its ANDA as described above, Hetero 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) ("Hetero's Paragraph IV Certification"), alleging that the claims of the '715 patent, the '151 patent, the '609 patent, the '597 patent, the '754 patent, the '976 patent, the '779 patent, the '133 patent, the '354 patent, and the '232 patent are invalid, unenforceable, and/or will not be infringed by the activities described in Hetero's ANDA.

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

Acts Giving Rise To Counts XXIX-XXXVIII Against Hikma

102. 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 certain patents-in-suit expire.

103. No earlier than August 1, 2023, Hikma sent written notice of a Paragraph IV Certification ("Hikma's Notice Letter") to Axsome. According to Hikma's 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®.

104. Hikma's Notice Letter alleges that the claims of certain patents-in-suit are invalid, unenforceable, and/or will not be infringed by the activities described in Hikma's ANDA.

105. On information and belief, in connection with the submission 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) ("Hikma's Paragraph IV Certification"), alleging that the claims of the '715 patent, the '151 patent, the '609 patent, the '597 patent, the '754 patent, the '976 patent, the '779 patent, the '133 patent, the '354 patent, and the '232 patent are invalid, unenforceable, and/or will not be infringed by the activities described in Hikma's ANDA.

106. 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 XXXIX-XLVIII Against Sandoz

107. 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 certain patents-in-suit expire.

108. No earlier than August 15, 2023, Sandoz sent written notice of a Paragraph IV Certification ("Sandoz's Notice Letter") to Axsome. According to Sandoz's 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®.

109. Sandoz's Notice Letter alleges that the claims of certain patents-in-suit are invalid and/or will not be infringed by the activities described in Sandoz's ANDA.

110. On information and belief, in connection with the submission 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) ("Sandoz's Paragraph IV Certification"), alleging that the claims of the '715 patent, the '151 patent, the '609 patent, the '597 patent, the '754 patent, the '976 patent, the '779 patent, the '133 patent, the '354 patent, and the '232 patent are invalid and/or will not be infringed by the activities described in Sandoz's ANDA.

111. 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 XLIX-LXI Against Unichem

112. 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.

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

114. Unichem's Notice Letter alleges that the claims of the patents-in-suit are invalid and/or will not be infringed by the activities described in Unichem's ANDA.

115. On information and belief, in connection with the submission 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) ("Unichem's Paragraph IV Certification"), alleging that the claims of the '715 patent, the '151 patent, the '609 patent, the '597 patent, the '754 patent, the '976 patent, the '779 patent, the '133 patent, the '354 patent, the '232 patent, the

’806 patent, the ’917 patent, and the ’517 patent are invalid and/or will not be infringed by the activities described in Unichem’s ANDA.

116. 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 ’715 Patent by Alkem

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

118. 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 ’715 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.

119. A justiciable controversy exists between Axsome and Alkem as to the infringement of the ’715 patent.

120. Unless enjoined by this Court, upon FDA approval of Alkem’s ANDA, Alkem will infringe one or more claims of the ’715 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.

121. Unless enjoined by this Court, upon FDA approval of Alkem’s ANDA, Alkem will induce infringement of one or more claims of the ’715 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 '715 patent and knowledge that its acts are encouraging infringement.

122. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem will contributorily infringe one or more claims of the '715 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 '715 patent, and Alkem's Proposed Product lacks a substantial non-infringing use.

123. Failure to enjoin Alkem's infringement of the '715 patent will substantially and irreparably damage and harm Axsome.

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

125. 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 '151 Patent by Alkem

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

127. 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 '151 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.

128. A justiciable controversy exists between Axsome and Alkem as to the infringement of the '151 patent.

129. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem will infringe one or more claims of the '151 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.

130. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem will induce infringement of one or more claims of the '151 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 '151 patent and knowledge that its acts are encouraging infringement.

131. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem will contributorily infringe one or more claims of the '151 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 '151 patent, and Alkem's Proposed Product lacks a substantial non-infringing use.

132. Failure to enjoin Alkem's infringement of the '151 patent will substantially and irreparably damage and harm Axsome.

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

134. 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 ’609 Patent by Alkem

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

136. 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 ’609 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

137. A justiciable controversy exists between Axsome and Alkem as to the infringement of the ’609 patent.

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

139. Unless enjoined by this Court, upon FDA approval of Alkem’s ANDA, Alkem will induce infringement of one or more claims of the ’609 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing 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 ’609 patent and knowledge that its acts are encouraging infringement.

140. Unless enjoined by this Court, upon FDA approval of Alkem’s ANDA, Alkem will contributorily infringe one or more claims of the ’609 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing 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 '609 patent, and Alkem's Proposed Product lacks a substantial non-infringing use.

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

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

143. 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 '597 Patent by Alkem

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

145. 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 '597 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.

146. A justiciable controversy exists between Axsome and Alkem as to the infringement of the '597 patent.

147. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem will infringe one or more claims of the '597 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.

148. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem will induce infringement of one or more claims of the '597 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 '597 patent and knowledge that its acts are encouraging infringement.

149. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem will contributorily infringe one or more claims of the '597 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 '597 patent, and Alkem's Proposed Product lacks a substantial non-infringing use.

150. Failure to enjoin Alkem's infringement of the '597 patent will substantially and irreparably damage and harm Axsome.

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

152. 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 '754 Patent by Alkem

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

154. 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 '754 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.

155. A justiciable controversy exists between Axsome and Alkem as to the infringement of the '754 patent.

156. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem will infringe one or more claims of the '754 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.

157. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem will induce infringement of one or more claims of the '754 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 '754 patent and knowledge that its acts are encouraging infringement.

158. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem will contributorily infringe one or more claims of the '754 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 '754 patent, and Alkem's Proposed Product lacks a substantial non-infringing use.

159. Failure to enjoin Alkem's infringement of the '754 patent will substantially and irreparably damage and harm Axsome.

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

161. 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 ’976 Patent by Alkem

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

163. 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 ’976 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.

164. A justiciable controversy exists between Axsome and Alkem as to the infringement of the ’976 patent.

165. Unless enjoined by this Court, upon FDA approval of Alkem’s ANDA, Alkem will infringe one or more claims of the ’976 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.

166. Unless enjoined by this Court, upon FDA approval of Alkem’s ANDA, Alkem will induce infringement of one or more claims of the ’976 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 ’976 patent and knowledge that its acts are encouraging infringement.

167. Unless enjoined by this Court, upon FDA approval of Alkem’s ANDA, Alkem will contributorily infringe one or more claims of the ’976 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 '976 patent, and Alkem's Proposed Product lacks a substantial non-infringing use.

168. Failure to enjoin Alkem's infringement of the '976 patent will substantially and irreparably damage and harm Axsome.

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

170. 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 '779 Patent by Alkem

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

172. 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 '779 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.

173. A justiciable controversy exists between Axsome and Alkem as to the infringement of the '779 patent.

174. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem will infringe one or more claims of the '779 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.

175. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem will induce infringement of one or more claims of the '779 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 '779 patent and knowledge that its acts are encouraging infringement.

176. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem will contributorily infringe one or more claims of the '779 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 '779 patent, and Alkem's Proposed Product lacks a substantial non-infringing use.

177. Failure to enjoin Alkem's infringement of the '779 patent will substantially and irreparably damage and harm Axsome.

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

179. 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 '133 Patent by Alkem

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

181. 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 '133 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.

182. A justiciable controversy exists between Axsome and Alkem as to the infringement of the '133 patent.

183. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem will infringe one or more claims of the '133 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.

184. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem will induce infringement of one or more claims of the '133 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 '133 patent and knowledge that its acts are encouraging infringement.

185. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem will contributorily infringe one or more claims of the '133 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 '133 patent, and Alkem's Proposed Product lacks a substantial non-infringing use.

186. Failure to enjoin Alkem's infringement of the '133 patent will substantially and irreparably damage and harm Axsome.

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

188. 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 ’354 Patent by Alkem

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

190. 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 ’354 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.

191. A justiciable controversy exists between Axsome and Alkem as to the infringement of the ’354 patent.

192. Unless enjoined by this Court, upon FDA approval of Alkem’s ANDA, Alkem will infringe one or more claims of the ’354 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.

193. Unless enjoined by this Court, upon FDA approval of Alkem’s ANDA, Alkem will induce infringement of one or more claims of the ’354 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 ’354 patent and knowledge that its acts are encouraging infringement.

194. Unless enjoined by this Court, upon FDA approval of Alkem’s ANDA, Alkem will contributorily infringe one or more claims of the ’354 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 '354 patent, and Alkem's Proposed Product lacks a substantial non-infringing use.

195. Failure to enjoin Alkem's infringement of the '354 patent will substantially and irreparably damage and harm Axsome.

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

197. 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 '232 Patent by Alkem

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

199. 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 '232 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.

200. A justiciable controversy exists between Axsome and Alkem as to the infringement of the '232 patent.

201. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem will infringe one or more claims of the '232 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.

202. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem will induce infringement of one or more claims of the '232 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 '232 patent and knowledge that its acts are encouraging infringement.

203. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem will contributorily infringe one or more claims of the '232 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 '232 patent, and Alkem's Proposed Product lacks a substantial non-infringing use.

204. Failure to enjoin Alkem's infringement of the '232 patent will substantially and irreparably damage and harm Axsome.

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

206. 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 '715 Patent by Aurobindo

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

208. Aurobindo's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Aurobindo's Proposed Product, prior to the expiration of the '715 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.

209. A justiciable controversy exists between Axsome and Aurobindo as to the infringement of the '715 patent.

210. Unless enjoined by this Court, upon FDA approval of Aurobindo's ANDA, Aurobindo will infringe one or more claims of the '715 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Aurobindo's Proposed Product in the United States.

211. Unless enjoined by this Court, upon FDA approval of Aurobindo's ANDA, Aurobindo will induce infringement of one or more claims of the '715 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Aurobindo's Proposed Product in the United States. On information and belief, upon FDA approval of Aurobindo's ANDA, Aurobindo will intentionally encourage acts of direct infringement with knowledge of the '715 patent and knowledge that its acts are encouraging infringement.

212. Unless enjoined by this Court, upon FDA approval of Aurobindo's ANDA, Aurobindo will contributorily infringe one or more claims of the '715 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Aurobindo's Proposed Product in the United States. On information and belief, Aurobindo knew and knows that Aurobindo's Proposed Product is designed for a use that infringes one or more claims of the '715 patent, and Aurobindo's Proposed Product lacks a substantial non-infringing use.

213. Failure to enjoin Aurobindo's infringement of the '715 patent will substantially and irreparably damage and harm Axsome.

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

215. 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 ’151 Patent by Aurobindo

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

217. Aurobindo’s submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Aurobindo’s Proposed Product, prior to the expiration of the ’151 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.

218. A justiciable controversy exists between Axsome and Aurobindo as to the infringement of the ’151 patent.

219. Unless enjoined by this Court, upon FDA approval of Aurobindo’s ANDA, Aurobindo will infringe one or more claims of the ’151 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Aurobindo’s Proposed Product in the United States.

220. Unless enjoined by this Court, upon FDA approval of Aurobindo’s ANDA, Aurobindo will induce infringement of one or more claims of the ’151 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Aurobindo’s Proposed Product in the United States. On information and belief, upon FDA approval of Aurobindo’s ANDA, Aurobindo will intentionally encourage acts of direct infringement with knowledge of the ’151 patent and knowledge that its acts are encouraging infringement.

221. Unless enjoined by this Court, upon FDA approval of Aurobindo’s ANDA, Aurobindo will contributorily infringe one or more claims of the ’151 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing

Aurobindo's Proposed Product in the United States. On information and belief, Aurobindo knew and knows that Aurobindo's Proposed Product is designed for a use that infringes one or more claims of the '151 patent, and Aurobindo's Proposed Product lacks a substantial non-infringing use.

222. Failure to enjoin Aurobindo's infringement of the '151 patent will substantially and irreparably damage and harm Axsome.

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

224. 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 '609 Patent by Aurobindo

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

226. Aurobindo's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Aurobindo's Proposed Product, prior to the expiration of the '609 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

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

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

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

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

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

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

233. 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 '597 Patent by Aurobindo

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

235. Aurobindo's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Aurobindo's Proposed Product, prior to the expiration of the '597 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.

236. A justiciable controversy exists between Axsome and Aurobindo as to the infringement of the '597 patent.

237. Unless enjoined by this Court, upon FDA approval of Aurobindo's ANDA, Aurobindo will infringe one or more claims of the '597 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Aurobindo's Proposed Product in the United States.

238. Unless enjoined by this Court, upon FDA approval of Aurobindo's ANDA, Aurobindo will induce infringement of one or more claims of the '597 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Aurobindo's Proposed Product in the United States. On information and belief, upon FDA approval of Aurobindo's ANDA, Aurobindo will intentionally encourage acts of direct infringement with knowledge of the '597 patent and knowledge that its acts are encouraging infringement.

239. Unless enjoined by this Court, upon FDA approval of Aurobindo's ANDA, Aurobindo will contributorily infringe one or more claims of the '597 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Aurobindo's Proposed Product in the United States. On information and belief, Aurobindo knew and knows that Aurobindo's Proposed Product is designed for a use that infringes one or more

claims of the ’597 patent, and Aurobindo’s Proposed Product lacks a substantial non-infringing use.

240. Failure to enjoin Aurobindo’s infringement of the ’597 patent will substantially and irreparably damage and harm Axsome.

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

242. 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 ’976 Patent by Aurobindo

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

244. Aurobindo’s submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Aurobindo’s Proposed Product, prior to the expiration of the ’976 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.

245. A justiciable controversy exists between Axsome and Aurobindo as to the infringement of the ’976 patent.

246. Unless enjoined by this Court, upon FDA approval of Aurobindo’s ANDA, Aurobindo will infringe one or more claims of the ’976 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Aurobindo’s Proposed Product in the United States.

247. Unless enjoined by this Court, upon FDA approval of Aurobindo’s ANDA, Aurobindo will induce infringement of one or more claims of the ’976 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing

Aurobindo's Proposed Product in the United States. On information and belief, upon FDA approval of Aurobindo's ANDA, Aurobindo will intentionally encourage acts of direct infringement with knowledge of the '976 patent and knowledge that its acts are encouraging infringement.

248. Unless enjoined by this Court, upon FDA approval of Aurobindo's ANDA, Aurobindo will contributorily infringe one or more claims of the '976 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Aurobindo's Proposed Product in the United States. On information and belief, Aurobindo knew and knows that Aurobindo's Proposed Product is designed for a use that infringes one or more claims of the '976 patent, and Aurobindo's Proposed Product lacks a substantial non-infringing use.

249. Failure to enjoin Aurobindo's infringement of the '976 patent will substantially and irreparably damage and harm Axsome.

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

251. 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 '779 Patent by Aurobindo

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

253. Aurobindo's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Aurobindo's Proposed Product, prior to the expiration of the '779 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.

254. A justiciable controversy exists between Axsome and Aurobindo as to the infringement of the ’779 patent.

255. Unless enjoined by this Court, upon FDA approval of Aurobindo’s ANDA, Aurobindo will infringe one or more claims of the ’779 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Aurobindo’s Proposed Product in the United States.

256. Unless enjoined by this Court, upon FDA approval of Aurobindo’s ANDA, Aurobindo will induce infringement of one or more claims of the ’779 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Aurobindo’s Proposed Product in the United States. On information and belief, upon FDA approval of Aurobindo’s ANDA, Aurobindo will intentionally encourage acts of direct infringement with knowledge of the ’779 patent and knowledge that its acts are encouraging infringement.

257. Unless enjoined by this Court, upon FDA approval of Aurobindo’s ANDA, Aurobindo will contributorily infringe one or more claims of the ’779 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Aurobindo’s Proposed Product in the United States. On information and belief, Aurobindo knew and knows that Aurobindo’s Proposed Product is designed for a use that infringes one or more claims of the ’779 patent, and Aurobindo’s Proposed Product lacks a substantial non-infringing use.

258. Failure to enjoin Aurobindo’s infringement of the ’779 patent will substantially and irreparably damage and harm Axsome.

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

260. 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 '354 Patent by Aurobindo

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

262. Aurobindo's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Aurobindo's Proposed Product, prior to the expiration of the '354 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.

263. A justiciable controversy exists between Axsome and Aurobindo as to the infringement of the '354 patent.

264. Unless enjoined by this Court, upon FDA approval of Aurobindo's ANDA, Aurobindo will infringe one or more claims of the '354 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Aurobindo's Proposed Product in the United States.

265. Unless enjoined by this Court, upon FDA approval of Aurobindo's ANDA, Aurobindo will induce infringement of one or more claims of the '354 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Aurobindo's Proposed Product in the United States. On information and belief, upon FDA approval of Aurobindo's ANDA, Aurobindo will intentionally encourage acts of direct infringement with knowledge of the '354 patent and knowledge that its acts are encouraging infringement.

266. Unless enjoined by this Court, upon FDA approval of Aurobindo's ANDA, Aurobindo will contributorily infringe one or more claims of the '354 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Aurobindo's Proposed Product in the United States. On information and belief, Aurobindo knew and knows that Aurobindo's Proposed Product is designed for a use that infringes one or more claims of the '354 patent, and Aurobindo's Proposed Product lacks a substantial non-infringing use.

267. Failure to enjoin Aurobindo's infringement of the '354 patent will substantially and irreparably damage and harm Axsome.

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

269. 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 '232 Patent by Aurobindo

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

271. Aurobindo's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Aurobindo's Proposed Product, prior to the expiration of the '232 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.

272. A justiciable controversy exists between Axsome and Aurobindo as to the infringement of the '232 patent.

273. Unless enjoined by this Court, upon FDA approval of Aurobindo's ANDA, Aurobindo will infringe one or more claims of the '232 patent under 35 U.S.C. § 271(a),

including at least claim 1, by making, using, offering to sell, selling, and/or importing Aurobindo's Proposed Product in the United States.

274. Unless enjoined by this Court, upon FDA approval of Aurobindo's ANDA, Aurobindo will induce infringement of one or more claims of the '232 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Aurobindo's Proposed Product in the United States. On information and belief, upon FDA approval of Aurobindo's ANDA, Aurobindo will intentionally encourage acts of direct infringement with knowledge of the '232 patent and knowledge that its acts are encouraging infringement.

275. Unless enjoined by this Court, upon FDA approval of Aurobindo's ANDA, Aurobindo will contributorily infringe one or more claims of the '232 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Aurobindo's Proposed Product in the United States. On information and belief, Aurobindo knew and knows that Aurobindo's Proposed Product is designed for a use that infringes one or more claims of the '232 patent, and Aurobindo's Proposed Product lacks a substantial non-infringing use.

276. Failure to enjoin Aurobindo's infringement of the '232 patent will substantially and irreparably damage and harm Axsome.

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

278. 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 ’715 Patent by Hetero

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

280. Hetero’s submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Hetero’s Proposed Product, prior to the expiration of the ’715 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.

281. A justiciable controversy exists between Axsome and Hetero as to the infringement of the ’715 patent.

282. Unless enjoined by this Court, upon FDA approval of Hetero’s ANDA, Hetero will infringe one or more claims of the ’715 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Hetero’s Proposed Product in the United States.

283. Unless enjoined by this Court, upon FDA approval of Hetero’s ANDA, Hetero will induce infringement of one or more claims of the ’715 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Hetero’s Proposed Product in the United States. On information and belief, upon FDA approval of Hetero’s ANDA, Hetero will intentionally encourage acts of direct infringement with knowledge of the ’715 patent and knowledge that its acts are encouraging infringement.

284. Unless enjoined by this Court, upon FDA approval of Hetero’s ANDA, Hetero will contributorily infringe one or more claims of the ’715 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Hetero’s Proposed Product in the United States. On information and belief, Hetero knew and knows that

Hetero's Proposed Product is designed for a use that infringes one or more claims of the '715 patent, and Hetero's Proposed Product lacks a substantial non-infringing use.

285. Failure to enjoin Hetero's infringement of the '715 patent will substantially and irreparably damage and harm Axsome.

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

287. 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 '151 Patent by Hetero

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

289. Hetero's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Hetero's Proposed Product, prior to the expiration of the '151 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.

290. A justiciable controversy exists between Axsome and Hetero as to the infringement of the '151 patent.

291. Unless enjoined by this Court, upon FDA approval of Hetero's ANDA, Hetero will infringe one or more claims of the '151 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Hetero's Proposed Product in the United States.

292. Unless enjoined by this Court, upon FDA approval of Hetero's ANDA, Hetero will induce infringement of one or more claims of the '151 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Hetero's

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

293. Unless enjoined by this Court, upon FDA approval of Hetero's ANDA, Hetero will contributorily infringe one or more claims of the '151 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Hetero's Proposed Product in the United States. On information and belief, Hetero knew and knows that Hetero's Proposed Product is designed for a use that infringes one or more claims of the '151 patent, and Hetero's Proposed Product lacks a substantial non-infringing use.

294. Failure to enjoin Hetero's infringement of the '151 patent will substantially and irreparably damage and harm Axsome.

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

296. 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 '609 Patent by Hetero

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

298. Hetero's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Hetero's Proposed Product, prior to the expiration of the '609 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

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

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

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

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

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

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

305. 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 ’597 Patent by Hetero

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

307. Hetero’s submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Hetero’s Proposed Product, prior to the expiration of the ’597 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.

308. A justiciable controversy exists between Axsome and Hetero as to the infringement of the ’597 patent.

309. Unless enjoined by this Court, upon FDA approval of Hetero’s ANDA, Hetero will infringe one or more claims of the ’597 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Hetero’s Proposed Product in the United States.

310. Unless enjoined by this Court, upon FDA approval of Hetero’s ANDA, Hetero will induce infringement of one or more claims of the ’597 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Hetero’s Proposed Product in the United States. On information and belief, upon FDA approval of Hetero’s ANDA, Hetero will intentionally encourage acts of direct infringement with knowledge of the ’597 patent and knowledge that its acts are encouraging infringement.

311. Unless enjoined by this Court, upon FDA approval of Hetero’s ANDA, Hetero will contributorily infringe one or more claims of the ’597 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Hetero’s Proposed Product in the United States. On information and belief, Hetero knew and knows that

Hetero's Proposed Product is designed for a use that infringes one or more claims of the '597 patent, and Hetero's Proposed Product lacks a substantial non-infringing use.

312. Failure to enjoin Hetero's infringement of the '597 patent will substantially and irreparably damage and harm Axsome.

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

314. 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 '754 Patent by Hetero

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

316. Hetero's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Hetero's Proposed Product, prior to the expiration of the '754 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.

317. A justiciable controversy exists between Axsome and Hetero as to the infringement of the '754 patent.

318. Unless enjoined by this Court, upon FDA approval of Hetero's ANDA, Hetero will infringe one or more claims of the '754 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Hetero's Proposed Product in the United States.

319. Unless enjoined by this Court, upon FDA approval of Hetero's ANDA, Hetero will induce infringement of one or more claims of the '754 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Hetero's

Proposed Product in the United States. On information and belief, upon FDA approval of Hetero's ANDA, Hetero will intentionally encourage acts of direct infringement with knowledge of the '754 patent and knowledge that its acts are encouraging infringement.

320. Unless enjoined by this Court, upon FDA approval of Hetero's ANDA, Hetero will contributorily infringe one or more claims of the '754 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Hetero's Proposed Product in the United States. On information and belief, Hetero knew and knows that Hetero's Proposed Product is designed for a use that infringes one or more claims of the '754 patent, and Hetero's Proposed Product lacks a substantial non-infringing use.

321. Failure to enjoin Hetero's infringement of the '754 patent will substantially and irreparably damage and harm Axsome.

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

323. 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 '976 Patent by Hetero

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

325. Hetero's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Hetero's Proposed Product, prior to the expiration of the '976 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.

326. A justiciable controversy exists between Axsome and Hetero as to the infringement of the '976 patent.

327. Unless enjoined by this Court, upon FDA approval of Hetero's ANDA, Hetero will infringe one or more claims of the '976 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Hetero's Proposed Product in the United States.

328. Unless enjoined by this Court, upon FDA approval of Hetero's ANDA, Hetero will induce infringement of one or more claims of the '976 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Hetero's Proposed Product in the United States. On information and belief, upon FDA approval of Hetero's ANDA, Hetero will intentionally encourage acts of direct infringement with knowledge of the '976 patent and knowledge that its acts are encouraging infringement.

329. Unless enjoined by this Court, upon FDA approval of Hetero's ANDA, Hetero will contributorily infringe one or more claims of the '976 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Hetero's Proposed Product in the United States. On information and belief, Hetero knew and knows that Hetero's Proposed Product is designed for a use that infringes one or more claims of the '976 patent, and Hetero's Proposed Product lacks a substantial non-infringing use.

330. Failure to enjoin Hetero's infringement of the '976 patent will substantially and irreparably damage and harm Axsome.

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

332. 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 ’779 Patent by Hetero

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

334. Hetero’s submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Hetero’s Proposed Product, prior to the expiration of the ’779 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.

335. A justiciable controversy exists between Axsome and Hetero as to the infringement of the ’779 patent.

336. Unless enjoined by this Court, upon FDA approval of Hetero’s ANDA, Hetero will infringe one or more claims of the ’779 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Hetero’s Proposed Product in the United States.

337. Unless enjoined by this Court, upon FDA approval of Hetero’s ANDA, Hetero will induce infringement of one or more claims of the ’779 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Hetero’s Proposed Product in the United States. On information and belief, upon FDA approval of Hetero’s ANDA, Hetero will intentionally encourage acts of direct infringement with knowledge of the ’779 patent and knowledge that its acts are encouraging infringement.

338. Unless enjoined by this Court, upon FDA approval of Hetero’s ANDA, Hetero will contributorily infringe one or more claims of the ’779 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Hetero’s Proposed Product in the United States. On information and belief, Hetero knew and knows that

Hetero's Proposed Product is designed for a use that infringes one or more claims of the '779 patent, and Hetero's Proposed Product lacks a substantial non-infringing use.

339. Failure to enjoin Hetero's infringement of the '779 patent will substantially and irreparably damage and harm Axsome.

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

341. 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 '133 Patent by Hetero

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

343. Hetero's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Hetero's Proposed Product, prior to the expiration of the '133 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.

344. A justiciable controversy exists between Axsome and Hetero as to the infringement of the '133 patent.

345. Unless enjoined by this Court, upon FDA approval of Hetero's ANDA, Hetero will infringe one or more claims of the '133 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Hetero's Proposed Product in the United States.

346. Unless enjoined by this Court, upon FDA approval of Hetero's ANDA, Hetero will induce infringement of one or more claims of the '133 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Hetero's

Proposed Product in the United States. On information and belief, upon FDA approval of Hetero's ANDA, Hetero will intentionally encourage acts of direct infringement with knowledge of the '133 patent and knowledge that its acts are encouraging infringement.

347. Unless enjoined by this Court, upon FDA approval of Hetero's ANDA, Hetero will contributorily infringe one or more claims of the '133 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Hetero's Proposed Product in the United States. On information and belief, Hetero knew and knows that Hetero's Proposed Product is designed for a use that infringes one or more claims of the '133 patent, and Hetero's Proposed Product lacks a substantial non-infringing use.

348. Failure to enjoin Hetero's infringement of the '133 patent will substantially and irreparably damage and harm Axsome.

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

350. 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 '354 Patent by Hetero

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

352. Hetero's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Hetero's Proposed Product, prior to the expiration of the '354 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.

353. A justiciable controversy exists between Axsome and Hetero as to the infringement of the '354 patent.

354. Unless enjoined by this Court, upon FDA approval of Hetero's ANDA, Hetero will infringe one or more claims of the '354 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Hetero's Proposed Product in the United States.

355. Unless enjoined by this Court, upon FDA approval of Hetero's ANDA, Hetero will induce infringement of one or more claims of the '354 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Hetero's Proposed Product in the United States. On information and belief, upon FDA approval of Hetero's ANDA, Hetero will intentionally encourage acts of direct infringement with knowledge of the '354 patent and knowledge that its acts are encouraging infringement.

356. Unless enjoined by this Court, upon FDA approval of Hetero's ANDA, Hetero will contributorily infringe one or more claims of the '354 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Hetero's Proposed Product in the United States. On information and belief, Hetero knew and knows that Hetero's Proposed Product is designed for a use that infringes one or more claims of the '354 patent, and Hetero's Proposed Product lacks a substantial non-infringing use.

357. Failure to enjoin Hetero's infringement of the '354 patent will substantially and irreparably damage and harm Axsome.

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

359. 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 ’232 Patent by Hetero

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

361. Hetero’s submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Hetero’s Proposed Product, prior to the expiration of the ’232 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.

362. A justiciable controversy exists between Axsome and Hetero as to the infringement of the ’232 patent.

363. Unless enjoined by this Court, upon FDA approval of Hetero’s ANDA, Hetero will infringe one or more claims of the ’232 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Hetero’s Proposed Product in the United States.

364. Unless enjoined by this Court, upon FDA approval of Hetero’s ANDA, Hetero will induce infringement of one or more claims of the ’232 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Hetero’s Proposed Product in the United States. On information and belief, upon FDA approval of Hetero’s ANDA, Hetero will intentionally encourage acts of direct infringement with knowledge of the ’232 patent and knowledge that its acts are encouraging infringement.

365. Unless enjoined by this Court, upon FDA approval of Hetero’s ANDA, Hetero will contributorily infringe one or more claims of the ’232 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Hetero’s Proposed Product in the United States. On information and belief, Hetero knew and knows that

Hetero's Proposed Product is designed for a use that infringes one or more claims of the '232 patent, and Hetero's Proposed Product lacks a substantial non-infringing use.

366. Failure to enjoin Hetero's infringement of the '232 patent will substantially and irreparably damage and harm Axsome.

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

368. 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 '715 Patent by Hikma

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

370. 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 '715 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.

371. A justiciable controversy exists between Axsome and Hikma as to the infringement of the '715 patent.

372. Unless enjoined by this Court, upon FDA approval of Hikma's ANDA, Hikma will infringe one or more claims of the '715 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.

373. Unless enjoined by this Court, upon FDA approval of Hikma's ANDA, Hikma will induce infringement of one or more claims of the '715 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 '715 patent and knowledge that its acts are encouraging infringement.

374. Unless enjoined by this Court, upon FDA approval of Hikma's ANDA, Hikma will contributorily infringe one or more claims of the '715 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 '715 patent, and Hikma's Proposed Product lacks a substantial non-infringing use.

375. Failure to enjoin Hikma's infringement of the '715 patent will substantially and irreparably damage and harm Axsome.

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

377. 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 '151 Patent by Hikma

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

379. 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 '151 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.

380. A justiciable controversy exists between Axsome and Hikma as to the infringement of the '151 patent.

381. Unless enjoined by this Court, upon FDA approval of Hikma's ANDA, Hikma will infringe one or more claims of the '151 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.

382. Unless enjoined by this Court, upon FDA approval of Hikma's ANDA, Hikma will induce infringement of one or more claims of the '151 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 '151 patent and knowledge that its acts are encouraging infringement.

383. Unless enjoined by this Court, upon FDA approval of Hikma's ANDA, Hikma will contributorily infringe one or more claims of the '151 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 '151 patent, and Hikma's Proposed Product lacks a substantial non-infringing use.

384. Failure to enjoin Hikma's infringement of the '151 patent will substantially and irreparably damage and harm Axsome.

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

386. 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 ’609 Patent by Hikma

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

388. Hikma’s submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Hikma’s Proposed Product, prior to the expiration of the ’609 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

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

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

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

392. Unless enjoined by this Court, upon FDA approval of Hikma’s ANDA, Hikma will contributorily infringe one or more claims of the ’609 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Hikma’s Proposed Product in the United States. On information and belief, Hikma knew and knows that

Hikma's Proposed Product is designed for a use that infringes one or more claims of the '609 patent, and Hikma's Proposed Product lacks a substantial non-infringing use.

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

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

395. 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 '597 Patent by Hikma

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

397. 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 '597 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.

398. A justiciable controversy exists between Axsome and Hikma as to the infringement of the '597 patent.

399. Unless enjoined by this Court, upon FDA approval of Hikma's ANDA, Hikma will infringe one or more claims of the '597 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.

400. Unless enjoined by this Court, upon FDA approval of Hikma's ANDA, Hikma will induce infringement of one or more claims of the '597 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 '597 patent and knowledge that its acts are encouraging infringement.

401. Unless enjoined by this Court, upon FDA approval of Hikma's ANDA, Hikma will contributorily infringe one or more claims of the '597 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 '597 patent, and Hikma's Proposed Product lacks a substantial non-infringing use.

402. Failure to enjoin Hikma's infringement of the '597 patent will substantially and irreparably damage and harm Axsome.

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

404. 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 '754 Patent by Hikma

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

406. 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 '754 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.

407. A justiciable controversy exists between Axsome and Hikma as to the infringement of the '754 patent.

408. Unless enjoined by this Court, upon FDA approval of Hikma's ANDA, Hikma will infringe one or more claims of the '754 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.

409. Unless enjoined by this Court, upon FDA approval of Hikma's ANDA, Hikma will induce infringement of one or more claims of the '754 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 '754 patent and knowledge that its acts are encouraging infringement.

410. Unless enjoined by this Court, upon FDA approval of Hikma's ANDA, Hikma will contributorily infringe one or more claims of the '754 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 '754 patent, and Hikma's Proposed Product lacks a substantial non-infringing use.

411. Failure to enjoin Hikma's infringement of the '754 patent will substantially and irreparably damage and harm Axsome.

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

413. 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 ’976 Patent by Hikma

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

415. 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 ’976 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.

416. A justiciable controversy exists between Axsome and Hikma as to the infringement of the ’976 patent.

417. Unless enjoined by this Court, upon FDA approval of Hikma’s ANDA, Hikma will infringe one or more claims of the ’976 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.

418. Unless enjoined by this Court, upon FDA approval of Hikma’s ANDA, Hikma will induce infringement of one or more claims of the ’976 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 ’976 patent and knowledge that its acts are encouraging infringement.

419. Unless enjoined by this Court, upon FDA approval of Hikma’s ANDA, Hikma will contributorily infringe one or more claims of the ’976 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 '976 patent, and Hikma's Proposed Product lacks a substantial non-infringing use.

420. Failure to enjoin Hikma's infringement of the '976 patent will substantially and irreparably damage and harm Axsome.

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

422. 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 '779 Patent by Hikma

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

424. 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 '779 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.

425. A justiciable controversy exists between Axsome and Hikma as to the infringement of the '779 patent.

426. Unless enjoined by this Court, upon FDA approval of Hikma's ANDA, Hikma will infringe one or more claims of the '779 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.

427. Unless enjoined by this Court, upon FDA approval of Hikma's ANDA, Hikma will induce infringement of one or more claims of the '779 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 '779 patent and knowledge that its acts are encouraging infringement.

428. Unless enjoined by this Court, upon FDA approval of Hikma's ANDA, Hikma will contributorily infringe one or more claims of the '779 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 '779 patent, and Hikma's Proposed Product lacks a substantial non-infringing use.

429. Failure to enjoin Hikma's infringement of the '779 patent will substantially and irreparably damage and harm Axsome.

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

431. 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 '133 Patent by Hikma

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

433. 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 '133 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.

434. A justiciable controversy exists between Axsome and Hikma as to the infringement of the '133 patent.

435. Unless enjoined by this Court, upon FDA approval of Hikma's ANDA, Hikma will infringe one or more claims of the '133 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.

436. Unless enjoined by this Court, upon FDA approval of Hikma's ANDA, Hikma will induce infringement of one or more claims of the '133 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 '133 patent and knowledge that its acts are encouraging infringement.

437. Unless enjoined by this Court, upon FDA approval of Hikma's ANDA, Hikma will contributorily infringe one or more claims of the '133 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 '133 patent, and Hikma's Proposed Product lacks a substantial non-infringing use.

438. Failure to enjoin Hikma's infringement of the '133 patent will substantially and irreparably damage and harm Axsome.

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

440. 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 ’354 Patent by Hikma

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

442. 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 ’354 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.

443. A justiciable controversy exists between Axsome and Hikma as to the infringement of the ’354 patent.

444. Unless enjoined by this Court, upon FDA approval of Hikma’s ANDA, Hikma will infringe one or more claims of the ’354 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.

445. Unless enjoined by this Court, upon FDA approval of Hikma’s ANDA, Hikma will induce infringement of one or more claims of the ’354 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 ’354 patent and knowledge that its acts are encouraging infringement.

446. Unless enjoined by this Court, upon FDA approval of Hikma’s ANDA, Hikma will contributorily infringe one or more claims of the ’354 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 '354 patent, and Hikma's Proposed Product lacks a substantial non-infringing use.

447. Failure to enjoin Hikma's infringement of the '354 patent will substantially and irreparably damage and harm Axsome.

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

449. 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 '232 Patent by Hikma

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

451. 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 '232 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.

452. A justiciable controversy exists between Axsome and Hikma as to the infringement of the '232 patent.

453. Unless enjoined by this Court, upon FDA approval of Hikma's ANDA, Hikma will infringe one or more claims of the '232 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.

454. Unless enjoined by this Court, upon FDA approval of Hikma's ANDA, Hikma will induce infringement of one or more claims of the '232 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 '232 patent and knowledge that its acts are encouraging infringement.

455. Unless enjoined by this Court, upon FDA approval of Hikma's ANDA, Hikma will contributorily infringe one or more claims of the '232 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 '232 patent, and Hikma's Proposed Product lacks a substantial non-infringing use.

456. Failure to enjoin Hikma's infringement of the '232 patent will substantially and irreparably damage and harm Axsome.

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

458. 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 '715 Patent by Sandoz

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

460. 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 '715 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.

461. A justiciable controversy exists between Axsome and Sandoz as to the infringement of the '715 patent.

462. Unless enjoined by this Court, upon FDA approval of Sandoz's ANDA, Sandoz will infringe one or more claims of the '715 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.

463. Unless enjoined by this Court, upon FDA approval of Sandoz's ANDA, Sandoz will induce infringement of one or more claims of the '715 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 '715 patent and knowledge that its acts are encouraging infringement.

464. Unless enjoined by this Court, upon FDA approval of Sandoz's ANDA, Sandoz will contributorily infringe one or more claims of the '715 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 '715 patent, and Sandoz's Proposed Product lacks a substantial non-infringing use.

465. Failure to enjoin Sandoz's infringement of the '715 patent will substantially and irreparably damage and harm Axsome.

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

467. 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 XL: Infringement of the ’151 Patent by Sandoz

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

469. 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 ’151 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.

470. A justiciable controversy exists between Axsome and Sandoz as to the infringement of the ’151 patent.

471. Unless enjoined by this Court, upon FDA approval of Sandoz’s ANDA, Sandoz will infringe one or more claims of the ’151 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.

472. Unless enjoined by this Court, upon FDA approval of Sandoz’s ANDA, Sandoz will induce infringement of one or more claims of the ’151 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 ’151 patent and knowledge that its acts are encouraging infringement.

473. Unless enjoined by this Court, upon FDA approval of Sandoz’s ANDA, Sandoz will contributorily infringe one or more claims of the ’151 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 '151 patent, and Sandoz's Proposed Product lacks a substantial non-infringing use.

474. Failure to enjoin Sandoz's infringement of the '151 patent will substantially and irreparably damage and harm Axsome.

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

476. 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 XLI: Infringement of the '609 Patent by Sandoz

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

478. 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 '609 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

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

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

481. Unless enjoined by this Court, upon FDA approval of Sandoz's ANDA, Sandoz will induce infringement of one or more claims of the '609 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing 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 '609 patent and knowledge that its acts are encouraging infringement.

482. Unless enjoined by this Court, upon FDA approval of Sandoz's ANDA, Sandoz will contributorily infringe one or more claims of the '609 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing 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 '609 patent, and Sandoz's Proposed Product lacks a substantial non-infringing use.

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

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

485. 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 XLII: Infringement of the '597 Patent by Sandoz

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

487. 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 '597 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.

488. A justiciable controversy exists between Axsome and Sandoz as to the infringement of the '597 patent.

489. Unless enjoined by this Court, upon FDA approval of Sandoz's ANDA, Sandoz will infringe one or more claims of the '597 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.

490. Unless enjoined by this Court, upon FDA approval of Sandoz's ANDA, Sandoz will induce infringement of one or more claims of the '597 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 '597 patent and knowledge that its acts are encouraging infringement.

491. Unless enjoined by this Court, upon FDA approval of Sandoz's ANDA, Sandoz will contributorily infringe one or more claims of the '597 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 '597 patent, and Sandoz's Proposed Product lacks a substantial non-infringing use.

492. Failure to enjoin Sandoz's infringement of the '597 patent will substantially and irreparably damage and harm Axsome.

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

494. 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 XLIII: Infringement of the ’754 Patent by Sandoz

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

496. 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 ’754 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.

497. A justiciable controversy exists between Axsome and Sandoz as to the infringement of the ’754 patent.

498. Unless enjoined by this Court, upon FDA approval of Sandoz’s ANDA, Sandoz will infringe one or more claims of the ’754 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.

499. Unless enjoined by this Court, upon FDA approval of Sandoz’s ANDA, Sandoz will induce infringement of one or more claims of the ’754 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 ’754 patent and knowledge that its acts are encouraging infringement.

500. Unless enjoined by this Court, upon FDA approval of Sandoz’s ANDA, Sandoz will contributorily infringe one or more claims of the ’754 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 '754 patent, and Sandoz's Proposed Product lacks a substantial non-infringing use.

501. Failure to enjoin Sandoz's infringement of the '754 patent will substantially and irreparably damage and harm Axsome.

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

503. 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 XLIV: Infringement of the '976 Patent by Sandoz

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

505. 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 '976 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.

506. A justiciable controversy exists between Axsome and Sandoz as to the infringement of the '976 patent.

507. Unless enjoined by this Court, upon FDA approval of Sandoz's ANDA, Sandoz will infringe one or more claims of the '976 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.

508. Unless enjoined by this Court, upon FDA approval of Sandoz's ANDA, Sandoz will induce infringement of one or more claims of the '976 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 '976 patent and knowledge that its acts are encouraging infringement.

509. Unless enjoined by this Court, upon FDA approval of Sandoz's ANDA, Sandoz will contributorily infringe one or more claims of the '976 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 '976 patent, and Sandoz's Proposed Product lacks a substantial non-infringing use.

510. Failure to enjoin Sandoz's infringement of the '976 patent will substantially and irreparably damage and harm Axsome.

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

512. 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 XLV: Infringement of the '779 Patent by Sandoz

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

514. 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 '779 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.

515. A justiciable controversy exists between Axsome and Sandoz as to the infringement of the '779 patent.

516. Unless enjoined by this Court, upon FDA approval of Sandoz's ANDA, Sandoz will infringe one or more claims of the '779 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.

517. Unless enjoined by this Court, upon FDA approval of Sandoz's ANDA, Sandoz will induce infringement of one or more claims of the '779 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 '779 patent and knowledge that its acts are encouraging infringement.

518. Unless enjoined by this Court, upon FDA approval of Sandoz's ANDA, Sandoz will contributorily infringe one or more claims of the '779 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 '779 patent, and Sandoz's Proposed Product lacks a substantial non-infringing use.

519. Failure to enjoin Sandoz's infringement of the '779 patent will substantially and irreparably damage and harm Axsome.

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

521. 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 XLVI: Infringement of the ’133 Patent by Sandoz

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

523. 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 ’133 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.

524. A justiciable controversy exists between Axsome and Sandoz as to the infringement of the ’133 patent.

525. Unless enjoined by this Court, upon FDA approval of Sandoz’s ANDA, Sandoz will infringe one or more claims of the ’133 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.

526. Unless enjoined by this Court, upon FDA approval of Sandoz’s ANDA, Sandoz will induce infringement of one or more claims of the ’133 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 ’133 patent and knowledge that its acts are encouraging infringement.

527. Unless enjoined by this Court, upon FDA approval of Sandoz’s ANDA, Sandoz will contributorily infringe one or more claims of the ’133 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 '133 patent, and Sandoz's Proposed Product lacks a substantial non-infringing use.

528. Failure to enjoin Sandoz's infringement of the '133 patent will substantially and irreparably damage and harm Axsome.

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

530. 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 XLVII: Infringement of the '354 Patent by Sandoz

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

532. 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 '354 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.

533. A justiciable controversy exists between Axsome and Sandoz as to the infringement of the '354 patent.

534. Unless enjoined by this Court, upon FDA approval of Sandoz's ANDA, Sandoz will infringe one or more claims of the '354 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.

535. Unless enjoined by this Court, upon FDA approval of Sandoz's ANDA, Sandoz will induce infringement of one or more claims of the '354 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 '354 patent and knowledge that its acts are encouraging infringement.

536. Unless enjoined by this Court, upon FDA approval of Sandoz's ANDA, Sandoz will contributorily infringe one or more claims of the '354 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 '354 patent, and Sandoz's Proposed Product lacks a substantial non-infringing use.

537. Failure to enjoin Sandoz's infringement of the '354 patent will substantially and irreparably damage and harm Axsome.

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

539. 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 XLVIII: Infringement of the '232 Patent by Sandoz

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

541. 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 '232 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.

542. A justiciable controversy exists between Axsome and Sandoz as to the infringement of the '232 patent.

543. Unless enjoined by this Court, upon FDA approval of Sandoz's ANDA, Sandoz will infringe one or more claims of the '232 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.

544. Unless enjoined by this Court, upon FDA approval of Sandoz's ANDA, Sandoz will induce infringement of one or more claims of the '232 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 '232 patent and knowledge that its acts are encouraging infringement.

545. Unless enjoined by this Court, upon FDA approval of Sandoz's ANDA, Sandoz will contributorily infringe one or more claims of the '232 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 '232 patent, and Sandoz's Proposed Product lacks a substantial non-infringing use.

546. Failure to enjoin Sandoz's infringement of the '232 patent will substantially and irreparably damage and harm Axsome.

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

548. 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 XLIX: Infringement of the ’715 Patent by Unichem

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

550. 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 ’715 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.

551. A justiciable controversy exists between Axsome and Unichem as to the infringement of the ’715 patent.

552. Unless enjoined by this Court, upon FDA approval of Unichem’s ANDA, Unichem will infringe one or more claims of the ’715 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.

553. Unless enjoined by this Court, upon FDA approval of Unichem’s ANDA, Unichem will induce infringement of one or more claims of the ’715 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 ’715 patent and knowledge that its acts are encouraging infringement.

554. Unless enjoined by this Court, upon FDA approval of Unichem’s ANDA, Unichem will contributorily infringe one or more claims of the ’715 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 '715 patent, and Unichem's Proposed Product lacks a substantial non-infringing use.

555. Failure to enjoin Unichem's infringement of the '715 patent will substantially and irreparably damage and harm Axsome.

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

557. 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 L: Infringement of the '151 Patent by Unichem

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

559. 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 '151 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.

560. A justiciable controversy exists between Axsome and Unichem as to the infringement of the '151 patent.

561. Unless enjoined by this Court, upon FDA approval of Unichem's ANDA, Unichem will infringe one or more claims of the '151 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.

562. Unless enjoined by this Court, upon FDA approval of Unichem's ANDA, Unichem will induce infringement of one or more claims of the '151 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 '151 patent and knowledge that its acts are encouraging infringement.

563. Unless enjoined by this Court, upon FDA approval of Unichem's ANDA, Unichem will contributorily infringe one or more claims of the '151 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 '151 patent, and Unichem's Proposed Product lacks a substantial non-infringing use.

564. Failure to enjoin Unichem's infringement of the '151 patent will substantially and irreparably damage and harm Axsome.

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

566. 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 LI: Infringement of the '609 Patent by Unichem

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

568. 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 '609 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

569. A justiciable controversy exists between Axsome and Unichem as to the infringement of the ’609 patent.

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

571. Unless enjoined by this Court, upon FDA approval of Unichem’s ANDA, Unichem will induce infringement of one or more claims of the ’609 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing 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 ’609 patent and knowledge that its acts are encouraging infringement.

572. Unless enjoined by this Court, upon FDA approval of Unichem’s ANDA, Unichem will contributorily infringe one or more claims of the ’609 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing 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 ’609 patent, and Unichem’s Proposed Product lacks a substantial non-infringing use.

573. Failure to enjoin Unichem’s infringement of the ’609 patent will substantially and irreparably damage and harm Axsome.

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

575. 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 LII: Infringement of the '597 Patent by Unichem

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

577. 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 '597 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.

578. A justiciable controversy exists between Axsome and Unichem as to the infringement of the '597 patent.

579. Unless enjoined by this Court, upon FDA approval of Unichem's ANDA, Unichem will infringe one or more claims of the '597 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.

580. Unless enjoined by this Court, upon FDA approval of Unichem's ANDA, Unichem will induce infringement of one or more claims of the '597 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 '597 patent and knowledge that its acts are encouraging infringement.

581. Unless enjoined by this Court, upon FDA approval of Unichem's ANDA, Unichem will contributorily infringe one or more claims of the '597 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 '597 patent, and Unichem's Proposed Product lacks a substantial non-infringing use.

582. Failure to enjoin Unichem's infringement of the '597 patent will substantially and irreparably damage and harm Axsome.

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

584. 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 LIII: Infringement of the '754 Patent by Unichem

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

586. 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 '754 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.

587. A justiciable controversy exists between Axsome and Unichem as to the infringement of the '754 patent.

588. Unless enjoined by this Court, upon FDA approval of Unichem's ANDA, Unichem will infringe one or more claims of the '754 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.

589. Unless enjoined by this Court, upon FDA approval of Unichem's ANDA, Unichem will induce infringement of one or more claims of the '754 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 '754 patent and knowledge that its acts are encouraging infringement.

590. Unless enjoined by this Court, upon FDA approval of Unichem's ANDA, Unichem will contributorily infringe one or more claims of the '754 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 '754 patent, and Unichem's Proposed Product lacks a substantial non-infringing use.

591. Failure to enjoin Unichem's infringement of the '754 patent will substantially and irreparably damage and harm Axsome.

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

593. 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 LIV: Infringement of the '976 Patent by Unichem

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

595. 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 ’976 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.

596. A justiciable controversy exists between Axsome and Unichem as to the infringement of the ’976 patent.

597. Unless enjoined by this Court, upon FDA approval of Unichem’s ANDA, Unichem will infringe one or more claims of the ’976 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.

598. Unless enjoined by this Court, upon FDA approval of Unichem’s ANDA, Unichem will induce infringement of one or more claims of the ’976 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 ’976 patent and knowledge that its acts are encouraging infringement.

599. Unless enjoined by this Court, upon FDA approval of Unichem’s ANDA, Unichem will contributorily infringe one or more claims of the ’976 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 ’976 patent, and Unichem’s Proposed Product lacks a substantial non-infringing use.

600. Failure to enjoin Unichem’s infringement of the ’976 patent will substantially and irreparably damage and harm Axsome.

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

602. 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 LV: Infringement of the '779 Patent by Unichem

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

604. 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 '779 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.

605. A justiciable controversy exists between Axsome and Unichem as to the infringement of the '779 patent.

606. Unless enjoined by this Court, upon FDA approval of Unichem's ANDA, Unichem will infringe one or more claims of the '779 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.

607. Unless enjoined by this Court, upon FDA approval of Unichem's ANDA, Unichem will induce infringement of one or more claims of the '779 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 '779 patent and knowledge that its acts are encouraging infringement.

608. Unless enjoined by this Court, upon FDA approval of Unichem's ANDA, Unichem will contributorily infringe one or more claims of the '779 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 '779 patent, and Unichem's Proposed Product lacks a substantial non-infringing use.

609. Failure to enjoin Unichem's infringement of the '779 patent will substantially and irreparably damage and harm Axsome.

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

611. 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 LVI: Infringement of the '133 Patent by Unichem

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

613. 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 '133 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.

614. A justiciable controversy exists between Axsome and Unichem as to the infringement of the '133 patent.

615. Unless enjoined by this Court, upon FDA approval of Unichem's ANDA, Unichem will infringe one or more claims of the '133 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.

616. Unless enjoined by this Court, upon FDA approval of Unichem's ANDA, Unichem will induce infringement of one or more claims of the '133 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 '133 patent and knowledge that its acts are encouraging infringement.

617. Unless enjoined by this Court, upon FDA approval of Unichem's ANDA, Unichem will contributorily infringe one or more claims of the '133 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 '133 patent, and Unichem's Proposed Product lacks a substantial non-infringing use.

618. Failure to enjoin Unichem's infringement of the '133 patent will substantially and irreparably damage and harm Axsome.

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

620. 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 LVII: Infringement of the '354 Patent by Unichem

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

622. 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 '354 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.

623. A justiciable controversy exists between Axsome and Unichem as to the infringement of the '354 patent.

624. Unless enjoined by this Court, upon FDA approval of Unichem's ANDA, Unichem will infringe one or more claims of the '354 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.

625. Unless enjoined by this Court, upon FDA approval of Unichem's ANDA, Unichem will induce infringement of one or more claims of the '354 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 '354 patent and knowledge that its acts are encouraging infringement.

626. Unless enjoined by this Court, upon FDA approval of Unichem's ANDA, Unichem will contributorily infringe one or more claims of the '354 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 '354 patent, and Unichem's Proposed Product lacks a substantial non-infringing use.

627. Failure to enjoin Unichem's infringement of the '354 patent will substantially and irreparably damage and harm Axsome.

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

629. 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 LVIII: Infringement of the '232 Patent by Unichem

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

631. 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 '232 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.

632. A justiciable controversy exists between Axsome and Unichem as to the infringement of the '232 patent.

633. Unless enjoined by this Court, upon FDA approval of Unichem's ANDA, Unichem will infringe one or more claims of the '232 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.

634. Unless enjoined by this Court, upon FDA approval of Unichem's ANDA, Unichem will induce infringement of one or more claims of the '232 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 '232 patent and knowledge that its acts are encouraging infringement.

635. Unless enjoined by this Court, upon FDA approval of Unichem's ANDA, Unichem will contributorily infringe one or more claims of the '232 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 '232 patent, and Unichem's Proposed Product lacks a substantial non-infringing use.

636. Failure to enjoin Unichem's infringement of the '232 patent will substantially and irreparably damage and harm Axsome.

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

638. 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 LIX: Infringement of the '806 Patent by Unichem

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

640. 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 '806 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.

641. A justiciable controversy exists between Axsome and Unichem as to the infringement of the '806 patent.

642. Unless enjoined by this Court, upon FDA approval of Unichem's ANDA, Unichem will infringe one or more claims of the '806 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.

643. Unless enjoined by this Court, upon FDA approval of Unichem's ANDA, Unichem will induce infringement of one or more claims of the '806 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 '806 patent and knowledge that its acts are encouraging infringement.

644. Unless enjoined by this Court, upon FDA approval of Unichem's ANDA, Unichem will contributorily infringe one or more claims of the '806 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 '806 patent, and Unichem's Proposed Product lacks a substantial non-infringing use.

645. Failure to enjoin Unichem's infringement of the '806 patent will substantially and irreparably damage and harm Axsome.

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

647. 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 LX: Infringement of the ’917 Patent by Unichem

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

649. 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 ’917 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.

650. A justiciable controversy exists between Axsome and Unichem as to the infringement of the ’917 patent.

651. Unless enjoined by this Court, upon FDA approval of Unichem’s ANDA, Unichem will infringe one or more claims of the ’917 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.

652. Unless enjoined by this Court, upon FDA approval of Unichem’s ANDA, Unichem will induce infringement of one or more claims of the ’917 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 ’917 patent and knowledge that its acts are encouraging infringement.

653. Unless enjoined by this Court, upon FDA approval of Unichem’s ANDA, Unichem will contributorily infringe one or more claims of the ’917 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 '917 patent, and Unichem's Proposed Product lacks a substantial non-infringing use.

654. Failure to enjoin Unichem's infringement of the '917 patent will substantially and irreparably damage and harm Axsome.

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

656. 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 LXI: Infringement of the '517 Patent by Unichem

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

658. 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 '517 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.

659. A justiciable controversy exists between Axsome and Unichem as to the infringement of the '517 patent.

660. Unless enjoined by this Court, upon FDA approval of Unichem's ANDA, Unichem will infringe one or more claims of the '517 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.

661. Unless enjoined by this Court, upon FDA approval of Unichem's ANDA, Unichem will induce infringement of one or more claims of the '517 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 '517 patent and knowledge that its acts are encouraging infringement.

662. Unless enjoined by this Court, upon FDA approval of Unichem's ANDA, Unichem will contributorily infringe one or more claims of the '517 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 '517 patent, and Unichem's Proposed Product lacks a substantial non-infringing use.

663. Failure to enjoin Unichem's infringement of the '517 patent will substantially and irreparably damage and harm Axsome.

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

665. 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 composition or 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 compositions or 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 AUROBINDO

WHEREFORE, Plaintiff Axsome respectfully requests the following relief:

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

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

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

(D) Preliminary and permanent injunctions enjoining Aurobindo and its officers, agents, attorneys and employees, and those acting in privity and/or concert with them, from making, using, offering to sell, selling, or importing Aurobindo's Proposed Product until after

the expiration of each of the patents-in-suit asserted against Aurobindo, or any later expiration of exclusivity to which Axsome is or becomes entitled;

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

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

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

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

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

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

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

PRAYER FOR RELIEF AGAINST HETERO

WHEREFORE, Plaintiff Axsome respectfully requests the following relief:

(A) A Judgment that Hetero infringed one or more claims of each of the patents-in-suit asserted against Hetero by submitting ANDA No. 218654;

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

(C) An Order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of FDA approval of ANDA No. 218654 be a date no earlier than the later of the expiration of each patent-in-suit asserted against Hetero, or any later expiration of exclusivity to which Axsome is or becomes entitled;

(D) Preliminary and permanent injunctions enjoining Hetero 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 Hetero's Proposed Product until after the expiration of each of the patents-in-suit asserted against Hetero, 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 Hetero, its officers, agents, attorneys and employees, and those acting in privity and/or concert with them, from practicing any composition or method claimed in the patents-in-suit asserted against Hetero, or from actively inducing or contributing to the infringement of any

claim of the patents-in-suit asserted against Hetero, 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 Hetero'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 Hetero;

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

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

(I) A Judgment declaring that each patent-in-suit asserted against Hetero 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 composition or 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 compositions or 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 composition or 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 compositions or 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 composition or 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 compositions or 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: September 13, 2023

By: s/ Charles M. Lizza

Charles M. Lizza
William C. Baton
Sarah A. Sullivan
Alexander L. Callo
SAUL EWING LLP
One Riverfront Plaza, Suite 1520
Newark, New Jersey 07102-5426
(973) 286-6700
clizza@saul.com

Attorneys for Plaintiffs Axsome Malta Ltd. and Axsome Therapeutics, Inc.

Of Counsel:

F. Dominic Cerrito
Eric C. Stops
Evangeline Shih
Gabriel P. Brier
Frank C. Calvosa
Abigail E. DeMasi
QUINN EMANUEL URQUHART & SULLIVAN, LLP
51 Madison Avenue, 22nd Floor
New York, New York 10010
(212) 849-7000

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 matter in controversy is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding.

Dated: September 13, 2023

By: s/ Charles M. Lizza

Charles M. Lizza
William C. Baton
Sarah A. Sullivan
Alexander L. Callo
SAUL EWING LLP
One Riverfront Plaza, Suite 1520
Newark, New Jersey 07102-5426
(973) 286-6700
clizza@saul.com

Attorneys for Plaintiffs Axsome Malta Ltd. and Axsome Therapeutics, Inc.

Of Counsel:

F. Dominic Cerrito
Eric C. Stops
Evangeline Shih
Gabriel P. Brier
Frank C. Calvosa
Abigail E. DeMasi
QUINN EMANUEL URQUHART & SULLIVAN, LLP
51 Madison Avenue, 22nd Floor
New York, New York 10010
(212) 849-7000