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 Plaintiff
GW Research Limited

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

GW RESEARCH LIMITED, **Plaintiff,** **v.** **TEVA PHARMACEUTICALS, INC., APOTEX INC., PADAGIS US LLC, INVAGEN PHARMACEUTICALS, INC., CIPLA LTD., CIPLA USA, INC., API PHARMA TECH LLC, LUPIN LTD., ALKEM LABORATORIES LTD., TARO PHARMACEUTICAL INDUSTRIES LTD., ASCENT PHARMACEUTICALS, INC., MSN LABORATORIES PRIVATE LTD., MSN PHARMACEUTICALS, INC., ZENARA PHARMA PRIVATE LTD., and BIOPHORE PHARMA, INC.,** **Defendants.**	**Civil Action No. _____** **COMPLAINT FOR PATENT INFRINGEMENT** **(Filed Electronically)**

Plaintiff GW Research Limited ("GW"), by its undersigned attorneys, for its Complaint against defendants Teva Pharmaceuticals, Inc. ("Teva"), Apotex Inc. ("Apotex"), Padagis US LLC ("Padagis"), InvaGen Pharmaceuticals, Inc. ("InvaGen"), Cipla Ltd., Cipla USA, Inc. ("Cipla USA") (Cipla Ltd. and Cipla USA, together, "Cipla"), API Pharma Tech LLC ("API

Pharma"), Lupin Ltd. ("Lupin"), Alkem Laboratories Ltd. ("Alkem"), Taro Pharmaceutical Industries Ltd. ("Taro"), Ascent Pharmaceuticals, Inc. ("Ascent"), MSN Laboratories Private Ltd. ("MSN Labs"), MSN Pharmaceuticals, Inc. ("MSN Pharmaceuticals") (MSN Labs and MSN Pharmaceuticals, together, "MSN"), Zenara Pharma Private Ltd. ("Zenara"), and Biophore Pharma, Inc. ("Biophore") (Teva, Apotex, Padagis, InvaGen, Cipla, API Pharma, Lupin, Alkem, Taro, Ascent, MSN, Zenara, and Biophore, collectively, "Defendants"), alleges 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 the Defendants' filing of their respective Abbreviated New Drug Applications ("ANDAs") Nos. 217508 ("Teva's ANDA"), 217699 ("Apotex's ANDA"), 215865 ("Padagis's ANDA"), 217522 ("InvaGen's ANDA"), 217871 ("Lupin's ANDA"), 217977 ("Alkem's ANDA"), 217930 ("Taro's ANDA"), 217994 ("Ascent's ANDA"), 217911 ("MSN's ANDA"), and 217910 ("Biophore and Zenara's ANDA"), with the United States Food and Drug Administration ("FDA") seeking approval to commercially market generic versions of GW's cannabidiol oral solution drug product prior to the expiration of United States Patent No. 11,633,369 ("the '369 patent"), owned by GW.

The Parties

2. Plaintiff GW is a biopharmaceutical company focused on discovering, developing, and commercializing novel therapeutics from its proprietary cannabinoid product platform in a broad range of disease areas. One such product, Epidiolex® (cannabidiol) oral solution, is approved in patients one-year and older for the treatment of seizures associated with Lennox-Gastaut Syndrome ("LGS"), Dravet Syndrome ("DS"), and Tuberous Sclerosis Complex ("TSC"), all of which are rare diseases characterized by severe early-onset epilepsy. Epidiolex® is the first and only plant-derived cannabinoid medicine approved by the FDA.

3. GW is a corporation existing under the laws of the United Kingdom, having a principal place of business in Cambridge, UK.

4. On information and belief, Teva is a corporation organized and existing under the laws of Delaware, having a principal place of business at 400 Interpace Parkway, Suite A1, Parsippany, New Jersey 07054.

5. On information and belief, Apotex is a corporation organized and existing under the laws of Canada, having a principal place of business at 150 Signet Drive, Toronto, Ontario, M9L 1T9 Canada.

6. On information and belief, Padagis is a corporation organized and existing under the laws of Delaware, having a principal place of business at 1251 Lincoln Road, Allegan, Michigan 49010.

7. On information and belief, InvaGen is a corporation organized and existing under the laws of New York, having a principal place of business at 7 Oser Avenue, Hauppauge, New York 11788. On further information and belief, InvaGen is an indirect, 100% wholly owned subsidiary of Cipla Ltd.

8. On information and belief, Cipla Ltd. is a corporation organized and existing under the laws of India, having a principal place of business at Cipla House, Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, Mumbai, 400 013, India.

9. On information and belief, Cipla USA is a corporation organized and existing under the laws of Delaware, having a principal place of business at 10 Independence Boulevard, Suite 300, Warren, New Jersey 07059. On further information and belief, Cipla USA is a 100% fully owned subsidiary of InvaGen.

10. On information and belief, API Pharma is a corporation organized and existing under the laws of New Jersey, having a principal place of business at 7 Deer Park Drive, Suite M1, Princeton Corporate Plaza, Monmouth Junction, New Jersey 08852.

11. On information and belief, Lupin is a corporation organized and existing under the laws of India, having a principal place of business at B/4 Laxmi Towers, Bandra Kurla Complex, Bandra (E), Mumbai, 400 051, India.

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

13. On information and belief, Taro is a corporation organized and existing under the laws of Israel, having a principal place of business at 14 Hakitor Street, Haifa Bay 26247, Israel.

14. On information and belief, Ascent is a corporation organized and existing under the laws of New York, having a principal place of business at 400 South Technology Drive, Central Islip, New York.

15. On information and belief, MSN Labs is a corporation organized and existing under the laws of India, having a principal place of business at MSN House, Plot No: C-24, Industrial Estate, Sanath Nagar, Hyderabad, 500 018, Telangana, India.

16. On information and belief, MSN Pharmaceuticals is a corporation organized and existing under the laws of Delaware, having a principal place of business at 20 Duke Road, Piscataway, New Jersey 08854.

17. On information and belief, Zenara is a corporation organized and existing under the laws of India, having a principal place of business at Plot No. 83/B, 84 & 87-96, Phase III, IDA Cherlapally, Hyderabad 500051, India.

18. On information and belief, Biophore is a corporation organized and existing under the laws of New Jersey, having a principal place of business at 1 Deerpark Drive, Suite F8, Monmouth Junction, NJ 08852.

The Patent-in-Suit

19. On April 25, 2023, the United States Patent and Trademark Office ("USPTO") duly and lawfully issued the '369 patent, entitled, "Use of Cannabinoids in the Treatment of Epilepsy" to GW as assignee. The face of the '369 patent identifies Geoffrey Guy, Stephen Wright, and Orrin Devinsky as the inventors. A copy of the '369 patent is attached hereto as Exhibit A.

The Epidiolex® Drug Product

20. GW 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 cannabidiol 100 mg/mL oral solution ("NDA No. 210365"), which is sold under the trade name Epidiolex®. Epidiolex® is approved in patients one year of age and older for the treatment of seizures associated with LGS, DS, or TSC, all of which are rare diseases characterized by severe early-onset epilepsy. Epidiolex® is the first and only plant-derived cannabinoid medicine approved by the FDA. The claims of the '369 patent cover, *inter alia*, cannabidiol pharmaceutical compositions and methods of using Epidiolex® to treat LGS, DS, and/or TSC.

21. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the '369 patent is listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to Epidiolex®.

Jurisdiction and Venue: Teva

22. This Court has jurisdiction over the subject matter of Count I against Teva pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

23. As set forth in Paragraphs 24-29 below, the Court has personal jurisdiction over Teva by virtue of, *inter alia*, its systematic and continuous contacts with the State of New Jersey.

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

25. On information and belief, Teva 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.

26. On information and belief, this Judicial District will be a destination for the generic version of GW's cannabidiol oral solution drug product for which Teva seeks FDA approval to manufacture, market, import, offer for sale, and/or sell pursuant to ANDA No. 217508 ("Teva's Proposed Product").

27. On information and belief, Teva maintains a physical place of business in this Judicial District, in at least Parsippany, New Jersey. Teva's website states that its "US Headquarters" is located in Parsippany, New Jersey. *See* https://www.tevausa.com/contact-us/ (last visited, July 21, 2023). In recent court filings, Teva has admitted that it has a "a principal place of business" in Parsippany, New Jersey. *See, e.g.*, *Neurocrine Biosci., Inc. v. Teva Pharm., Inc., et. al.*, No. 22-cv-965, ECF No. 14 at ¶ 12 (D. Del. Nov. 1, 2022).

28. On information and belief, Teva 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. 0450614134.

29. In *GW Research Ltd. v. Teva Pharm., Inc., et al.*, No. 23-cv-00018 (MEF)(AME) (D.N.J.), involving the same parties, Teva did not contest personal jurisdiction or venue.

30. For at least the foregoing reasons set forth above in Paragraphs 24-29 above, venue is proper in this Judicial District with respect to Teva pursuant to 28 U.S.C. § 1400(b).

Jurisdiction and Venue: Apotex

31. This Court has jurisdiction over the subject matter of Count II against Apotex pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

32. As set forth in Paragraphs 33-37 below, the Court has personal jurisdiction over Apotex by virtue of, *inter alia*, its systematic and continuous contacts with the State of New Jersey.

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

34. On information and belief, Apotex 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.

35. On information and belief, this Judicial District will be a destination for the generic version of GW's cannabidiol oral solution drug product for which Apotex seeks FDA approval to manufacture, market, import, offer for sale, and/or sell pursuant to ANDA No. 217699 ("Apotex's Proposed Product").

36. Apotex has consented to personal jurisdiction in this Court in numerous recent actions arising out of its ANDA filings and has filed counterclaims in such cases. *See, e.g., Amgen Inc. v. Apotex Inc.*, No. 22-cv-03827 (D.N.J.); *Supernus Pharms., Inc. v. Apotex Inc. et al.*, No. 20-cv-07870 (D.N.J.); *Boehringer Ingelheim Pharms., Inc. et al. v. Apotex Inc. et al.*, No. 18-cv-11350 (D.N.J.); *Pantheon Softgels Inc. et al. v. Apotex Inc. et al.*, No. 17-cv-13819 (D.N.J.); *Merck Sharp & Dohme Corp. v. Apotex Inc. et al.*, No. 17-cv-5399 (D.N.J.); *Dexcel Pharma Techs. Ltd. et al. v. Apotex Corp. et al.*, No. 17-cv-2423 (D.N.J.). Apotex has

purposefully availed itself of the rights, benefits, and privileges of New Jersey by asserting counterclaims in this Court.

37. In *GW Research Ltd. v. Teva Pharm., Inc., et al.*, No. 23-cv-00018 (MEF)(AME) (D.N.J.), involving the same parties, Apotex did not contest personal jurisdiction or venue.

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

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

Jurisdiction and Venue: Padagis

40. This Court has jurisdiction over the subject matter of Count III against Padagis pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

41. As set forth in Paragraphs 42-48 below, the Court has personal jurisdiction over Padagis by virtue of, *inter alia*, its systematic and continuous contacts with the State of New Jersey.

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

43. On information and belief, Padagis 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.

44. On information and belief, this Judicial District will be a destination for the generic version of GW's cannabidiol oral solution drug product for which Padagis seeks FDA approval to manufacture, market, import, offer for sale, and/or sell pursuant to ANDA No. 215865 ("Padagis's Proposed Product").

45. On information and belief, Padagis 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. 0600473527.

46. On information and belief, Padagis is registered with the State of New Jersey's Department of Health as a drug wholesaler and manufacturer operating in New Jersey under the registration number 5006088.

47. Padagis has consented to personal jurisdiction in this Court in recent actions arising out of its ANDA filings and has filed counterclaims in such cases. *See, e.g., Bausch Health Ireland Ltd et al. v. Padagis Israel Pharm. Ltd et al.*, No. 22-cv-4248 (D.N.J.). Padagis has purposefully availed itself of the rights, benefits, and privileges of New Jersey by asserting counterclaims in this Court.

48. In *GW Research Ltd. v. Teva Pharm., Inc., et al.*, No. 23-cv-00018 (MEF)(AME) (D.N.J.), involving the same parties, Padagis did not contest personal jurisdiction or venue.

49. For at least the foregoing reasons set forth above in Paragraphs 42-48, venue is proper in this Judicial District with respect to Padagis pursuant to 28 U.S.C. § 1400(b).

Jurisdiction and Venue: InvaGen, Cipla, and API Pharma

50. This Court has jurisdiction over the subject matter of Count IV against InvaGen, Cipla, and API Pharma pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

51. As set forth in Paragraphs 52-62 below, the Court has personal jurisdiction over InvaGen by virtue of, *inter alia*, its systematic and continuous contacts with the State of New Jersey.

52. On information and belief, InvaGen, alone or in concert with Cipla Ltd. and/or Cipla USA, purposefully has conducted and continues to conduct business in this Judicial District.

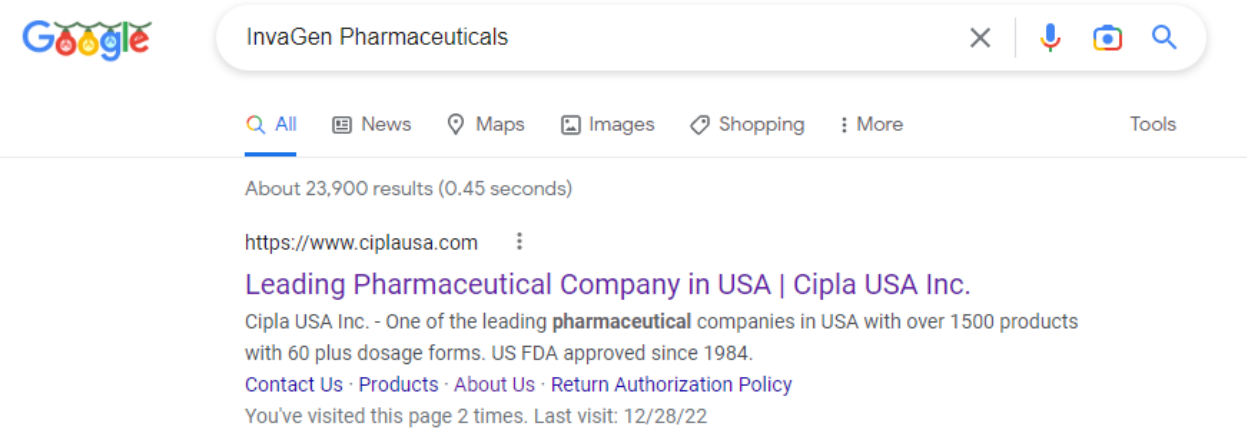
53. On information and belief, InvaGen is in the business of, among other things, manufacturing, marketing, importing, offering for sale, and selling pharmaceutical products, including generic drug products, throughout the United States, including in this Judicial District.

54. On information and belief, this Judicial District will be a destination for the generic version of GW's cannabidiol oral solution drug product for which InvaGen seeks FDA approval to manufacture, market, import, offer for sale, and/or sell pursuant to ANDA No. 217522 ("InvaGen's Proposed Product").

55. On information and belief, InvaGen will work in concert with API Pharma, Cipla Ltd., and/or Cipla USA toward the regulatory approval, manufacturing, use, importation, marketing, offer for sale, sale, and distribution of generic pharmaceutical products, including InvaGen's Proposed Product, throughout the United States, including in New Jersey and in this Judicial District, prior to the expiration of the '369 patent.

56. On information and belief, InvaGen conducts business in this Judicial District through its wholly owned subsidiary, Cipla USA. On information and belief, InvaGen does not

maintain its own website. Potential customers who search the internet for "InvaGen Pharmaceuticals" are instead directed to the webpage of Cipla USA:



57. In recent filings with the Patent Trial and Appeal Board, InvaGen represented that it "has a 100% fully owned subsidiary named Cipla USA Inc.," and that Cipla USA was a "real party-in-interest" to InvaGen's Petition for Inter Partes Review. *See* Petition for Inter Partes Review of U.S. Patent No. 10,828,310, *InvaGen Pharmaceuticals, Inc. v. Bayer Pharma*, Case IPR2022-01515 (P.T.A.B. Sept. 8, 2022).

58. On information and belief, Cipla USA acts at the direction, and for the benefit, of InvaGen, and is an agent / alter ego of InvaGen.

59. On information and belief, InvaGen 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. 0450360045.

60. InvaGen has consented to personal jurisdiction in this Court in recent actions arising out of its ANDA filings and has filed counterclaims in such cases. *See, e.g.*, *Sumitomo Dainippon Pharma Co., Ltd. v. Aurobindo Pharma Ltd., et al.*, No. 18-cv-2620 (D.N.J.).

InvaGen has purposefully availed itself of the rights, benefits, and privileges of New Jersey by asserting counterclaims in this Court.

61. Further, InvaGen has previously submitted to the jurisdiction of this Court and has availed itself of the legal protections of the State of New Jersey, having previously transferred a case into this Judicial District by stating that "personal jurisdiction exists in New Jersey over both InvaGen and [its co-defendant]." *Roxane Labs., Inc. v. Camber Pharms., Inc.*, No. 14-cv-4042, ECF No. 28 at 18 (D.N.J. Apr. 4, 2014).

62. In *GW Research Ltd. v. Teva Pharm., Inc., et al.*, No. 23-cv-00018 (MEF)(AME) (D.N.J.), involving the same parties, InvaGen stipulated that it would not contest personal jurisdiction or venue. *See id.* at ECF No. 45.

63. For at least the foregoing reasons set forth above in Paragraphs 52-62, venue is proper in this Judicial District with respect to InvaGen pursuant to 28 U.S.C. § 1400(b).

64. As set forth in Paragraphs 65-71 below, the Court has personal jurisdiction over Cipla USA by virtue of, *inter alia*, its systematic and continuous contacts with the State of New Jersey.

65. On information and belief, Cipla USA, alone or at the direction of Cipla Ltd. and/or InvaGen, purposefully has conducted and continues to conduct business in this Judicial District.

66. On information and belief, Cipla USA, 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.

67. On information and belief, Cipla USA will work in concert with API Pharma, Cipla Ltd., and/or InvaGen toward the regulatory approval, manufacturing, use, importation,

marketing, offer for sale, sale, and distribution of generic pharmaceutical products, including InvaGen's Proposed Product, throughout the United States, including in New Jersey and in this Judicial District, prior to the expiration of the '369 patent.

68. On information and belief, Cipla USA maintains a physical place of business in this Judicial District, in at least Warren, New Jersey. *See* https://www.ciplausa.com/about-us (last visited, July 21, 2023).

69. On information and belief, Cipla USA 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. 0450318628.

70. On information and belief, Cipla USA is registered with the State of New Jersey's Department of Health as a drug manufacturer and wholesaler operating in New Jersey under the registration number 5005183.

71. In *GW Research Ltd. v. Teva Pharm., Inc., et al.*, No. 23-cv-00018 (MEF)(AME) (D.N.J.), involving the same parties, Cipla USA stipulated that it would not contest personal jurisdiction or venue. *See id.* at ECF No. 45.

72. For at least the foregoing reasons set forth above in Paragraphs 65-71, venue is proper in this Judicial District with respect to Cipla USA pursuant to 28 U.S.C. § 1400(b).

73. As set forth in Paragraphs 74-83 below, the Court has personal jurisdiction over Cipla Ltd. by virtue of, *inter alia*, its systematic and continuous contacts with the State of New Jersey.

74. On information and belief, Cipla Ltd., alone or through its indirect, wholly owned subsidiaries Cipla USA and InvaGen, purposefully has conducted and continues to conduct business in this Judicial District.

75. On information and belief, Cipla Ltd., alone or through its indirect, wholly owned subsidiaries Cipla USA and InvaGen, 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.

76. On information and belief, Cipla Ltd. will work in concert with API Pharma, Cipla USA, and/or InvaGen toward the regulatory approval, manufacturing, use, importation, marketing, offer for sale, sale, and distribution of generic pharmaceutical products, including InvaGen's Proposed Product, throughout the United States, including in New Jersey and in this Judicial District, prior to the expiration of the '369 patent.

77. On information and belief, InvaGen acts at the direction, and for the benefit, of Cipla Ltd., and is an agent/alter ego of Cipla Ltd.

78. On information and belief, Cipla Ltd. considers ANDAs owned by InvaGen amongst the ANDAs owned by Cipla Ltd. *See* Cipla Ltd. 2022 Annual Report at 63 (available at https://www.cipla.com/sites/default/files/Annual-Report-2021-22-single-page.pdf (last visited, July 21, 2023)); *see also id.* at 116 (figures "include ANDAs owned by Cipla and InvaGen Pharmaceuticals Inc.").

79. On information and belief, Cipla Ltd. "includes" revenues raised by InvaGen in its own year-over-year sales figures for the North American region. *See id.* at 115.

80. On information and belief, several individuals are directors of both Cipla Ltd. and InvaGen. *Id.* at 172 (identifying "Ms Punita Lal," "Mr P R Ramesh," and "Mr Robert Stewart" as "Independent Directors" of both InvaGen and Cipla Ltd.).

81. On information and belief, Cipla Ltd. "has given guarantees in favour of various banks" in connection with loans obtained by InvaGen. *See id.* at 256, 268.

82. This Court has personal jurisdiction over Cipla Ltd. because, *inter alia*, it: (1) has purposefully availed itself of the privilege of doing business in New Jersey, including directly or indirectly through its subsidiary, agent, and/or alter ego, InvaGen.; and (2) maintains extensive and systematic contacts with the State of New Jersey, including the marketing, distribution, and/or sale of generic pharmaceutical drugs in New Jersey, including through, directly or indirectly, InvaGen. On information and belief, InvaGen acts at the direction, and for the benefit, of Cipla Ltd., and is controlled and/or dominated by Cipla Ltd.

83. In *GW Research Ltd. v. Teva Pharm., Inc., et al.*, No. 23-cv-00018 (MEF)(AME) (D.N.J.), involving the same parties, Cipla Ltd. stipulated that it would not contest personal jurisdiction or venue. *See id.* at ECF No. 45.

84. In the alternative, this Court has personal jurisdiction over Cipla Ltd. because the requirements of Fed. R. Civ. P. 4(k)(2) are met as (a) GW's claims arise under federal law; (b) Cipla Ltd. is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Cipla 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, and/or selling pharmaceutical products that are distributed throughout the United States, such that this Court's exercise of jurisdiction over Cipla Ltd. satisfies due process.

85. At least because, on information and belief, Cipla Ltd. is a foreign company, venue is proper in this Judicial District pursuant to 28 U.S.C. §§ 1391 and/or 1400(b).

86. As set forth in Paragraphs 87-93 below, the Court has personal jurisdiction over API Pharma by virtue of, *inter alia*, its systematic and continuous contacts with the State of New Jersey.

87. On information and belief, API Pharma purposefully has conducted and continues to conduct business in this Judicial District.

88. On information and belief, API Pharma 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.

89. On information and belief, API Pharma will work in concert with Cipla USA, Cipla Ltd., and/or InvaGen toward the regulatory approval, manufacturing, use, importation, marketing, offer for sale, sale, and distribution of generic pharmaceutical products, including InvaGen's Proposed Product, throughout the United States, including in New Jersey and in this Judicial District, prior to the expiration of the '369 patent.

90. On information and belief, API Pharma is incorporated in New Jersey and maintains a physical place of business in this Judicial District, in at least Monmouth Junction, New Jersey. *See* https://www.apipharmatech.com/about-us/vision-mission/ (last visited, July 21, 2023).

91. On information and belief, API Pharma 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. 0450081108.

92. On information and belief, API Pharma is registered with the State of New Jersey's Department of Health as a drug manufacturer operating in New Jersey under the registration number 5005711.

93. In *GW Research Ltd. v. Teva Pharm., Inc., et al.*, No. 23-cv-00018 (MEF)(AME) (D.N.J.), involving the same parties, API Pharma stipulated that it would not contest personal jurisdiction or venue. *See id.* at ECF No. 45.

94. For at least the foregoing reasons set forth above in Paragraphs 87-93, venue is proper in this Judicial District with respect to API Pharma pursuant to 28 U.S.C. § 1400(b).

Jurisdiction and Venue: Lupin

95. This Court has jurisdiction over the subject matter of Count V against Lupin pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

96. As set forth in Paragraphs 97-101 below, the Court has personal jurisdiction over Lupin by virtue of, *inter alia*, its systematic and continuous contacts with the State of New Jersey.

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

98. On information and belief, Lupin 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.

99. On information and belief, this Judicial District will be a destination for the generic version of GW's cannabidiol oral solution drug product for which Lupin seeks FDA approval to manufacture, market, import, offer for sale, and/or sell pursuant to ANDA No. 217871 ("Lupin's Proposed Product").

100. On information and belief, Lupin maintains a physical place of business in this Judicial District, in at least Somerset, New Jersey. Lupin's website states that its "first and only commercial manufacturing facility in the United States is located in Somerset, New Jersey. Lupin's New Jersey facility encompasses all functional areas of pharmaceutical manufacturing including quality control, packaging, production, quality assurance, regulatory affairs, research and development, formulation, and technical services." *See* https://www.lupin.com/US/lupin-u-s-locations/ (last visited, July 21, 2023). Accordingly, Lupin's most recent annual report,

specifically points to both "research" and "manufacturing" activities in New Jersey when describing the company's "Global Footprint." *See* https://www.lupin.com/wp-content/uploads/2022/07/integrated-report-consolidated.pdf (last visited, July 21, 2023).

101. In *GW Research Ltd. v. Teva Pharm., Inc., et al.*, No. 23-cv-00018 (MEF)(AME) (D.N.J.), involving the same parties, Lupin did not contest personal jurisdiction or venue.

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

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

Jurisdiction and Venue: Alkem

104. This Court has jurisdiction over the subject matter of Count VI against Alkem pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

105. As set forth in Paragraphs 106-110 below, the Court has personal jurisdiction over Alkem by virtue of, *inter alia*, its systematic and continuous contacts with the State of New Jersey.

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

107. 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.

108. On information and belief, this Judicial District will be a destination for the generic version of GW's cannabidiol oral solution drug product for which Alkem seeks FDA approval to manufacture, market, import, offer for sale, and/or sell pursuant to ANDA No. 217977 ("Alkem's Proposed Product").

109. Alkem has consented to personal jurisdiction in this Court in numerous recent actions arising out of its ANDA filings and has filed counterclaims in such cases. *See, e.g., Azurity Pharm., Inc. v. Alkem Labs. Ltd.*, No. 22-cv-0143 (D.N.J.); *Celgene Corp. v. Alkem Labs. Ltd*., No. 18-cv-11265 (D.N.J.); *Valeant Pharm. N. Am. LLC v. Alkem Labs. Ltd*., No. 18-cv-13905 (D.N.J.); *Sumitomo Dainippon Pharma Co. v. Alkem Labs. Ltd*., 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.

110. In *GW Research Ltd. v. Teva Pharm., Inc., et al.*, No. 23-cv-00018 (MEF)(AME) (D.N.J.), involving the same parties, Alkem did not contest personal jurisdiction or venue.

111. 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) GW'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.

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

Jurisdiction and Venue: Taro

113. This Court has jurisdiction over the subject matter of Count VII against Taro pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

114. As set forth in Paragraphs 115-121 below, the Court has personal jurisdiction over Taro by virtue of, *inter alia*, its systematic and continuous contacts with the State of New Jersey.

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

116. On information and belief, Taro 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.

117. On information and belief, this Judicial District will be a destination for the generic version of GW's cannabidiol oral solution drug product for which Taro seeks FDA approval to manufacture, market, import, offer for sale, and/or sell pursuant to ANDA No. 217930 ("Taro's Proposed Product").

118. On information and belief, Taro maintains a physical place of business in this Judicial District, in at least Cranbury, New Jersey. On information and belief, Taro Pharmaceuticals USA, Inc. ("Taro USA") is an indirect, wholly owned subsidiary of Taro. On information and belief, Taro maintains a physical place of business in Cranbury through its wholly owned subsidiary, Taro USA.

119. Taro has consented to personal jurisdiction in this Court in recent actions arising out of its ANDA filings and has filed counterclaims in such cases. *See, e.g., Horizon Therapeutics, LLC v. Taro Pharm. Indus. Ltd. et al.*, No. 22-cv-04663 (D.N.J.). Taro has purposefully availed itself of the rights, benefits, and privileges of New Jersey by asserting counterclaims in this Court.

120. Taro's Notice Letter consents to jurisdiction in the State of New Jersey by directing that "service of process for Taro in connection with the Taro ANDA" is to be carried out in Princeton, New Jersey.

121. In *GW Research Ltd. v. Teva Pharm., Inc., et al.*, No. 23-cv-00018 (MEF)(AME) (D.N.J.), involving the same parties, Taro did not contest personal jurisdiction or venue.

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

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

Jurisdiction and Venue: Ascent

124. This Court has jurisdiction over the subject matter of VIII against Ascent pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

125. As set forth in Paragraphs 126-131 below, the Court has personal jurisdiction over Ascent by virtue of, *inter alia*, its systematic and continuous contacts with the State of New Jersey.

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

127. On information and belief, Ascent 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.

128. On information and belief, this Judicial District will be a destination for the generic version of GW's cannabidiol oral solution drug product for which Ascent seeks FDA approval to manufacture, market, import, offer for sale, and/or sell pursuant to ANDA No. 217994 ("Ascent's Proposed Product").

129. On information and belief, Ascent has registered with the State of New Jersey's Department of Health as a drug wholesaler and manufacturer operating in New Jersey under the registration number 5005459.

130. Ascent has consented to personal jurisdiction in this Court in recent actions arising out of its ANDA filings and has filed counterclaims in such cases. *See, e.g., Tris Pharma, Inc. v. Ascent Pharm., Inc.*, No. 21-cv-12867 (D.N.J.). Ascent has purposefully availed itself of the rights, benefits, and privileges of New Jersey by asserting counterclaims in this Court.

131. In *GW Research Ltd. v. Teva Pharm., Inc., et al.*, No. 23-cv-00018 (MEF)(AME) (D.N.J.), involving the same parties, Ascent did not contest personal jurisdiction or venue.

132. For at least the foregoing reasons set forth above in Paragraphs 126-131, venue is proper in this Judicial District with respect to Ascent pursuant to 28 U.S.C. § 1400(b).

Jurisdiction and Venue: MSN Pharmaceuticals and MSN Labs

133. This Court has jurisdiction over the subject matter of Count IX against MSN pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

134. As set forth in Paragraphs 135-141 below, the Court has personal jurisdiction over MSN Pharmaceuticals by virtue of, *inter alia*, its systematic and continuous contacts with the State of New Jersey.

135. On information and belief, MSN Pharmaceuticals purposefully has conducted and continues to conduct business in this Judicial District.

136. On information and belief, MSN Pharmaceuticals 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.

137. On information and belief, this Judicial District will be a destination for the generic version of GW's cannabidiol oral solution drug product for which MSN seeks FDA approval to manufacture, market, import, offer for sale, and/or sell pursuant to ANDA No. 217911 ("MSN's Proposed Product").

138. On information and belief, MSN Pharmaceuticals maintains a physical place of business in this Judicial District, in at least Piscataway, New Jersey. MSN Pharmaceutical's website states that MSN Pharmaceuticals maintains "a state-of-the-art finished dosage manufacturing facility based out of Piscataway, New Jersey." *See* https://msnpi.com/msnpi-index.html (last visited, July 21, 2023). In recent court filings, MSN Pharmaceuticals has admitted that it has a "a principal place of business" in Piscataway, New Jersey. *See, e.g.*, *Chiesi*

USA Inc. et al. v. MSN Pharmaceuticals Inc. et al., No. 19-cv-18564, ECF No. 16 at ¶ 6 (D.N.J. Dec. 23, 2019).

139. On information and belief, MSN Pharmaceuticals 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. 0400627791.

140. On information and belief, MSN Pharmaceuticals is registered with the State of New Jersey's Department of Health as a drug wholesaler and manufacturer operating in New Jersey under the registration number 5006107.

141. In *GW Research Ltd. v. Teva Pharm., Inc., et al.*, No. 23-cv-00018 (MEF)(AME) (D.N.J.), involving the same parties, MSN Pharmaceuticals did not contest personal jurisdiction or venue.

142. For at least the foregoing reasons set forth above in Paragraphs 135-141, venue is proper in this Judicial District with respect to MSN Pharmaceuticals pursuant to 28 U.S.C. § 1400(b).

143. As set forth in Paragraphs 144-148 below, the Court has personal jurisdiction over MSN Labs by virtue of, *inter alia*, its systematic and continuous contacts with the State of New Jersey.

144. On information and belief, MSN Labs purposefully has conducted and continues to conduct business in this Judicial District.

145. On information and belief, MSN Labs 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.

146. On information and belief, this Judicial District will be a destination for MSN's Proposed Product.

147. On information and belief, MSN Labs maintains a physical place of business in this Judicial District, through its wholly owned subsidiary MSN Pharmaceuticals, in at least Piscataway, New Jersey. MSN Labs' website identifies "a state-of-the-art finished dosage manufacturing facility based out of Piscataway, New Jersey" as part of its own "Global Presence." *See* https://www.msnlabs.com/msn-usa.html (last visited, July 21, 2023).

148. In *GW Research Ltd. v. Teva Pharm., Inc., et al.*, No. 23-cv-00018 (MEF)(AME) (D.N.J.), involving the same parties, MSN Labs did not contest personal jurisdiction or venue.

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

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

Jurisdiction and Venue: Biophore and Zenara

151. This Court has jurisdiction over the subject matter of Count X against Biophore and Zenara pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

152. As set forth in Paragraphs 153-158 below, the Court has personal jurisdiction over Biophore by virtue of, *inter alia*, its systematic and continuous contacts with the State of New Jersey.

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

154. On information and belief, Biophore 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.

155. On information and belief, this Judicial District will be a destination for the generic version of GW's cannabidiol oral solution drug product for which Biophore and Zenara seek FDA approval to manufacture, market, import, offer for sale, and/or sell pursuant to ANDA No. 217910 ("Biophore and Zenara's Proposed Product").

156. On information and belief, Biophore is incorporated in the state of New Jersey and maintains a physical place of business in this Judicial District, in at least Monmouth Junction, New Jersey.

157. On information and belief, Biophore 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. 0400378257.

158. In *GW Research Ltd. v. Teva Pharm., Inc., et al.*, No. 23-cv-00018 (MEF)(AME) (D.N.J.), involving the same parties, Biophore did not contest personal jurisdiction or venue.

159. For at least the foregoing reasons set forth above in Paragraphs 153-158, venue is proper in this Judicial District with respect to Biophore pursuant to 28 U.S.C. § 1400(b).

160. As set forth in Paragraphs 161-164 below, the Court has personal jurisdiction over Zenara by virtue of, *inter alia*, its systematic and continuous contacts with the State of New Jersey.

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

162. On information and belief, Zenara 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.

163. On information and belief, this Judicial District will be a destination for Biophore and Zenara's Proposed Product.

164. In *GW Research Ltd. v. Teva Pharm., Inc., et al.*, No. 23-cv-00018 (MEF)(AME) (D.N.J.), involving the same parties, Zenara did not contest personal jurisdiction or venue.

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

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

Acts Giving Rise To Count I Against Teva

167. Pursuant to Section 505 of the FFDCA, Teva filed ANDA No. 217508 seeking approval to engage in the commercial manufacture, use, sale, offer for sale, or importation of Teva's Proposed Product, before the '369 patent expires.

168. No earlier than November 21, 2022, Teva sent written notice of a Paragraph IV Certification ("Teva's Notice Letter") to GW. According to Teva's Notice Letter, Teva filed 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 Teva's Proposed Product before expiration of the patents listed in the Orange Book with respect to Epidiolex®.

169. No earlier than December 14, 2022, Teva sent written notice of a second Paragraph IV Certification ("Teva's Second Notice Letter") to GW. According to Teva's Second Notice Letter, Teva filed 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 Teva's Proposed Product before expiration of the patents listed in the Orange Book with respect to Epidiolex®.

170. No earlier than June 12, 2023, Teva sent written notice of a third Paragraph IV Certification ("Teva's Third Notice Letter") to GW. According to Teva's Third Notice Letter, Teva filed 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 Teva's Proposed Product before expiration of the '369 patent.

171. On information and belief, in connection with the filing of its ANDA as described above, Teva provided written certifications to the FDA, as called for by Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), indicating that it seeks to obtain approval of its ANDA to engage in the commercial manufacture, use, or sale of Teva's Proposed Product before

the expiration of the Orange Book patents with respect to Epidiolex®, one of which is the '369 patent.

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

Acts Giving Rise To Count II Against Apotex

173. Pursuant to Section 505 of the FFDCA, Apotex filed ANDA No. 217699 seeking approval to engage in the commercial manufacture, use, sale, offer for sale, or importation of Apotex's Proposed Product, before the '369 patent expires.

174. No earlier than November 28, 2022, Apotex sent written notice of a Paragraph IV Certification ("Apotex's Notice Letter") to GW. According to Apotex's Notice Letter, Apotex filed 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 Apotex's Proposed Product before expiration of the patents listed in the Orange Book with respect to Epidiolex®.

175. On information and belief, in connection with the filing of its ANDA as described above, Apotex provided a written certification to the FDA, as called for by Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), indicating that it seeks to obtain approval of its ANDA to engage in the commercial manufacture, use, or sale of Apotex's Proposed Product before the expiration of the Orange Book patents with respect to Epidiolex®, one of which is the '369 patent.

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

Acts Giving Rise To Count III Against Padagis

177. Pursuant to Section 505 of the FFDCA, Padagis filed ANDA No. 215865 seeking approval to engage in the commercial manufacture, use, sale, offer for sale, or importation of Padagis's Proposed Product, before the '369 patent expires.

178. No earlier than November 28, 2022, Padagis sent written notice of a Paragraph IV Certification ("Padagis's Notice Letter") to GW. According to Padagis's Notice Letter, Padagis filed 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 Padagis's Proposed Product before expiration of the patents listed in the Orange Book with respect to Epidiolex®.

179. No earlier than June 15, 2023, Padagis sent written notice of a second Paragraph IV Certification ("Padagis's Second Notice Letter") to GW. According to Padagis's Second Notice Letter, Padagis filed 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 Padagis's Proposed Product before expiration of the '369 patent.

180. On information and belief, in connection with the filing of its ANDA as described above, Padagis provided written certifications to the FDA, as called for by Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), indicating that it seeks to obtain approval of its ANDA to engage in the commercial manufacture, use, or sale of Padagis's Proposed Product before the expiration of the Orange Book patents with respect to Epidiolex®, one of which is the '369 patent.

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

Acts Giving Rise To Count IV Against InvaGen, Cipla, and API Pharma

182. Pursuant to Section 505 of the FFDCA, API Pharma filed ANDA No. 217522 seeking approval to engage in the commercial manufacture, use, sale, offer for sale, or importation of InvaGen's Proposed Product, before the '369 patent expires.

183. No earlier than December 2, 2022, InvaGen sent written notice of a Paragraph IV Certification ("InvaGen's Notice Letter") to GW. According to InvaGen's Notice Letter, API Pharma filed 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 InvaGen's Proposed Product before expiration of the patents listed in the Orange Book with respect to Epidiolex®.

184. On information and belief, in connection with the filing of the ANDA as described above, API Pharma provided a written certification to the FDA, as called for by Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), indicating that it seeks to obtain approval of its ANDA to engage in the commercial manufacture, use, or sale of InvaGen's Proposed Product before the expiration of the Orange Book patents with respect to Epidiolex®, one of which is the '369 patent.

185. According to InvaGen's Notice Letter, after the FDA had received API Pharma's Paragraph IV Certification, API Pharma transferred ownership of ANDA No. 217522 to InvaGen "in accordance with 21 CFR § 314.72(a)(1)."

186. On information and belief, and as evidenced by the facts set forth in Paragraphs 50-93 and 182-185 above, following FDA approval of ANDA No. 217522, InvaGen, Cipla, and API Pharma will act in concert to make, use, offer to sell, or sell InvaGen's Proposed Product throughout the United States, or import such a generic product into the United States.

187. On information and belief, and as evidenced by the facts set forth in Paragraphs 50-93 and 182-186 above, following FDA approval of ANDA No. 217522, InvaGen, Cipla, and API Pharma intend to directly benefit from sales of InvaGen's Proposed Product.

Acts Giving Rise to Count V Against Lupin

188. Pursuant to Section 505 of the FFDCA, Lupin filed ANDA No. 217871 seeking approval to engage in the commercial manufacture, use, sale, offer for sale, or importation of Lupin's Proposed Product, before the '369 patent expires.

189. No earlier than December 2, 2022, Lupin sent written notice of a Paragraph IV Certification ("Lupin's Notice Letter") to GW. According to Lupin's Notice Letter, Lupin filed 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 Lupin's Proposed Product before expiration of the patents listed in the Orange Book with respect to Epidiolex®.

190. No earlier than July 7, 2023, Lupin sent written notice of a second Paragraph IV Certification ("Lupin's Second Notice Letter") to GW. According to Lupin's Second Notice Letter, Lupin filed 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 Lupin's Proposed Product before expiration of the '369 patent.

191. On information and belief, in connection with the filing of its ANDA as described above, Lupin provided a written certification to the FDA, as called for by Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), indicating that it seeks to obtain approval of its ANDA to engage in the commercial manufacture, use, or sale of Lupin's Proposed Product before the expiration of the Orange Book patents with respect to Epidiolex®, one of which is the '369 patent.

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

Acts Giving Rise to Count VI Against Alkem

193. Pursuant to Section 505 of the FFDCA, Alkem filed ANDA No. 217977 seeking approval to engage in the commercial manufacture, use, sale, offer for sale, or importation of Alkem's Proposed Product, before the '369 patent expires.

194. No earlier than December 5, 2022, Alkem sent written notice of a Paragraph IV Certification ("Alkem's Notice Letter") to GW. According to Alkem's Notice Letter, Alkem filed 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 the patents listed in the Orange Book with respect to Epidiolex®.

195. No earlier than February 24, 2023, Alkem sent written notice of a second Paragraph IV Certification ("Alkem's Second Notice Letter") to GW. According to Alkem's Second Notice Letter, Alkem filed 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 the patents listed in the Orange Book with respect to Epidiolex®.

196. No earlier than June 9, 2023, Alkem sent written notice of a third Paragraph IV Certification ("Alkem's Third Notice Letter") to GW. According to Alkem's Third Notice Letter, Alkem filed 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 the '369 patent.

197. On information and belief, in connection with the filing of its ANDA as described above, Alkem provided written certifications to the FDA, as called for by Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), indicating that it seeks to obtain approval of its ANDA to engage in the commercial manufacture, use, or sale of Alkem's Proposed Product before the expiration of the Orange Book patents with respect to Epidiolex®, one of which is the '369 patent.

198. 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 Count VII Against Taro

199. Pursuant to Section 505 of the FFDCA, Taro filed ANDA No. 217930 seeking approval to engage in the commercial manufacture, use, sale, offer for sale, or importation of Taro's Proposed Product, before the '369 patent expires.

200. No earlier than December 5, 2022, Taro sent written notice of a Paragraph IV Certification ("Taro's Notice Letter") to GW. According to Taro's Notice Letter, Taro filed 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 Taro's Proposed Product before expiration of the patents listed in the Orange Book with respect to Epidiolex®.

201. No earlier than June 23, 2023, Taro sent written notice of a second Paragraph IV Certification ("Taro's Second Notice Letter") to GW. According to Taro's Second Notice Letter, Taro filed 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 Taro's Proposed Product before expiration of the '369 patent.

202. On information and belief, in connection with the filing of its ANDA as described above, Taro provided written certifications to the FDA, as called for by Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), indicating that it seeks to obtain approval of its ANDA to engage in the commercial manufacture, use, or sale of Taro's Proposed Product before the expiration of the Orange Book patents with respect to Epidiolex®, one of which is the '369 patent.

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

Acts Giving Rise to Count VIII Against Ascent

204. Pursuant to Section 505 of the FFDCA, Ascent filed ANDA No. 217994 seeking approval to engage in the commercial manufacture, use, sale, offer for sale, or importation of Ascent's Proposed Product, before the '369 patent expires.

205. No earlier than December 6, 2022, Ascent sent written notice of a Paragraph IV Certification ("Ascent's Notice Letter") to GW. According to Ascent's Notice Letter, Ascent filed 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 Ascent's Proposed Product before expiration of the patents listed in the Orange Book with respect to Epidiolex®.

206. On information and belief, in connection with the filing of its ANDA as described above, Ascent provided a written certification to the FDA, as called for by Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), indicating that it seeks to obtain approval of its ANDA to engage in the commercial manufacture, use, or sale of Ascent's Proposed Product

before the expiration of the Orange Book patents with respect to Epidiolex®, one of which is the '369 patent.

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

Acts Giving Rise to Count IX Against MSN

208. Pursuant to Section 505 of the FFDCA, MSN filed ANDA No. 217911 seeking approval to engage in the commercial manufacture, use, sale, offer for sale, or importation of MSN's Proposed Product, before the '369 patent expires.

209. No earlier than December 6, 2022, MSN sent written notice of a Paragraph IV Certification ("MSN's Notice Letter") to GW. According to MSN's Notice Letter, MSN filed 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 MSN's Proposed Product before expiration of the patents listed in the Orange Book with respect to Epidiolex®.

210. MSN's Notice Letter "collectively" refers to both MSN Labs and MSN Pharmaceuticals as "MSN" and states that these entities filed ANDA No. 217911, which "includes a Paragraph IV certification to obtain approval to engage in the commercial manufacture, use or sale of MSN's cannabidiol solution 100 mg/mL before the expiration of [certain of the patents listed in the Orange Book with respect to Epidiolex®]."

211. No earlier than December 8, 2022, MSN sent written notice of a second Paragraph IV Certification ("MSN's Second Notice Letter") to GW. According to MSN's Second Notice Letter, MSN filed 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 MSN's Proposed Product before expiration of the patents listed in the Orange Book with respect to Epidiolex®.

212. On information and belief, in connection with the filing of its ANDA as described above, MSN provided written certifications to the FDA, as called for by Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), indicating that it seeks to obtain approval of its ANDA to engage in the commercial manufacture, use, or sale of MSN's Proposed Product before the expiration of the Orange Book patents with respect to Epidiolex®, one of which is the '369 patent.

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

Acts Giving Rise to Count X Against Biophore and Zenara

214. Pursuant to Section 505 of the FFDCA, Biophore and Zenara filed ANDA No. 217910 seeking approval to engage in the commercial manufacture, use, sale, offer for sale, or importation of Biophore and Zenara's Proposed Product, before the '369 patent expires.

215. No earlier than December 6, 2022, Biophore and Zenara sent written notice of a Paragraph IV Certification ("Biophore and Zenara's Notice Letter") to GW. According to Biophore and Zenara's Notice Letter, Biophore and Zenara filed 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 Biophore and Zenara's Proposed Product before expiration of the patents listed in the Orange Book with respect to Epidiolex®.

216. Biophore and Zenara's Notice Letter collectively refers to both Biophore and Zenara as "Zenara" and states that these two entities "collectively . . . filed an Abbreviated New Drug Application ('ANDA') under 21 U.S.C. § 355(j) to obtain approval from the U.S. Food &

Drug Administration ('FDA') to market cannabidiol oral solution, 100 mg/mL . . . prior to the expiration of [certain of the patents listed in the Orange Book with respect to Epidiolex®]."

217. No earlier than June 2, 2023, Biophore and Zenara sent written notice of a second Paragraph IV Certification ("Biophore and Zenara's Second Notice Letter") to GW. According to Biophore and Zenara's Second Notice Letter, Biophore and Zenara filed 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 Biophore and Zenara's Proposed Product before expiration of the '369 patent.

218. On information and belief, in connection with the filing of their ANDA as described above, Biophore and Zenara provided written certifications to the FDA, as called for by Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), indicating that they seek to obtain approval of its ANDA to engage in the commercial manufacture, use, or sale of Biophore and Zenara's Proposed Product before the expiration of the Orange Book patents with respect to Epidiolex®, one of which is the '369 patent.

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

Count I: Infringement of the '369 Patent by Teva

220. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

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

expiration of the '369 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.

222. A justiciable controversy exists between the parties hereto as to the infringement of the '369 patent.

223. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will infringe one or more claims of the '369 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Teva's Proposed Product in the United States.

224. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will induce infringement of one or more claims of the '369 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Teva's Proposed Product in the United States. On information and belief, upon FDA approval of Teva's ANDA, Teva will intentionally encourage acts of direct infringement with knowledge of the '369 patent and knowledge that its acts are encouraging infringement.

225. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will contributorily infringe one or more claims of the '369 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Teva's Proposed Product in the United States. On information and belief, Teva knew and knows that Teva's Proposed Product is designed for a use that infringes one or more claims of the '369 patent, and Teva's Proposed Product lacks a substantial non-infringing use.

226. Failure to enjoin Teva's infringement of the '369 patent will substantially and irreparably damage GW.

227. GW does not have an adequate remedy at law.

Count II: Infringement of the '369 Patent by Apotex

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

229. Apotex's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Apotex's Proposed Product, prior to the expiration of the '369 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

230. A justiciable controversy exists between the parties hereto as to the infringement of the '369 patent.

231. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will infringe one or more claims of the '369 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States.

232. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will induce infringement of one or more claims of the '369 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, upon FDA approval of Apotex's ANDA, Apotex will intentionally encourage acts of direct infringement with knowledge of the '369 patent and knowledge that its acts are encouraging infringement.

233. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex will contributorily infringe one or more claims of the '369 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Apotex's Proposed Product in the United States. On information and belief, Apotex knew and knows that

Apotex's Proposed Product is designed for a use that infringes one or more claims of the '369 patent, and Apotex's Proposed Product lacks a substantial non-infringing use.

234. Failure to enjoin Apotex's infringement of the '369 patent will substantially and irreparably damage GW.

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

Count III: Infringement of the '369 Patent by Padagis

236. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

237. Padagis's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Padagis's Proposed Product, prior to the expiration of the '369 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.

238. A justiciable controversy exists between the parties hereto as to the infringement of the '369 patent.

239. Unless enjoined by this Court, upon FDA approval of Padagis's ANDA, Padagis will infringe one or more claims of the '369 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Padagis's Proposed Product in the United States.

240. Unless enjoined by this Court, upon FDA approval of Padagis's ANDA, Padagis will induce infringement of one or more claims of the '369 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Padagis's Proposed Product in the United States. On information and belief, upon FDA approval of

Padagis's ANDA, Padagis will intentionally encourage acts of direct infringement with knowledge of the '369 patent and knowledge that its acts are encouraging infringement.

241. Unless enjoined by this Court, upon FDA approval of Padagis's ANDA, Padagis will contributorily infringe one or more claims of the '369 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Padagis's Proposed Product in the United States. On information and belief, Padagis knew and knows that Padagis's Proposed Product is designed for a use that infringes one or more claims of the '369 patent, and Padagis's Proposed Product lacks a substantial non-infringing use.

242. Failure to enjoin Padagis's infringement of the '369 patent will substantially and irreparably damage GW.

243. GW does not have an adequate remedy at law.

Count IV: Infringement of the '369 Patent by InvaGen, Cipla and API Pharma

244. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

245. The submission of ANDA No. 217522 to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of InvaGen's Proposed Product, prior to the expiration of the '369 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.

246. A justiciable controversy exists between the parties hereto as to the infringement of the '369 patent.

247. Unless enjoined by this Court, upon FDA approval of InvaGen's ANDA, InvaGen, Cipla, and API Pharma will infringe one or more claims of the '369 patent under 35

U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing InvaGen's Proposed Product in the United States.

248. Unless enjoined by this Court, upon FDA approval of InvaGen's ANDA, InvaGen, Cipla, and/or API Pharma will induce infringement of one or more claims of the '369 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing InvaGen's Proposed Product in the United States. On information and belief, upon FDA approval of InvaGen's ANDA, InvaGen, Cipla and/or API Pharma will intentionally encourage acts of direct infringement with knowledge of the '369 patent and knowledge that their acts are encouraging infringement.

249. Unless enjoined by this Court, upon FDA approval of InvaGen's ANDA, InvaGen, Cipla, and/or API Pharma will contributorily infringe one or more claims of the '369 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing InvaGen's Proposed Product in the United States. On information and belief, InvaGen, Cipla, and/or API Pharma knew and knows that InvaGen's Proposed Product is designed for a use that infringes one or more claims of the '369 patent, and InvaGen's Proposed Product lacks a substantial non-infringing use.

250. Failure to enjoin InvaGen, Cipla, and API Pharma's infringement of the '369 patent will substantially and irreparably damage GW.

251. GW does not have an adequate remedy at law.

Count V: Infringement of the '369 Patent by Lupin

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

253. Lupin's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Lupin's Proposed Product, prior to the expiration of the '369 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 the parties hereto as to the infringement of the '369 patent.

255. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin will infringe one or more claims of the '369 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Lupin's Proposed Product in the United States.

256. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin will induce infringement of one or more claims of the '369 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Lupin's Proposed Product in the United States. On information and belief, upon FDA approval of Lupin's ANDA, Lupin will intentionally encourage acts of direct infringement with knowledge of the '369 patent and knowledge that its acts are encouraging infringement.

257. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin will contributorily infringe one or more claims of the '369 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Lupin's Proposed Product in the United States. On information and belief, Lupin knew and knows that Lupin's Proposed Product is designed for a use that infringes one or more claims of the '369 patent, and Lupin's Proposed Product lacks a substantial non-infringing use.

258. Failure to enjoin Lupin's infringement of the '369 patent will substantially and irreparably damage GW.

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

Count VI: Infringement of the '369 Patent by Alkem

260. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

261. 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 '369 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.

262. A justiciable controversy exists between the parties hereto as to the infringement of the '369 patent.

263. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem will infringe one or more claims of the '369 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.

264. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem will induce infringement of one or more claims of the '369 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 '369 patent and knowledge that its acts are encouraging infringement.

265. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem will contributorily infringe one or more claims of the '369 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 '369 patent, and Alkem's Proposed Product lacks a substantial non-infringing use.

266. Failure to enjoin Alkem's infringement of the '369 patent will substantially and irreparably damage GW.

267. GW does not have an adequate remedy at law.

Count VII: Infringement of the '369 Patent by Taro

268. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

269. Taro's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Taro's Proposed Product, prior to the expiration of the '369 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.

270. A justiciable controversy exists between the parties hereto as to the infringement of the '369 patent.

271. Unless enjoined by this Court, upon FDA approval of Taro's ANDA, Taro will infringe one or more claims of the '369 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Taro's Proposed Product in the United States.

272. Unless enjoined by this Court, upon FDA approval of Taro's ANDA, Taro will induce infringement of one or more claims of the '369 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Taro's Proposed Product in the United States. On information and belief, upon FDA approval of Taro's ANDA, Taro will intentionally encourage acts of direct infringement with knowledge of the '369 patent and knowledge that its acts are encouraging infringement.

273. Unless enjoined by this Court, upon FDA approval of Taro's ANDA, Taro will contributorily infringe one or more claims of the '369 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Taro's Proposed Product in the United States. On information and belief, Taro knew and knows that Taro's Proposed Product is designed for a use that infringes one or more claims of the '369 patent, and Taro's Proposed Product lacks a substantial non-infringing use.

274. Failure to enjoin Taro's infringement of the '369 patent will substantially and irreparably damage GW.

275. GW does not have an adequate remedy at law.

Count VIII: Infringement of the '369 Patent by Ascent

276. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

277. Ascent's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Ascent's Proposed Product, prior to the expiration of the '369 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.

278. A justiciable controversy exists between the parties hereto as to the infringement of the '369 patent.

279. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent will infringe one or more claims of the '369 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Ascent's Proposed Product in the United States.

280. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent will induce infringement of one or more claims of the '369 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Ascent's Proposed Product in the United States. On information and belief, upon FDA approval of Ascent's ANDA, Ascent will intentionally encourage acts of direct infringement with knowledge of the '369 patent and knowledge that its acts are encouraging infringement.

281. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent will contributorily infringe one or more claims of the '369 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Ascent's Proposed Product in the United States. On information and belief, Ascent knew and knows that Ascent's Proposed Product is designed for a use that infringes one or more claims of the '369 patent, and Ascent's Proposed Product lacks a substantial non-infringing use.

282. Failure to enjoin Ascent's infringement of the '369 patent will substantially and irreparably damage GW.

283. GW does not have an adequate remedy at law.

Count IX: Infringement of the '369 Patent by MSN

284. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

285. MSN's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of MSN's Proposed Product, prior to the expiration of the '369 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.

286. A justiciable controversy exists between the parties hereto as to the infringement of the '369 patent.

287. Unless enjoined by this Court, upon FDA approval of MSN's ANDA, MSN will infringe one or more claims of the '369 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing MSN's Proposed Product in the United States.

288. Unless enjoined by this Court, upon FDA approval of MSN's ANDA, MSN will induce infringement of one or more claims of the '369 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing MSN's Proposed Product in the United States. On information and belief, upon FDA approval of MSN's ANDA, MSN will intentionally encourage acts of direct infringement with knowledge of the '369 patent and knowledge that its acts are encouraging infringement.

289. Unless enjoined by this Court, upon FDA approval of MSN's ANDA, MSN will contributorily infringe one or more claims of the '369 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing MSN's Proposed Product in the United States. On information and belief, MSN knew and knows that MSN's

Proposed Product is designed for a use that infringes one or more claims of the '369 patent, and MSN's Proposed Product lacks a substantial non-infringing use.

290. Failure to enjoin MSN's infringement of the '369 patent will substantially and irreparably damage GW.

291. GW does not have an adequate remedy at law.

Count X: Infringement of the '369 Patent by Biophore and Zenara

292. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

293. Biophore and Zenara's submission of their ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Biophore and Zenara's Proposed Product, prior to the expiration of the '369 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.

294. A justiciable controversy exists between the parties hereto as to the infringement of the '369 patent.

295. Unless enjoined by this Court, upon FDA approval of Biophore and Zenara's ANDA, Biophore and Zenara will infringe one or more claims of the '369 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Biophore and Zenara's Proposed Product in the United States.

296. Unless enjoined by this Court, upon FDA approval of Biophore and Zenara's ANDA, Biophore and Zenara will induce infringement of one or more claims of the '369 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Biophore and Zenara's Proposed Product in the United States. On information

and belief, upon FDA approval of Biophore and Zenara's ANDA, Biophore and Zenara will intentionally encourage acts of direct infringement with knowledge of the '369 patent and knowledge that their acts are encouraging infringement.

297. Unless enjoined by this Court, upon FDA approval of Biophore and Zenara's ANDA, Biophore and Zenara will contributorily infringe one or more claims of the '369 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Biophore and Zenara's Proposed Product in the United States. On information and belief, Biophore and Zenara knew and know that Biophore and Zenara's Proposed Product is designed for a use that infringes one or more claims of the '369 patent, and Biophore and Zenara's Proposed Product lacks a substantial non-infringing use.

298. Failure to enjoin Biophore and Zenara's infringement of the '369 patent will substantially and irreparably damage GW.

299. GW does not have an adequate remedy at law.

PRAYER FOR RELIEF AGAINST TEVA

WHEREFORE, Plaintiff GW respectfully requests the following relief:

(A) A Judgment that Teva infringed one or more claims of the '369 patent by submitting ANDA No. 217508;

(B) A Judgment that Teva has infringed, and that Teva's making, using, offering to sell, selling, or importing Teva's Proposed Product will infringe one or more claims of the '369 patent;

(C) An Order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of FDA approval of ANDA No. 217508 be a date no earlier than the later of the expiration of the '369 patent, or any later expiration of exclusivity to which GW is or becomes entitled;

(D) Preliminary and permanent injunctions enjoining Teva and its officers, agents, attorneys and employees, and those acting in privity or concert with them, from making, using, offering to sell, selling, or importing Teva's Proposed Product until after the expiration of the '369 patent, or any later expiration of exclusivity to which GW is or becomes entitled;

(E) A permanent injunction, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Teva, its officers, agents, attorneys and employees, and those acting in privity or concert with them, from practicing any method claimed in the '369 patent, or from actively inducing or contributing to the infringement of any claim of the '369 patent, until after the expiration of the '369 patent, or any later expiration of exclusivity to which GW is or becomes entitled;

(F) A Judgment that the commercial manufacture, use, importation into the United States, offer for sale, and/or sale of Teva's Proposed Product will directly infringe, induce and/or contribute to infringement of one or more claims of the '369 patent;

(G) To the extent that Teva has committed any acts with respect to the methods claimed in the '369 patent, other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), a Judgment awarding GW damages for such acts;

(H) If Teva engages in the commercial manufacture, use, importation into the United States, offer for sale, and/or sale of Teva's Proposed Product prior to the expiration of the '369 patent, a Judgment awarding damages to GW resulting from such infringement, together with interest;

(I) A Judgment declaring that the '369 patent remains valid and enforceable;

(J) A Judgment that this is an exceptional case pursuant to 35 U.S.C. § 285 and awarding GW 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 APOTEX

WHEREFORE, Plaintiff GW respectfully requests the following relief:

(A) A Judgment that Apotex infringed one or more claims of the '369 patent by submitting ANDA No. 217699;

(B) A Judgment that Apotex has infringed, and that Apotex's making, using, offering to sell, selling, or importing Apotex's Proposed Product will infringe one or more claims of the '369 patent;

(C) An Order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of FDA approval of ANDA No. 217699 be a date no earlier than the later of the expiration of the '369 patent, or any later expiration of exclusivity to which GW is or becomes entitled;

(D) Preliminary and permanent injunctions enjoining Apotex and its officers, agents, attorneys and employees, and those acting in privity or concert with them, from making, using, offering to sell, selling, or importing Apotex's Proposed Product until after the expiration of the '369 patent, or any later expiration of exclusivity to which GW is or becomes entitled;

(E) A permanent injunction, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Apotex, its officers, agents, attorneys and employees, and those acting in privity or concert with them, from practicing any method claimed in the '369 patent, or from actively inducing or contributing to the infringement of any claim of the '369 patent, until after the expiration of the '369 patent, or any later expiration of exclusivity to which GW is or becomes entitled;

(F) A Judgment that the commercial manufacture, use, importation into the United States, offer for sale, and/or sale of Apotex's Proposed Product will directly infringe, induce and/or contribute to infringement of one or more claims of the '369 patent;

(G) To the extent that Apotex has committed any acts with respect to the methods claimed in the '369 patent, other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), a Judgment awarding GW damages for such acts;

(H) If Apotex engages in the commercial manufacture, use, importation into the United States, offer for sale, and/or sale of Apotex's Proposed Product prior to the expiration of the '369 patent, a Judgment awarding damages to GW resulting from such infringement, together with interest;

(I) A Judgment declaring that the '369 patent remains valid and enforceable;

(J) A Judgment that this is an exceptional case pursuant to 35 U.S.C. § 285 and awarding GW 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 PADAGIS

WHEREFORE, Plaintiff GW respectfully requests the following relief:

(A) A Judgment that Padagis infringed one or more claims of the '369 patent by submitting ANDA No. 215865;

(B) A Judgment that Padagis has infringed, and that Padagis's making, using, offering to sell, selling, or importing Padagis's Proposed Product will infringe one or more claims of the '369 patent;

(C) An Order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of FDA approval of ANDA No. 215865 be a date no earlier than the later of the expiration of the '369 patent, or any later expiration of exclusivity to which GW is or becomes entitled;

(D) Preliminary and permanent injunctions enjoining Padagis and its officers, agents, attorneys and employees, and those acting in privity or concert with them, from making, using,

offering to sell, selling, or importing Padagis's Proposed Product until after the expiration of the '369 patent, or any later expiration of exclusivity to which GW is or becomes entitled;

(E) A permanent injunction, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Padagis, its officers, agents, attorneys and employees, and those acting in privity or concert with them, from practicing any method claimed in the '369 patent, or from actively inducing or contributing to the infringement of any claim of the '369 patent, until after the expiration of the '369 patent, or any later expiration of exclusivity to which GW is or becomes entitled;

(F) A Judgment that the commercial manufacture, use, importation into the United States, offer for sale, and/or sale of Padagis's Proposed Product will directly infringe, induce and/or contribute to infringement of one or more claims of the '369 patent;

(G) To the extent that Padagis has committed any acts with respect to the methods claimed in the '369 patent, other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), a Judgment awarding GW damages for such acts;

(H) If Padagis engages in the commercial manufacture, use, importation into the United States, offer for sale, and/or sale of Padagis's Proposed Product prior to the expiration of the '369 patent, a Judgment awarding damages to GW resulting from such infringement, together with interest;

(I) A Judgment declaring that the '369 patent remains valid and enforceable;

(J) A Judgment that this is an exceptional case pursuant to 35 U.S.C. § 285 and awarding GW 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 INVAGEN, CIPLA, AND API PHARMA

WHEREFORE, Plaintiff GW respectfully requests the following relief:

(A) A Judgment that InvaGen, Cipla, and/or API Pharma infringed one or more claims of the ’369 patent by submitting ANDA No. 217522;

(B) A Judgment that InvaGen, Cipla, and/or API Pharma have infringed, and that InvaGen, Cipla, and API Pharma’s making, using, offering to sell, selling, or importing InvaGen’s Proposed Product will infringe one or more claims of the ’369 patent;

(C) An Order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of FDA approval of ANDA No. 217522 be a date no earlier than the later of the expiration of the ’369 patent, or any later expiration of exclusivity to which GW is or becomes entitled;

(D) Preliminary and permanent injunctions enjoining InvaGen, Cipla, and API Pharma, and their officers, agents, attorneys and employees, and those acting in privity or concert with them, from making, using, offering to sell, selling, or importing InvaGen’s Proposed Product until after the expiration of the ’369 patent, or any later expiration of exclusivity to which GW is or becomes entitled;

(E) A permanent injunction, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining InvaGen, Cipla, and API Pharma, and their officers, agents, attorneys and employees, and those acting in privity or concert with them, from practicing any method claimed in the ’369 patent, or from actively inducing or contributing to the infringement of any claim of the ’369 patent, until after the expiration of the ’369 patent, or any later expiration of exclusivity to which GW is or becomes entitled;

(F) A Judgment that the commercial manufacture, use, importation into the United States, offer for sale, and/or sale of InvaGen’s Proposed Product will directly infringe, induce and/or contribute to infringement of one or more claims of the ’369 patent;

(G) To the extent that InvaGen, Cipla, and/or API Pharma have committed any acts with respect to the methods claimed in the '369 patent, other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), a Judgment awarding GW damages for such acts;

(H) If InvaGen, Cipla, and/or API Pharma engages in the commercial manufacture, use, importation into the United States, offer for sale, and/or sale of InvaGen's Proposed Product prior to the expiration of the '369 patent, a Judgment awarding damages to GW resulting from such infringement, together with interest;

(I) A Judgment declaring that the '369 patent remains valid and enforceable;

(J) A Judgment that this case is exceptional pursuant to 35 U.S.C. § 285 and awarding GW 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 LUPIN

WHEREFORE, Plaintiff GW respectfully requests the following relief:

(A) A Judgment that Lupin infringed one or more claims of the '369 patent by submitting ANDA No. 217871;

(B) A Judgment that Lupin has infringed, and that Lupin's making, using, offering to sell, selling, or importing Lupin's Proposed Product will infringe one or more claims of the '369 patent;

(C) An Order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of FDA approval of ANDA No. 217871 be a date no earlier than the later of the expiration of the '369 patent, or any later expiration of exclusivity to which GW is or becomes entitled;

(D) Preliminary and permanent injunctions enjoining Lupin and its officers, agents, attorneys and employees, and those acting in privity or concert with them, from making, using,

offering to sell, selling, or importing Lupin's Proposed Product until after the expiration of the '369 patent, or any later expiration of exclusivity to which GW is or becomes entitled;

(E) A permanent injunction, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Lupin, its officers, agents, attorneys and employees, and those acting in privity or concert with them, from practicing any method claimed in the '369 patent, or from actively inducing or contributing to the infringement of any claim of the '369 patent, until after the expiration of the '369 patent, or any later expiration of exclusivity to which GW is or becomes entitled;

(F) A Judgment that the commercial manufacture, use, importation into the United States, offer for sale, and/or sale of Lupin's Proposed Product will directly infringe, induce and/or contribute to infringement of one or more claims of the '369 patent;

(G) To the extent that Lupin has committed any acts with respect to the methods claimed in the '369 patent, other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), a Judgment awarding GW damages for such acts;

(H) If Lupin engages in the commercial manufacture, use, importation into the United States, offer for sale, and/or sale of Lupin's Proposed Product prior to the expiration of the '369 patent, a Judgment awarding damages to GW resulting from such infringement, together with interest;

(I) A Judgment declaring that the '369 patent remains valid and enforceable;

(J) A Judgment that this case is exceptional pursuant to 35 U.S.C. § 285 and awarding GW 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 ALKEM

WHEREFORE, Plaintiff GW respectfully requests the following relief:

(A) A Judgment that Alkem infringed one or more claims of the ’369 patent by submitting ANDA No. 217977;

(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 the ’369 patent;

(C) An Order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of FDA approval of ANDA No. 217977 be a date no earlier than the later of the expiration of the ’369 patent, or any later expiration of exclusivity to which GW is or becomes entitled;

(D) Preliminary and permanent injunctions enjoining Alkem and its officers, agents, attorneys and employees, and those acting in privity or concert with them, from making, using, offering to sell, selling, or importing Alkem’s Proposed Product until after the expiration of the ’369 patent, or any later expiration of exclusivity to which GW 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 or concert with them, from practicing any method claimed in the ’369 patent, or from actively inducing or contributing to the infringement of any claim of the ’369 patent, until after the expiration of the ’369 patent, or any later expiration of exclusivity to which GW 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 the ’369 patent;

(G) To the extent that Alkem has committed any acts with respect to the methods claimed in the '369 patent, other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), a Judgment awarding GW 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 '369 patent, a Judgment awarding damages to GW resulting from such infringement, together with interest;

(I) A Judgment declaring that the '369 patent remains valid and enforceable;

(J) A Judgment that this case is exceptional pursuant to 35 U.S.C. § 285 and awarding GW 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 TARO

WHEREFORE, Plaintiff GW respectfully requests the following relief:

(A) A Judgment that Taro infringed one or more claims of the '369 patent by submitting ANDA No. 217930;

(B) A Judgment that Taro has infringed, and that Taro's making, using, offering to sell, selling, or importing Taro's Proposed Product will infringe one or more claims of the '369 patent;

(C) An Order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of FDA approval of ANDA No. 217930 be a date no earlier than the later of the expiration of the '369 patent, or any later expiration of exclusivity to which GW is or becomes entitled;

(D) Preliminary and permanent injunctions enjoining Taro and its officers, agents, attorneys and employees, and those acting in privity or concert with them, from making, using,

offering to sell, selling, or importing Taro's Proposed Product until after the expiration of the '369 patent, or any later expiration of exclusivity to which GW is or becomes entitled;

(E) A permanent injunction, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Taro, its officers, agents, attorneys and employees, and those acting in privity or concert with them, from practicing any method claimed in the '369 patent, or from actively inducing or contributing to the infringement of any claim of the '369 patent, until after the expiration of the '369 patent, or any later expiration of exclusivity to which GW is or becomes entitled;

(F) A Judgment that the commercial manufacture, use, importation into the United States, offer for sale, and/or sale of Taro's Proposed Product will directly infringe, induce and/or contribute to infringement of one or more claims of the '369 patent;

(G) To the extent that Taro has committed any acts with respect to the methods claimed in the '369 patent, other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), a Judgment awarding GW damages for such acts;

(H) If Taro engages in the commercial manufacture, use, importation into the United States, offer for sale, and/or sale of Taro's Proposed Product prior to the expiration of the '369 patent, a Judgment awarding damages to GW resulting from such infringement, together with interest;

(I) A Judgment declaring that the '369 patent remains valid and enforceable;

(J) A Judgment that this case is exceptional pursuant to 35 U.S.C. § 285 and awarding GW 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 ASCENT

WHEREFORE, Plaintiff GW respectfully requests the following relief:

(A) A Judgment that Ascent infringed one or more claims of the ’369 patent by submitting ANDA No. 217994;

(B) A Judgment that Ascent has infringed, and that Ascent’s making, using, offering to sell, selling, or importing Ascent’s Proposed Product will infringe one or more claims of the ’369 patent;

(C) An Order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of FDA approval of ANDA No. 217994 be a date no earlier than the later of the expiration of the ’369 patent, or any later expiration of exclusivity to which GW is or becomes entitled;

(D) Preliminary and permanent injunctions enjoining Ascent and its officers, agents, attorneys and employees, and those acting in privity or concert with them, from making, using, offering to sell, selling, or importing Ascent’s Proposed Product until after the expiration of the ’369 patent, or any later expiration of exclusivity to which GW is or becomes entitled;

(E) A permanent injunction, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Ascent, its officers, agents, attorneys and employees, and those acting in privity or concert with them, from practicing any method claimed in the ’369 patent, or from actively inducing or contributing to the infringement of any claim of the ’369 patent, until after the expiration of the ’369 patent, or any later expiration of exclusivity to which GW is or becomes entitled;

(F) A Judgment that the commercial manufacture, use, importation into the United States, offer for sale, and/or sale of Ascent’s Proposed Product will directly infringe, induce and/or contribute to infringement of one or more claims of the ’369 patent;

(G) To the extent that Ascent has committed any acts with respect to the methods claimed in the '369 patent, other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), a Judgment awarding GW damages for such acts;

(H) If Ascent engages in the commercial manufacture, use, importation into the United States, offer for sale, and/or sale of Ascent's Proposed Product prior to the expiration of the '369 patent, a Judgment awarding damages to GW resulting from such infringement, together with interest;

(I) A Judgment declaring that the '369 patent remains valid and enforceable;

(J) A Judgment that this case is exceptional pursuant to 35 U.S.C. § 285 and awarding GW 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 MSN

WHEREFORE, Plaintiff GW respectfully requests the following relief:

(A) A Judgment that MSN infringed one or more claims of the '369 patent by submitting ANDA No. 217911;

(B) A Judgment that MSN has infringed, and that MSN's making, using, offering to sell, selling, or importing MSN's Proposed Product will infringe one or more claims of the '369 patent;

(C) An Order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of FDA approval of ANDA No. 217911 be a date no earlier than the later of the expiration of the '369 patent, or any later expiration of exclusivity to which GW is or becomes entitled;

(D) Preliminary and permanent injunctions enjoining MSN and its officers, agents, attorneys and employees, and those acting in privity or concert with them, from making, using,

offering to sell, selling, or importing MSN's Proposed Product until after the expiration of the '369 patent, or any later expiration of exclusivity to which GW is or becomes entitled;

(E) A permanent injunction, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining MSN, its officers, agents, attorneys and employees, and those acting in privity or concert with them, from practicing any method claimed in the '369 patent, or from actively inducing or contributing to the infringement of any claim of the '369 patent, until after the expiration of the '369 patent, or any later expiration of exclusivity to which GW is or becomes entitled;

(F) A Judgment that the commercial manufacture, use, importation into the United States, offer for sale, and/or sale of MSN's Proposed Product will directly infringe, induce and/or contribute to infringement of one or more claims of the '369 patent;

(G) To the extent that MSN has committed any acts with respect to the methods claimed in the '369 patent, other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), a Judgment awarding GW damages for such acts;

(H) If MSN engages in the commercial manufacture, use, importation into the United States, offer for sale, and/or sale of MSN's Proposed Product prior to the expiration of the '369 patent, a Judgment awarding damages to GW resulting from such infringement, together with interest;

(I) A Judgment declaring that the '369 patent remains valid and enforceable;

(J) A Judgment that this case is exceptional pursuant to 35 U.S.C. § 285 and awarding GW 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 BIOPHORE AND ZENARA

WHEREFORE, Plaintiff GW respectfully requests the following relief:

(A) A Judgment that Biophore and Zenara infringed one or more claims of the '369 patent by submitting ANDA No. 217910;

(B) A Judgment that Biophore and Zenara have infringed, and that Biophore and Zenara's making, using, offering to sell, selling, or importing Biophore and Zenara's Proposed Product will infringe one or more claims of the '369 patent;

(C) An Order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of FDA approval of ANDA No. 217910 be a date no earlier than the later of the expiration of the '369 patent, or any later expiration of exclusivity to which GW is or becomes entitled;

(D) Preliminary and permanent injunctions enjoining Biophore and Zenara and their officers, agents, attorneys and employees, and those acting in privity or concert with them, from making, using, offering to sell, selling, or importing Biophore and Zenara's Proposed Product until after the expiration of the '369 patent, or any later expiration of exclusivity to which GW is or becomes entitled;

(E) A permanent injunction, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Biophore and Zenara, their officers, agents, attorneys and employees, and those acting in privity or concert with them, from practicing any method claimed in the '369 patent, or from actively inducing or contributing to the infringement of any claim of the '369 patent, until after the expiration of the '369 patent, or any later expiration of exclusivity to which GW is or becomes entitled;

(F) A Judgment that the commercial manufacture, use, importation into the United States, offer for sale, and/or sale of Biophore and Zenara's Proposed Product will directly infringe, induce and/or contribute to infringement of one or more claims of the '369 patent;

(G) To the extent that Biophore and Zenara have committed any acts with respect to the methods claimed in the '369 patent, other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), a Judgment awarding GW damages for such acts;

(H) If Biophore and Zenara engage in the commercial manufacture, use, importation into the United States, offer for sale, and/or sale of Biophore and Zenara's Proposed Product prior to the expiration of the '369 patent, a Judgment awarding damages to GW resulting from such infringement, together with interest;

(I) A Judgment declaring that the '369 patent remains valid and enforceable;

(J) A Judgment that this case is exceptional pursuant to 35 U.S.C. § 285 and awarding GW 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: July 21, 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 Plaintiff
GW Research Limited

Of Counsel:

F. Dominic Cerrito
Eric C. Stops
Evangeline Shih
Daniel C. Wiesner
Gabriel P. Brier
Nicholas A. LoCastro
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 captioned *GW Research Ltd. v. Teva Pharm., Inc., et al.*, Civil Action No. 23-cv-00018 (MEF)(AME) (D.N.J.) is related to the matter in controversy because the matter in controversy involves the same parties, because the matters involve related patents with common inventors, and because Defendants are seeking FDA approval to market a generic version of the same pharmaceutical product.

I further certify that, to the best of my knowledge, 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: July 21, 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 Plaintiff
GW Research Limited

Of Counsel:

F. Dominic Cerrito
Eric C. Stops
Evangeline Shih
Daniel C. Wiesner
Gabriel P. Brier
Nicholas A. LoCastro
QUINN EMANUEL URQUHART & SULLIVAN, LLP
51 Madison Avenue, 22nd Floor
New York, New York 10010
(212) 849-7000