IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK

GW RESEARCH LIMITED, **Plaintiff,** **v.** **INVAGEN PHARMACEUTICALS, INC., CIPLA LTD., CIPLA USA, INC., API PHARMA TECH LLC,** **Defendants.**	**Civil Action No. _____** **COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiff GW Research Limited ("GW"), by its undersigned attorneys, for its Complaint against defendants InvaGen Pharmaceuticals, Inc. ("InvaGen"), Cipla Ltd., Cipla USA, Inc. ("Cipla USA") (Cipla Ltd. and Cipla USA, together, "Cipla"), and API Pharma Tech LLC ("API Pharma") (InvaGen, Cipla, API Pharma, collectively, "Defendants"), alleges as follows:

INTRODUCTION

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 filing of Abbreviated New Drug Application No. 217522 ("InvaGen's ANDA") with the United States Food and Drug Administration ("FDA"), which seeks approval to commercially market a generic version of GW's cannabidiol oral solution drug product prior to the expiration of United States Patent Nos. 9,949,937 ("the '937 patent"), 9,956,183 ("the '183 patent"), 9,956,184 ("the '184 patent"), 9,956,185 ("the '185 patent"), 9,956,186 ("the '186 patent"), 10,092,525 ("the '525 patent"), 10,111,840 ("the '840 patent"), 10,137,095 ("the '095 patent"), 10,603,288 ("the '288 patent"), 10,709,671 ("the '671 patent"), 10,709,673 ("the '673 patent"), 10,709,674 ("the '674 patent"), 10,849,860 ("the '860 patent"), 10,966,939 ("the '939 patent"), 11,096,905 ("the '905 patent"), 11,154,516 ("the '516 patent"), 11,207,292 ("the '292 patent"), 11,311,498 ("the '498 patent"), 11,357,741 ("the '741 patent"), and 11,446,258 ("the '258 patent") (together, "the patents-in-suit"), all owned by GW.

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, 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.

5. 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.

6. 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.

7. 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.

JURISDICTION AND VENUE

8. This Court has jurisdiction over the subject matter of Counts I through XX against InvaGen, Cipla, and API Pharma pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

9. As set forth in Paragraphs 10-15 below, the Court has personal jurisdiction over InvaGen by virtue of, *inter alia*, its systematic and continuous contacts with the State of New York.

10. 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.

11. 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.

12. 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").

13. 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 York and in this Judicial District, prior to the expiration of the patents-in-suit.

14. On information and belief, InvaGen maintains a physical place of business in this Judicial District, in Hauppauge, New York.

15. On information and belief, InvaGen is registered with the New York Department of State Division of Corporations as a business operating in New York under Department of State (DOS) ID number 2980487.

16. For at least the foregoing reasons set forth above in Paragraphs 10-15, venue is proper in this Judicial District with respect to InvaGen pursuant to 28 U.S.C. § 1400(b).

17. As set forth in Paragraphs 18-24 below, the Court has personal jurisdiction over Cipla USA by virtue of, *inter alia*, its systematic and continuous contacts with the State of New York.

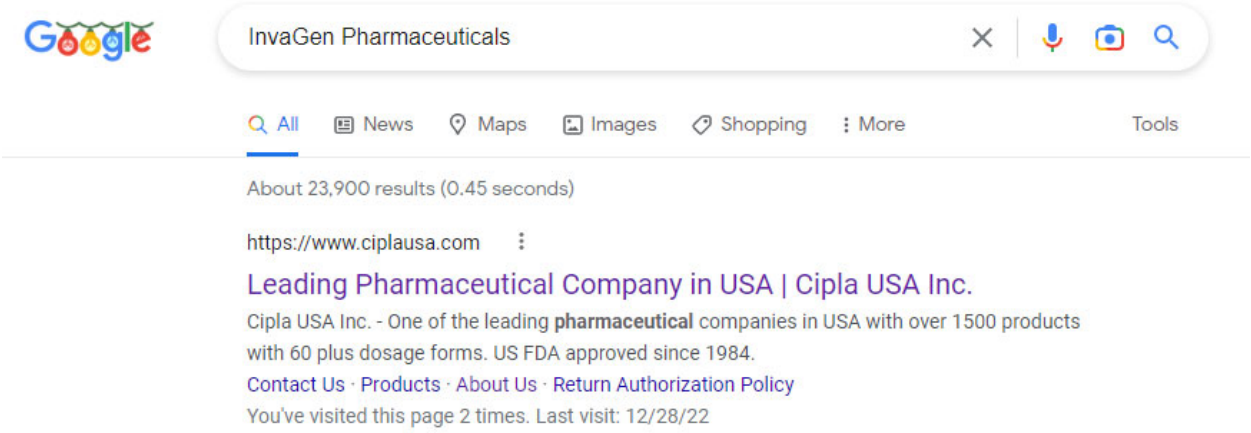
18. On information and belief, Cipla USA, alone or at the direction of Cipla Ltd. and/or InvaGen, purposefully has conducted and continues to conduct business in this Judicial District.

19. 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.

20. 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 York and in this Judicial District, prior to the expiration of the patents-in-suit.

21. On information and belief, Cipla USA maintains a physical place of business in this Judicial District, in at least Central Islip, New York. *See* https://www.ciplausa.com/contact-us (last visited, Dec. 28, 2022).

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



23. 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).

24. On information and belief, Cipla USA is registered with the New York Department of State Division of Corporations as a foreign business corporation in New York under the DOS ID 5641567.

25. For at least the foregoing reasons set forth above in Paragraphs 18-24, venue is proper in this Judicial District with respect to Cipla USA pursuant to 28 U.S.C. § 1400(b).

26. As set forth in Paragraphs 27-36 below, the Court has personal jurisdiction over Cipla Ltd. by virtue of, *inter alia*, its systematic and continuous contacts with the State of New York.

27. 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.

28. 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.

29. 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 York and in this Judicial District, prior to the expiration of the patents-in-suit.

30. 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.

31. On information and belief, Cipla Ltd. considers ANDA applications owned by InvaGen amongst the ANDA filings 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, December 28, 2022)); *see also id.* at 116 (figures "include ANDAs owned by Cipla and InvaGen Pharmaceuticals Inc.").

32. 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.

33. 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.).

34. 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.

35. 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 York, 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 York, including the marketing, distribution, and/or sale of generic pharmaceutical drugs in New York, 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.

36. 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.

37. 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).

38. As set forth in Paragraphs 39-42 below, the Court has personal jurisdiction over API Pharma by virtue of, *inter alia*, its systematic and continuous contacts with the State of New York.

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

40. 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.

41. 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 York and in this Judicial District, prior to the expiration of the patents-in-suit.

42. For at least the foregoing reasons set forth above in Paragraphs 39-42, venue is proper in this Judicial District with respect to API Pharma pursuant to 28 U.S.C. § 1400(b).

FACTUAL BACKGROUND

The Patents-in-Suit

43. On April 24, 2018, the United States Patent and Trademark Office ("USPTO") duly and lawfully issued the '937 patent, entitled, "Use of Cannabinoids in the Treatment of Epilepsy." The face of the '937 patent identifies Geoffrey Guy, Stephen Wright, Alice Mead, and Orrin Devinsky as the inventors. Plaintiff GW is the present assignee of the '937 patent; the assignments recorded with the USPTO at Reel: 047190, Frame: 0253 and Reel: 042294, Frame: 0829. A copy of the '937 patent is attached hereto as Exhibit A.

44. On May 1, 2018, the USPTO duly and lawfully issued the '183 patent, entitled, "Use of Cannabinoids in the Treatment of Epilepsy." The face of the '183 patent identifies Geoffrey Guy, Stephen Wright, Alice Mead, and Orrin Devinsky as the inventors. Plaintiff GW is the present assignee of the '183 patent; the assignments are recorded with the USPTO at Reel:

047189, Frame: 0746 and Reel: 042294, Frame: 0172. A copy of the '183 patent is attached hereto as Exhibit B.

45. On May 1, 2018, the USPTO duly and lawfully issued the '184 patent, entitled, "Use of Cannabinoids in the Treatment of Epilepsy." The face of the '184 patent identifies Geoffrey Guy, Stephen Wright, Alice Mead, and Orrin Devinsky as the inventors. Plaintiff GW is the present assignee of the '184 patent; the assignments are recorded with the USPTO at Reel: 047189, Frame: 0683 and Reel: 042294, Frame: 0661. A copy of the '184 patent is attached hereto as Exhibit C.

46. On May 1, 2018, the USPTO duly and lawfully issued the '185 patent, entitled, "Use of Cannabinoids in the Treatment of Epilepsy." The face of the '185 patent identifies Geoffrey Guy, Stephen Wright, Alice Mead, and Orrin Devinsky as the inventors. Plaintiff GW is the present assignee of the '185 patent; the assignments are recorded with the USPTO at Reel: 047189, Frame: 0891 and Reel: 042298, Frame: 0226. A copy of the '185 patent is attached hereto as Exhibit D.

47. On May 1, 2018, the USPTO duly and lawfully issued the '186 patent, entitled, "Use of Cannabinoids in the Treatment of Epilepsy." The face of the '186 patent identifies Geoffrey Guy, Stephen Wright, Alice Mead, and Orrin Devinsky as the inventors. Plaintiff GW is the present assignee of the '186 patent; the assignments are recorded with the USPTO at Reel: 047190, Frame: 0123 and Reel: 042298, Frame: 0023. A copy of the '186 patent is attached hereto as Exhibit E.

48. On October 9, 2018, the USPTO duly and lawfully issued the '525 patent, entitled, "Use of Cannabinoids in the Treatment of Epilepsy." The face of the '525 patent identifies Geoffrey Guy, Stephen Wright, Alice Mead, and Orrin Devinsky as the inventors.

Plaintiff GW is the present assignee of the ’525 patent; the assignments are recorded with the USPTO at Reel: 047189, Frame: 0818 and Reel: 042301, Frame: 0452. A copy of the ’525 patent is attached hereto as Exhibit F.

49. On October 30, 2018, the USPTO duly and lawfully issued the ’840 patent, entitled, “Use of Cannabinoids in the Treatment of Epilepsy.” The face of the ’840 patent identifies Geoffrey Guy, Stephen Wright, Alice Mead, and Orrin Devinsky as the inventors. Plaintiff GW is the present assignee of the ’840 patent; the assignments are recorded with the USPTO at Reel: 047191, Frame: 0800 and Reel: 039174, Frame: 0494. A copy of the ’840 patent is attached hereto as Exhibit G.

50. On November 27, 2018, the USPTO duly and lawfully issued the ’095 patent, entitled, “Use of Cannabinoids in the Treatment of Epilepsy.” The face of the ’095 patent identifies Geoffrey Guy, Stephen Wright, Alice Mead, and Orrin Devinsky as the inventors. Plaintiff GW is the present assignee of the ’095 patent; the assignments are recorded with the USPTO at Reel: 047191, Frame: 0870 and Reel: 042301, Frame: 0792. A copy of the ’095 patent is attached hereto as Exhibit H.

51. On March 31, 2020, the USPTO duly and lawfully issued the ’288 patent, entitled, “Use of Cannabinoids in the Treatment of Epilepsy” to GW as assignee. The face of the ’288 patent identifies Geoffrey Guy, Stephen Wright, Alice Mead, and Orrin Devinsky as the inventors. A copy of the ’288 patent is attached hereto as Exhibit I.

52. On July 14, 2020, the USPTO duly and lawfully issued the ’671 patent, entitled, “Use of Cannabinoids in the Treatment of Epilepsy” to GW as assignee. The face of the ’671 patent identifies Geoffrey Guy, Stephen Wright, and Orrin Devinsky as the inventors. A copy of the ’671 patent is attached hereto as Exhibit J.

53. On July 14, 2020, the USPTO duly and lawfully issued the '673 patent, entitled, "Use of Cannabinoids in the Treatment of Epilepsy" to GW as assignee. The face of the '673 patent identifies Geoffrey Guy as the inventor. A copy of the '673 patent is attached hereto as Exhibit K.

54. On July 14, 2020, the USPTO duly and lawfully issued the '674 patent, entitled, "Use of Cannabinoids in the Treatment of Epilepsy" to GW as assignee. The face of the '674 patent identifies Geoffrey Guy, Stephen Wright, and Orrin Devinsky as the inventors. A copy of the '674 patent is attached hereto as Exhibit L.

55. On December 1, 2020, the USPTO duly and lawfully issued the '860 patent, entitled, "Use of Cannabinoids in the Treatment of Epilepsy" to GW as assignee. The face of the '860 patent identifies Geoffrey Guy, Stephen Wright, and Orrin Devinsky as the inventors. A copy of the '860 patent is attached hereto as Exhibit M.

56. On April 6, 2021, the USPTO duly and lawfully issued the '939 patent, entitled, "Use of Cannabinoids in the Treatment of Epilepsy" to GW as assignee. The face of the '939 patent identifies Geoffrey Guy, Stephen Wright, and Orrin Devinsky as the inventors. A copy of the '939 patent is attached hereto as Exhibit N.

57. On August 24, 2021, the USPTO duly and lawfully issued the '905 patent, entitled, "Use of Cannabinoids in the Treatment of Epilepsy" to GW as assignee. The face of the '905 patent identifies Geoffrey Guy, Stephen Wright, and Orrin Devinsky as the inventors. A copy of the '905 patent is attached hereto as Exhibit O.

58. On October 26, 2021, the USPTO duly and lawfully issued the '516 patent, entitled, "Use of Cannabinoids in the Treatment of Epilepsy" to GW as assignee. The face of the

'516 patent identifies Geoffrey Guy, Stephen Wright, and Orrin Devinsky as the inventors. A copy of the '516 patent is attached hereto as Exhibit P.

59. On December 28, 2021, the USPTO duly and lawfully issued the '292 patent, entitled, "Cannabidiol preparations and its uses" to GW as assignee. The face of the '292 patent identifies Geoffrey Guy, Volker Knappertz, Benjamin Whalley, Marie Woolley-Roberts, James Brodie, Katarzyna Lach-Falcone, Alan Sutton, Royston Gray, and Rohini Rajyalaxmi Rana as the inventors. A copy of the '292 patent is attached hereto as Exhibit Q.

60. On April 26, 2022, the USPTO duly and lawfully issued the '498 patent, entitled, "Use of Cannabinoids in the Treatment of Epilepsy" to GW as assignee. The face of the '498 patent identifies Geoffrey Guy, Stephen Wright, and Orrin Devinsky as the inventors. A copy of the '498 patent is attached hereto as Exhibit R.

61. On June 14, 2022, the USPTO duly and lawfully issued the '741 patent, entitled, "Use of Cannabinoids in the Treatment of Epilepsy" to GW as assignee. The face of the '741 patent identifies Geoffrey Guy, Stephen Wright, and Orrin Devinsky as the inventors. A copy of the '741 patent is attached hereto as Exhibit S.

62. On September 20, 2022, the USPTO duly and lawfully issued the '258 patent, entitled, "Use of Cannabinoids in the Treatment of Epilepsy" to GW as assignee. The face of the '258 patent identifies Geoffrey Guy, Stephen Wright, and Orrin Devinsky as the inventors. A copy of the '258 patent is attached hereto as Exhibit T.

The Epidiolex® Drug Product

63. 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 patents-in-suit cover, *inter alia*, cannabidiol pharmaceutical compositions and methods of using Epidiolex® to treat LGS, DS, and/or TSC.

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

Actions Giving Rise to Suit

65. 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 patents-in-suit expire.

66. 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 the expiration of certain patents listed in the Orange Book with respect to Epidiolex®.

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

68. 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) ("API Pharma's Paragraph IV

Certification"), alleging that the claims of the '937 patent, the '183 patent, the '184 patent, the '185 patent, the '186 patent, the '525 patent, the '840 patent, the '095 patent, the '288 patent, the '671 patent, the '673 patent, the '674 patent, the '860 patent, the '939 patent, the '905 patent, the '516 patent, the '292 patent, the '498 patent, the '741 patent, and the '258 patent are invalid, unenforceable, and/or will not be infringed by the activities described in ANDA No. 217522.

69. 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)."

70. On information and belief, and as evidenced by the facts set forth in Paragraphs 10-41 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.

71. On information and belief, and as evidenced by the facts set forth in Paragraphs 10-41 above, following FDA approval of ANDA No. 217522, InvaGen, Cipla, and API Pharma intend to directly benefit from sales of InvaGen's Proposed Product.

COUNT I: INFRINGEMENT OF THE '937 PATENT

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

73. 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 '937 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.

74. A justiciable controversy exists between the parties hereto as to the infringement of the '937 patent.

75. 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 '937 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.

76. 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 '937 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 '937 patent and knowledge that their acts are encouraging infringement.

77. 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 '937 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 '937 patent, and InvaGen's Proposed Product lacks a substantial non-infringing use.

78. Failure to enjoin InvaGen, Cipla, and API Pharma's infringement of the '937 patent will substantially and irreparably damage GW.

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

COUNT II: INFRINGEMENT OF THE '183 PATENT

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

81. 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 '183 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.

82. A justiciable controversy exists between the parties hereto as to the infringement of the '183 patent.

83. 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 '183 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.

84. 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 '183 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 '183 patent and knowledge that their acts are encouraging infringement.

85. 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 '183 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 '183 patent, and InvaGen's Proposed Product lacks a substantial non-infringing use.

86. Failure to enjoin InvaGen, Cipla, and API Pharma's infringement of the '183 patent will substantially and irreparably damage GW.

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

COUNT III: INFRINGEMENT OF THE '184 PATENT

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

89. 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 '184 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.

90. A justiciable controversy exists between the parties hereto as to the infringement of the '184 patent.

91. 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 '184 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.

92. 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 '184 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 '184 patent and knowledge that their acts are encouraging infringement.

93. 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 '184 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 '184 patent, and InvaGen's Proposed Product lacks a substantial non-infringing use.

94. Failure to enjoin InvaGen, Cipla, and API Pharma's infringement of the '184 patent will substantially and irreparably damage GW.

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

COUNT IV: INFRINGEMENT OF THE '185 PATENT

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

97. 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 '185 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.

98. A justiciable controversy exists between the parties hereto as to the infringement of the '185 patent.

99. 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 '185 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.

100. 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 '185 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 '185 patent and knowledge that their acts are encouraging infringement.

101. 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 '185 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 '185 patent, and InvaGen's Proposed Product lacks a substantial non-infringing use.

102. Failure to enjoin InvaGen, Cipla, and API Pharma's infringement of the '185 patent will substantially and irreparably damage GW.

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

COUNT V: INFRINGEMENT OF THE '186 PATENT

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

105. 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 '186 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.

106. A justiciable controversy exists between the parties hereto as to the infringement of the '186 patent.

107. 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 '186 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.

108. 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 '186 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 '186 patent and knowledge that their acts are encouraging infringement.

109. 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 '186 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 '186 patent, and InvaGen's Proposed Product lacks a substantial non-infringing use.

110. Failure to enjoin InvaGen, Cipla, and API Pharma's infringement of the '186 patent will substantially and irreparably damage GW.

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

COUNT VI: INFRINGEMENT OF THE '525 PATENT

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

113. 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 '525 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.

114. A justiciable controversy exists between the parties hereto as to the infringement of the '525 patent.

115. 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 '525 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.

116. 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 '525 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 '525 patent and knowledge that their acts are encouraging infringement.

117. 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 '525 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 '525 patent, and InvaGen's Proposed Product lacks a substantial non-infringing use.

118. Failure to enjoin InvaGen, Cipla, and API Pharma's infringement of the '525 patent will substantially and irreparably damage GW.

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

COUNT VII: INFRINGEMENT OF THE '840 PATENT

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

121. 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 '840 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

122. A justiciable controversy exists between the parties hereto as to the infringement of the '840 patent.

123. 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 '840 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.

124. 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 '840 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 '840 patent and knowledge that their acts are encouraging infringement.

125. 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 '840 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 '840 patent, and InvaGen's Proposed Product lacks a substantial non-infringing use.

126. Failure to enjoin InvaGen, Cipla, and API Pharma's infringement of the '840 patent will substantially and irreparably damage GW.

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

COUNT VIII: INFRINGEMENT OF THE '095 PATENT

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

129. 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 '095 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.

130. A justiciable controversy exists between the parties hereto as to the infringement of the '095 patent.

131. 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 '095 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.

132. 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 '095 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 '095 patent and knowledge that their acts are encouraging infringement.

133. 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 '095 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 '095 patent, and InvaGen's Proposed Product lacks a substantial non-infringing use.

134. Failure to enjoin InvaGen, Cipla, and API Pharma's infringement of the '095 patent will substantially and irreparably damage GW.

135. GW does not have an adequate remedy at law

COUNT IX: INFRINGEMENT OF THE '288 PATENT

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

137. 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 '288 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.

138. A justiciable controversy exists between the parties hereto as to the infringement of the '288 patent.

139. 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 '288 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.

140. 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 '288 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 '288 patent and knowledge that their acts are encouraging infringement.

141. 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 '288 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 '288 patent, and InvaGen's Proposed Product lacks a substantial non-infringing use.

142. Failure to enjoin InvaGen, Cipla, and API Pharma's infringement of the '288 patent will substantially and irreparably damage GW.

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

COUNT X: INFRINGEMENT OF THE '671 PATENT

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

145. 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 '671 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

146. A justiciable controversy exists between the parties hereto as to the infringement of the '671 patent.

147. 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 '671 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.

148. 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 '671 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 '671 patent and knowledge that their acts are encouraging infringement.

149. 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 '671 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 '671 patent, and InvaGen's Proposed Product lacks a substantial non-infringing use.

150. Failure to enjoin InvaGen, Cipla, and API Pharma's infringement of the '671 patent will substantially and irreparably damage GW.

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

COUNT XI: INFRINGEMENT OF THE '673 PATENT

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

153. 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 '673 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.

154. A justiciable controversy exists between the parties hereto as to the infringement of the '673 patent.

155. 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 '673 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.

156. 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 '673 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 '673 patent and knowledge that their acts are encouraging infringement.

157. 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 '673 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 '673 patent, and InvaGen's Proposed Product lacks a substantial non-infringing use.

158. Failure to enjoin InvaGen, Cipla, and API Pharma's infringement of the '673 patent will substantially and irreparably damage GW.

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

COUNT XII: INFRINGEMENT OF THE '674 PATENT

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

161. 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 '674 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.

162. A justiciable controversy exists between the parties hereto as to the infringement of the '674 patent.

163. 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 '674 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.

164. 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 '674 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 '674 patent and knowledge that their acts are encouraging infringement.

165. 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 '674 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 '674 patent, and InvaGen's Proposed Product lacks a substantial non-infringing use.

166. Failure to enjoin InvaGen, Cipla, and API Pharma's infringement of the '674 patent will substantially and irreparably damage GW.

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

COUNT XIII: INFRINGEMENT OF THE '860 PATENT

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

169. 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 '860 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.

170. A justiciable controversy exists between the parties hereto as to the infringement of the '860 patent.

171. 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 '860 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.

172. 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 '860 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 '860 patent and knowledge that their acts are encouraging infringement.

173. 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 '860 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 '860 patent, and InvaGen's Proposed Product lacks a substantial non-infringing use.

174. Failure to enjoin InvaGen, Cipla, and API Pharma's infringement of the '860 patent will substantially and irreparably damage GW.

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

COUNT XIV: INFRINGEMENT OF THE '939 PATENT

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

177. 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 '939 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.

178. A justiciable controversy exists between the parties hereto as to the infringement of the '939 patent.

179. 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 '939 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.

180. 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 '939 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 '939 patent and knowledge that their acts are encouraging infringement.

181. 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 '939 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 '939 patent, and InvaGen's Proposed Product lacks a substantial non-infringing use.

182. Failure to enjoin InvaGen, Cipla, and API Pharma's infringement of the '939 patent will substantially and irreparably damage GW.

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

COUNT XV: INFRINGEMENT OF THE '905 PATENT

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

185. 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 '905 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.

186. A justiciable controversy exists between the parties hereto as to the infringement of the '905 patent.

187. 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 '905 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.

188. 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 '905 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 '905 patent and knowledge that their acts are encouraging infringement.

189. 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 '905 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 '905 patent, and InvaGen's Proposed Product lacks a substantial non-infringing use.

190. Failure to enjoin InvaGen, Cipla, and API Pharma's infringement of the '905 patent will substantially and irreparably damage GW.

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

COUNT XVI: INFRINGEMENT OF THE '516 PATENT

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

193. 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 '516 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

194. A justiciable controversy exists between the parties hereto as to the infringement of the '516 patent.

195. 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 '516 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.

196. 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 '516 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 '516 patent and knowledge that their acts are encouraging infringement.

197. 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 '516 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 '516 patent, and InvaGen's Proposed Product lacks a substantial non-infringing use.

198. Failure to enjoin InvaGen, Cipla, and API Pharma's infringement of the '516 patent will substantially and irreparably damage GW.

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

COUNT XVII: INFRINGEMENT OF THE '292 PATENT

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

201. 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 '292 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.

202. A justiciable controversy exists between the parties hereto as to the infringement of the '292 patent.

203. 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 '292 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.

204. 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 '292 patent under 35 U.S.C. § 271(b), including at least claim 18, 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 '292 patent and knowledge that their acts are encouraging infringement.

205. 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 '292 patent under 35 U.S.C. § 271(c), including at least claim 18, 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 '292 patent, and InvaGen's Proposed Product lacks a substantial non-infringing use.

206. Failure to enjoin InvaGen, Cipla, and API Pharma's infringement of the '292 patent will substantially and irreparably damage GW.

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

COUNT XVIII: INFRINGEMENT OF THE '498 PATENT

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

209. 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 '498 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.

210. A justiciable controversy exists between the parties hereto as to the infringement of the '498 patent.

211. 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 '498 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.

212. 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 '498 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 '498 patent and knowledge that their acts are encouraging infringement.

213. 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 '498 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 '498 patent, and InvaGen's Proposed Product lacks a substantial non-infringing use.

214. Failure to enjoin InvaGen, Cipla, and API Pharma's infringement of the '498 patent will substantially and irreparably damage GW.

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

COUNT XIX: INFRINGEMENT OF THE '741 PATENT

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

217. 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 '741 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

218. A justiciable controversy exists between the parties hereto as to the infringement of the '741 patent.

219. 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 '741 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.

220. 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 '741 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 '741 patent and knowledge that their acts are encouraging infringement.

221. 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 '741 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 '741 patent, and InvaGen's Proposed Product lacks a substantial non-infringing use.

222. Failure to enjoin InvaGen, Cipla, and API Pharma's infringement of the '741 patent will substantially and irreparably damage GW.

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

COUNT XX: INFRINGEMENT OF THE '258 PATENT

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

225. 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 '258 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.

226. A justiciable controversy exists between the parties hereto as to the infringement of the '258 patent.

227. 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 '258 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.

228. 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 '258 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 '258 patent and knowledge that their acts are encouraging infringement.

229. 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 '258 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 '258 patent, and InvaGen's Proposed Product lacks a substantial non-infringing use.

230. Failure to enjoin InvaGen, Cipla, and API Pharma's infringement of the '258 patent will substantially and irreparably damage GW.

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

PRAYER FOR RELIEF

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 patents-in-suit 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 patents-in-suit;

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 each patent-in-suit, 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 each patent-in-suit, 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, their officers, agents, attorneys and employees, and those acting in privity or concert with them, from practicing any method claimed in the patents-in-suit, or from actively inducing or contributing to the infringement of any claim of the patents-in-suit, until after the expiration of each patent-in-suit, 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 each of the patents-in-suit;

G. To the extent that InvaGen, Cipla, and/or API Pharma have committed any acts with respect to the methods claimed in the patents-in-suit, 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 patents-in-suit, a Judgment awarding damages to GW resulting from such infringement, together with interest;

I. A Judgment declaring that each patent-in-suit 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, equitable, and appropriate.

Dated: January 13, 2023

Respectfully Submitted,
Quinn Emanuel Urquhart & Sullivan, LLP

By: */s/ Eric C. Stops*

F. Dominic Cerrito
Eric C. Stops
Evangeline Shih
Daniel C. Wiesner
Gabriel P. Brier
Nicholas A. LoCastro
51 Madison Avenue, 22nd Floor
New York, New York 10010
Tel: (212) 849-7000
Fax: (212) 849-7100
nickcerrito@quinnemanuel.com
ericstops@quinnemanuel.com
evangelineshih@quinnemanuel.com
danielwiesner@quinnemanuel.com
gabrielbrier@quinnemanuel.com
nicholaslocastro@quinnemanuel.com

Counsel for Plaintiff,
GW Research Limited