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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 one or more 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"), 10,918,608 ("the '608 patent"), 10,966,939 ("the '939 patent"), 11,065,209 ("the '209 patent"), 11,096,905 ("the '905 patent"), 11,154,516 ("the '516 patent"), 11,160,795 ("the '795 patent"), 11,207,292 ("the '292 patent"), 11,311,498 ("the '498 patent"), 11,357,741 ("the '741 patent"), 11,400,055 ("the '055 patent"),

11,406,623 ("the '623 patent"), and 11,446,258 ("the '258 patent") (together, "the patents-insuit"), all 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.
- 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 Patents-in-Suit

- 19. 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 are 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.
- 20. 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.

- 21. 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.
- 22. 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.
- 23. 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.
- 24. 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.

- 25. 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.
- 26. 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.
- 27. 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.
- 28. 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.

- 29. 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.
- 30. 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.
- 31. 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.
- 32. On February 16, 2021, the USPTO duly and lawfully issued the '608 patent, entitled, "Use of Cannabidiol in the Treatment of Epilepsy" to GW as assignee. The face of the '608 patent identifies Geoffrey Guy, Stephen Wright, and Elizabeth Thiele as the inventors. A copy of the '608 patent is attached hereto as Exhibit N.
- 33. 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 O.
- 34. On July 20, 2021, the USPTO duly and lawfully issued the '209 patent, entitled, "Use of Cannabidiol in the Treatment of Epilepsy" to GW as assignee. The face of the '209

patent identifies Geoffrey Guy, Stephen Wright, and Elizabeth Thiele as the inventors. A copy of the '209 patent is attached hereto as Exhibit P.

- 35. 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 Q.
- 36. 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 R.
- 37. On November 2, 2021, the USPTO duly and lawfully issued the '795 patent, entitled, "Methods of Treating Tuberous Sclerosis Complex with Cannabidiol and Everolimus" to GW as assignee. The face of the '795 patent identifies Geoffrey Guy, Volker Knappertz, Eduardo Dunayevich, and David Critchley as the inventors. A copy of the '795 patent is attached hereto as Exhibit S.
- 38. 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 T.
- 39. 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 U.

- 40. 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 V.
- 41. On August 2, 2022, the USPTO duly and lawfully issued the '055 patent, entitled, "Use of Cannabidiol in the Treatment of Epilepsy" to GW as assignee. The face of the '055 patent identifies Geoffrey Guy, Stephen Wright, and Elizabeth Thiele as the inventors. A copy of the '055 patent is attached hereto as Exhibit W.
- 42. On August 9, 2022, the USPTO duly and lawfully issued the '623 patent, entitled, "Methods of Treating Tuberous Sclerosis Complex with Cannabidiol and Everolimus" to GW as assignee. The face of the '623 patent identifies Geoffrey Guy, Volker Knappertz, Eduardo Dunayevich, and David Critchley as the inventors. A copy of the '623 patent is attached hereto as Exhibit X.
- 43. 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 Y.

The Epidiolex® Drug Product

44. 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.

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

Jurisdiction and Venue: Teva

- 46. This Court has jurisdiction over the subject matter of Counts I through XX against Teva pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.
- 47. As set forth in Paragraphs 48-52 below, the Court has personal jurisdiction over Teva by virtue of, *inter alia*, its systematic and continuous contacts with the State of New Jersey.
- 48. On information and belief, Teva purposefully has conducted and continues to conduct business in this Judicial District.
- 49. 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.
- 50. 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").
- 51. 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, Dec. 30, 2022). 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).

- 52. 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.
- 53. For at least the foregoing reasons set forth above in Paragraphs 48-52 above, venue is proper in this Judicial District with respect to Teva pursuant to 28 U.S.C. § 1400(b).

Jurisdiction and Venue: Apotex

- 54. This Court has jurisdiction over the subject matter of Counts XXI through XL against Apotex pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.
- 55. As set forth in Paragraphs 56-59 below, the Court has personal jurisdiction over Apotex by virtue of, *inter alia*, its systematic and continuous contacts with the State of New Jersey.
- 56. On information and belief, Apotex purposefully has conducted and continues to conduct business in this Judicial District.
- 57. 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.
- 58. 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").

- 59. 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.
- 60. 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.
- 61. 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

62. This Court has jurisdiction over the subject matter of Counts XLI through LX against Padagis pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

- 63. As set forth in Paragraphs 64-69 below, the Court has personal jurisdiction over Padagis by virtue of, *inter alia*, its systematic and continuous contacts with the State of New Jersey.
- 64. On information and belief, Padagis purposefully has conducted and continues to conduct business in this Judicial District.
- 65. 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.
- 66. 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").
- 67. 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.
- 68. 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.
- 69. 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.

70. For at least the foregoing reasons set forth above in Paragraphs 64-69, 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

- 71. This Court has jurisdiction over the subject matter of Counts LXI through LXXX against InvaGen, Cipla, and API Pharma pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.
- 72. As set forth in Paragraphs 73-82 below, the Court has personal jurisdiction over InvaGen by virtue of, *inter alia*, its systematic and continuous contacts with the State of New Jersey.
- 73. 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.
- 74. 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.
- 75. 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").
- 76. 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 patents-in-suit.

77. 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:



- 78. 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).
- 79. On information and belief, Cipla USA acts at the direction, and for the benefit, of InvaGen, and is an agent / alter ego of InvaGen.
- 80. 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.
- 81. 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.

- 82. 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).
- 83. For at least the foregoing reasons set forth above in Paragraphs 73-82, venue is proper in this Judicial District with respect to InvaGen pursuant to 28 U.S.C. § 1400(b).
- 84. As set forth in Paragraphs 85-90 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.
- 85. 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.
- 86. 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.
- 87. 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 patents-in-suit.

- 88. 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, Dec. 30, 2022).
- 89. 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.
- 90. 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.
- 91. For at least the foregoing reasons set forth above in Paragraphs 85-90, venue is proper in this Judicial District with respect to Cipla USA pursuant to 28 U.S.C. § 1400(b).
- 92. As set forth in Paragraphs 93-101 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.
- 93. 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.
- 94. 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.

- 95. 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 patents-in-suit.
- 96. 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.
- 97. 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, December 30, 2022)); *see also id.* at 116 (figures "include ANDAs owned by Cipla and InvaGen Pharmaceuticals Inc.").
- 98. 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.
- 99. 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.).
- 100. 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.
- 101. 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.

- 102. 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.
- 103. 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).
- 104. As set forth in Paragraphs 105-110 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.
- 105. On information and belief, API Pharma purposefully has conducted and continues to conduct business in this Judicial District.
- 106. 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.
- 107. 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 patents-in-suit.

- 108. 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, Dec. 30, 2022).
- 109. 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.
- 110. 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.
- 111. For at least the foregoing reasons set forth above in Paragraphs 105-110, venue is proper in this Judicial District with respect to API Pharma pursuant to 28 U.S.C. § 1400(b).

Jurisdiction and Venue: Lupin

- 112. This Court has jurisdiction over the subject matter of Counts LXXXI through C against Lupin pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.
- 113. As set forth in Paragraphs 114-117 below, the Court has personal jurisdiction over Lupin by virtue of, *inter alia*, its systematic and continuous contacts with the State of New Jersey.
- 114. On information and belief, Lupin purposefully has conducted and continues to conduct business in this Judicial District.

- 115. 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.
- 116. 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").
- 117. 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-us-locations/ (last visited, Dec. 30, 2022). 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, Dec. 30, 2022).
- 118. 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.

119. 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

- 120. This Court has jurisdiction over the subject matter of Counts CI through CXX against Alkem pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.
- 121. As set forth in Paragraphs 122-125 below, the Court has personal jurisdiction over Alkem by virtue of, *inter alia*, its systematic and continuous contacts with the State of New Jersey.
- 122. On information and belief, Alkem purposefully has conducted and continues to conduct business in this Judicial District.
- 123. 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.
- 124. 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").
- 125. 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.
- 126. 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.
- 127. 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

- 128. This Court has jurisdiction over the subject matter of Counts CXXI through CXL against Taro pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.
- 129. As set forth in Paragraphs 130-135 below, the Court has personal jurisdiction over Taro by virtue of, *inter alia*, its systematic and continuous contacts with the State of New Jersey.
- 130. On information and belief, Taro purposefully has conducted and continues to conduct business in this Judicial District.
- 131. 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.
- 132. 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").

- 133. 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.
- 134. 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.
- 135. 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.
- 136. 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.

137. 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

- 138. This Court has jurisdiction over the subject matter of CXLI through CLXV against Ascent pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.
- 139. As set forth in Paragraphs 140-144 below, the Court has personal jurisdiction over Ascent by virtue of, *inter alia*, its systematic and continuous contacts with the State of New Jersey.
- 140. On information and belief, Ascent purposefully has conducted and continues to conduct business in this Judicial District.
- 141. 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.
- 142. 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").
- 143. 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.
- 144. 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.

145. For at least the foregoing reasons set forth above in Paragraphs 140-144, 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

- 146. This Court has jurisdiction over the subject matter of Counts CLXVI through CLXXX against MSN pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.
- 147. As set forth in Paragraphs 148-153 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.
- 148. On information and belief, MSN Pharmaceuticals purposefully has conducted and continues to conduct business in this Judicial District.
- 149. 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.
- 150. 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").
- 151. 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, Dec. 30, 2022). 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).

- 152. 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.
- 153. 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.
- 154. For at least the foregoing reasons set forth above in Paragraphs 148-153, venue is proper in this Judicial District with respect to MSN Pharmaceuticals pursuant to 28 U.S.C. § 1400(b).
- 155. As set forth in Paragraphs 156-159 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.
- 156. On information and belief, MSN Labs purposefully has conducted and continues to conduct business in this Judicial District.
- 157. 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.
- 158. On information and belief, this Judicial District will be a destination for MSN's Proposed Product.

- 159. 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, Dec. 30, 2022).
- 160. 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.
- 161. 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

- 162. This Court has jurisdiction over the subject matter of Counts CLXXXI through CCV against Biophore and Zenara pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.
- 163. As set forth in Paragraphs 164-168 below, the Court has personal jurisdiction over Biophore by virtue of, *inter alia*, its systematic and continuous contacts with the State of New Jersey.
- 164. On information and belief, Biophore purposefully has conducted and continues to conduct business in this Judicial District.

- 165. 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.
- 166. 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").
- 167. 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.
- 168. 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.
- 169. For at least the foregoing reasons set forth above in Paragraphs 164-168, venue is proper in this Judicial District with respect to Biophore pursuant to 28 U.S.C. § 1400(b).
- 170. As set forth in Paragraphs 171-173 below, the Court has personal jurisdiction over Zenara by virtue of, *inter alia*, its systematic and continuous contacts with the State of New Jersey.
- 171. On information and belief, Zenara purposefully has conducted and continues to conduct business in this Judicial District.
- 172. 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.

- 173. On information and belief, this Judicial District will be a destination for Biophore and Zenara's Proposed Product.
- 174. 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.
- 175. 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 Counts I-XX Against Teva

- 176. 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 certain patents-in-suit expire.
- 177. 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[®].
- 178. Teva's Notice Letter alleges that the claims of certain patents-in-suit are invalid and/or will not be infringed by the activities described in Teva's ANDA.

- 179. On information and belief, in connection with the filing of its ANDA as described above, Teva 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) ("Teva'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, and the '741 patent are invalid, unenforceable, and/or will not be infringed by the activities described in Teva's ANDA.
- 180. 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 submitted ANDA No. 217508 to the FDA before the '258 patent had been listed in the Orange Book with respect to Epidiolex[®]. According to Teva's Second Notice Letter, Teva provided a second written certification to the FDA ("Teva's Second Paragraph IV Certification"), alleging that the '258 patent is invalid, unenforceable, and/or will not be infringed by the activities described in Teva's ANDA.
- 181. 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 Counts XXI-XL Against Apotex

- 182. 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 certain patents-in-suit expire.
- 183. 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[®].

- 184. Apotex's Notice Letter alleges that the claims of certain patents-in-suit are invalid and/or will not be infringed by the activities described in Apotex's ANDA.
- 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) ("Apotex's Paragraph IV Certification"), alleging that the claims of 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 Apotex's ANDA.
- 186. 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 Counts XLI-LX Against Padagis

- 187. 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 certain patents-in-suit expire.
- 188. 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[®].

- 189. Padagis's Notice Letter alleges that the claims of certain patents-in-suit are invalid and/or will not be infringed by the activities described in Padagis's ANDA.
- 190. On information and belief, in connection with the filing of its ANDA as described above, Padagis 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) ("Padagis'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 Padagis's ANDA.
- 191. 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 Counts LXI-LXXX Against InvaGen, Cipla, and API Pharma

- 192. 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 certain patents-in-suit expire.
- 193. 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[®].

- 194. InvaGen's Notice Letter alleges that the claims of certain patents-in-suit are invalid and/or will not be infringed by the activities described in InvaGen's ANDA.
- 195. 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.
- 196. 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)."
- 197. On information and belief, and as evidenced by the facts set forth in Paragraphs 71-110 and 192-196 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.
- 198. On information and belief, and as evidenced by the facts set forth in Paragraphs
 71-110 and 192-196 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 Counts LXXXI-C Against Lupin

- 199. 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 certain patents-in-suit expire.
- 200. 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[®].
- 201. Lupin's Notice Letter alleges that the claims of certain patents-in-suit are invalid and/or will not be infringed by the activities described in Lupin's ANDA.
- 202. 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) ("Lupin'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 Lupin's ANDA.
- 203. 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 Counts CI-CXX Against Alkem

- 204. 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 certain patents-in-suit expire.
- 205. 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[®].
- 206. Alkem's Notice Letter alleges that the claims of certain patents-in-suit are invalid and/or will not be infringed by the activities described in Alkem's ANDA.
- 207. On information and belief, in connection with the filing of its ANDA as described above, Alkem provided a written certification to the FDA, as called for by Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Alkem'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, and the '741 patent are invalid, unenforceable, and/or will not be infringed by the activities described in Alkem's ANDA.
- 208. On information and belief, following FDA approval of Alkem's ANDA, Alkem will make, use, offer to sell, or sell Alkem's Proposed Product throughout the United States, or import such a generic product into the United States.

Acts Giving Rise to Counts CXXI-CXL Against Taro

- 209. 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 certain patents-in-suit expire.
- 210. 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[®].
- 211. Taro's Notice Letter alleges that the claims of certain patents-in-suit are invalid and/or will not be infringed by the activities described in Taro's ANDA.
- 212. On information and belief, in connection with the filing of its ANDA as described above, Taro 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) ("Taro'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 Taro's ANDA.
- 213. 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 Counts CXLI-CLXV Against Ascent

- 214. 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 patents-in-suit expire.
- 215. 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[®].
- 216. Ascent'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 Ascent's ANDA.
- 217. 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) ("Ascent'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 '608 patent, the '939 patent, the '209 patent, the '905 patent, the '516 patent, the '795 patent, the '292 patent, the '498 patent, the '741 patent, the '055 patent, the '623 patent, and the '258 patent are invalid, unenforceable, and/or will not be infringed by the activities described in Ascent's ANDA.
- 218. 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 Counts CLXVI-CLXXX Against MSN

- 219. 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 certain patents-in-suit expire.
- 220. 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®.
- 221. 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-in-suit]."
- 222. MSN's Notice Letter alleges that the claims of certain patents-in-suit are invalid and/or will not be infringed by the activities described in MSN's ANDA.
- 223. On information and belief, in connection with the filing of its ANDA as described above, MSN 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) ("MSN's Paragraph IV Certification"), alleging that the claims of the '183 patent, the '184 patent, the '186 patent, the '840 patent, the '095 patent, the '288 patent, the '673 patent, the '674 patent, the '860 patent, the '939 patent, the '905 patent, the '516 patent, the '292 patent, and the '498 patent are invalid, unenforceable, and/or will not be infringed by the activities described in MSN's ANDA.

- 224. 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 submitted ANDA No. 217911 to the FDA before the '258 patent had been listed in the Orange Book with respect to Epidiolex[®]. According to MSN's Second Notice Letter, MSN provided a second written certification to the FDA ("MSN's Second Paragraph IV Certification"), alleging that the '258 patent is invalid, unenforceable, and/or will not be infringed by the activities described in MSN's ANDA.
- 225. 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 Counts CLXXXI-CCV Against Biophore and Zenara

- 226. 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 patents-in-suit expire.
- 227. 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®.
- 228. 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 [the patents-in-suit]."

- 229. Biophore and Zenara'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 Biophore and Zenara's ANDA.
- 230. On information and belief, in connection with the filing of their ANDA as described above, Biophore and Zenara 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) ("Biophore and Zenara'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 '608 patent, the '939 patent, the '209 patent, the '905 patent, the '516 patent, the '795 patent, the '292 patent, the '498 patent, the '741 patent, the '055 patent, the '623 patent, and the '258 patent are invalid, unenforceable, and/or will not be infringed by the activities described in Biophore and Zenara's ANDA.
- 231. 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 '937 Patent by Teva

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

- 233. 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 '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.
- 234. A justiciable controversy exists between the parties hereto as to the infringement of the '937 patent.
- 235. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva 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 Teva's Proposed Product in the United States.
- 236. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva 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 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 '937 patent and knowledge that its acts are encouraging infringement.
- 237. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva 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 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 '937 patent, and Teva's Proposed Product lacks a substantial non-infringing use.

- 238. Failure to enjoin Teva's infringement of the '937 patent will substantially and irreparably damage GW.
 - 239. GW does not have an adequate remedy at law.

Count II: Infringement of the '183 Patent by Teva

- 240. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 241. 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 '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.
- 242. A justiciable controversy exists between the parties hereto as to the infringement of the '183 patent.
- 243. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva 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 Teva's Proposed Product in the United States.
- 244. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva 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 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 '183 patent and knowledge that its acts are encouraging infringement.

- 245. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva 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 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 '183 patent, and Teva's Proposed Product lacks a substantial non-infringing use.
- 246. Failure to enjoin Teva's infringement of the '183 patent will substantially and irreparably damage GW.
 - 247. GW does not have an adequate remedy at law.

Count III: Infringement of the '184 Patent by Teva

- 248. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 249. 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 '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.
- 250. A justiciable controversy exists between the parties hereto as to the infringement of the '184 patent.
- 251. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva 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 Teva's Proposed Product in the United States.

- 252. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva 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 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 '184 patent and knowledge that its acts are encouraging infringement.
- 253. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva 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 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 '184 patent, and Teva's Proposed Product lacks a substantial non-infringing use.
- 254. Failure to enjoin Teva's infringement of the '184 patent will substantially and irreparably damage GW.
 - 255. GW does not have an adequate remedy at law.

Count IV: Infringement of the '185 Patent by Teva

- 256. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 257. 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 '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.

- 258. A justiciable controversy exists between the parties hereto as to the infringement of the '185 patent.
- 259. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva 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 Teva's Proposed Product in the United States.
- 260. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva 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 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 '185 patent and knowledge that its acts are encouraging infringement.
- 261. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva 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 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 '185 patent, and Teva's Proposed Product lacks a substantial non-infringing use.
- 262. Failure to enjoin Teva's infringement of the '185 patent will substantially and irreparably damage GW.
 - 263. GW does not have an adequate remedy at law.

Count V: Infringement of the '186 Patent by Teva

- 264. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 265. 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 '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.
- 266. A justiciable controversy exists between the parties hereto as to the infringement of the '186 patent.
- 267. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva 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 Teva's Proposed Product in the United States.
- 268. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva 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 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 '186 patent and knowledge that its acts are encouraging infringement.
- 269. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva 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 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 '186 patent, and Teva's Proposed Product lacks a substantial non-infringing use.

- 270. Failure to enjoin Teva's infringement of the '186 patent will substantially and irreparably damage GW.
 - 271. GW does not have an adequate remedy at law.

Count VI: Infringement of the '525 Patent by Teva

- 272. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 273. 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 '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.
- A justiciable controversy exists between the parties hereto as to the infringement of the '525 patent.
- 275. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva 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 Teva's Proposed Product in the United States.
- 276. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva 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 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 '525 patent and knowledge that its acts are encouraging infringement.

- 277. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva 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 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 '525 patent, and Teva's Proposed Product lacks a substantial non-infringing use.
- 278. Failure to enjoin Teva's infringement of the '525 patent will substantially and irreparably damage GW.
 - 279. GW does not have an adequate remedy at law.

Count VII: Infringement of the '840 Patent by Teva

- 280. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 281. 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 '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.
- 282. A justiciable controversy exists between the parties hereto as to the infringement of the '840 patent.
- 283. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva 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 Teva's Proposed Product in the United States.
- Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva 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 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 '840 patent and knowledge that its acts are encouraging infringement.
- 285. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva 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 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 '840 patent, and Teva's Proposed Product lacks a substantial non-infringing use.
- 286. Failure to enjoin Teva's infringement of the '840 patent will substantially and irreparably damage GW.
 - 287. GW does not have an adequate remedy at law.

Count VIII: Infringement of the '095 Patent by Teva

- 288. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 289. 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 '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.

- 290. A justiciable controversy exists between the parties hereto as to the infringement of the '095 patent.
- 291. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva 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 Teva's Proposed Product in the United States.
- 292. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva 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 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 '095 patent and knowledge that its acts are encouraging infringement.
- 293. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva 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 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 '095 patent, and Teva's Proposed Product lacks a substantial non-infringing use.
- 294. Failure to enjoin Teva's infringement of the '095 patent will substantially and irreparably damage GW.
 - 295. GW does not have an adequate remedy at law.

Count IX: Infringement of the '288 Patent by Teva

- 296. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 297. 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 '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.
- 298. A justiciable controversy exists between the parties hereto as to the infringement of the '288 patent.
- 299. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva 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 Teva's Proposed Product in the United States.
- 300. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva 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 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 '288 patent and knowledge that its acts are encouraging infringement.
- 301. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva 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 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 '288 patent, and Teva's Proposed Product lacks a substantial non-infringing use.

- 302. Failure to enjoin Teva's infringement of the '288 patent will substantially and irreparably damage GW.
 - 303. GW does not have an adequate remedy at law.

Count X: Infringement of the '671 Patent by Teva

- 304. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 305. 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 '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.
- 306. A justiciable controversy exists between the parties hereto as to the infringement of the '671 patent.
- 307. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva 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 Teva's Proposed Product in the United States.
- 308. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva 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 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 '671 patent and knowledge that its acts are encouraging infringement.

- 309. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva 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 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 '671 patent, and Teva's Proposed Product lacks a substantial non-infringing use.
- 310. Failure to enjoin Teva's infringement of the '671 patent will substantially and irreparably damage GW.
 - 311. GW does not have an adequate remedy at law.

Count XI: Infringement of the '673 Patent by Teva

- 312. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 313. 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 '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.
- 314. A justiciable controversy exists between the parties hereto as to the infringement of the '673 patent.
- 315. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva 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 Teva's Proposed Product in the United States.
- 316. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva 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 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 '673 patent and knowledge that its acts are encouraging infringement.
- 317. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva 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 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 '673 patent, and Teva's Proposed Product lacks a substantial non-infringing use.
- 318. Failure to enjoin Teva's infringement of the '673 patent will substantially and irreparably damage GW.
 - 319. GW does not have an adequate remedy at law.

Count XII: Infringement of the '674 Patent by Teva

- 320. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 321. 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 '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.

- 322. A justiciable controversy exists between the parties hereto as to the infringement of the '674 patent.
- 323. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva 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 Teva's Proposed Product in the United States.
- 324. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva 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 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 '674 patent and knowledge that its acts are encouraging infringement.
- 325. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva 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 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 '674 patent, and Teva's Proposed Product lacks a substantial non-infringing use.
- 326. Failure to enjoin Teva's infringement of the '674 patent will substantially and irreparably damage GW.
 - 327. GW does not have an adequate remedy at law.

Count XIII: Infringement of the '860 Patent by Teva

- 328. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 329. 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 '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.
- 330. A justiciable controversy exists between the parties hereto as to the infringement of the '860 patent.
- 331. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva 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 Teva's Proposed Product in the United States.
- 332. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva 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 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 '860 patent and knowledge that its acts are encouraging infringement.
- 333. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva 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 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 '860 patent, and Teva's Proposed Product lacks a substantial non-infringing use.

- 334. Failure to enjoin Teva's infringement of the '860 patent will substantially and irreparably damage GW.
 - 335. GW does not have an adequate remedy at law.

Count XIV: Infringement of the '939 Patent by Teva

- 336. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 337. 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 '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.
- 338. A justiciable controversy exists between the parties hereto as to the infringement of the '939 patent.
- 339. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva 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 Teva's Proposed Product in the United States.
- 340. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva 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 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 '939 patent and knowledge that its acts are encouraging infringement.

- 341. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva 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 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 '939 patent, and Teva's Proposed Product lacks a substantial non-infringing use.
- 342. Failure to enjoin Teva's infringement of the '939 patent will substantially and irreparably damage GW.
 - 343. GW does not have an adequate remedy at law.

Count XV: Infringement of the '905 Patent by Teva

- 344. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 345. 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 '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.
- 346. A justiciable controversy exists between the parties hereto as to the infringement of the '905 patent.
- 347. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva 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 Teva's Proposed Product in the United States.
- 348. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva 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 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 '905 patent and knowledge that its acts are encouraging infringement.
- 349. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva 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 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 '905 patent, and Teva's Proposed Product lacks a substantial non-infringing use.
- 350. Failure to enjoin Teva's infringement of the '905 patent will substantially and irreparably damage GW.
 - 351. GW does not have an adequate remedy at law.

Count XVI: Infringement of the '516 Patent by Teva

- 352. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 353. 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 '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.

- 354. A justiciable controversy exists between the parties hereto as to the infringement of the '516 patent.
- 355. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva 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 Teva's Proposed Product in the United States.
- 356. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva 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 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 '516 patent and knowledge that its acts are encouraging infringement.
- 357. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva 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 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 '516 patent, and Teva's Proposed Product lacks a substantial non-infringing use.
- 358. Failure to enjoin Teva's infringement of the '516 patent will substantially and irreparably damage GW.
 - 359. GW does not have an adequate remedy at law.

Count XVII: Infringement of the '292 Patent by Teva

- 360. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 361. 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 '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.
- 362. A justiciable controversy exists between the parties hereto as to the infringement of the '292 patent.
- 363. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva 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 Teva's Proposed Product in the United States.
- 364. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva 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 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 '292 patent and knowledge that its acts are encouraging infringement.
- 365. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva 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 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 '292 patent, and Teva's Proposed Product lacks a substantial non-infringing use.

- 366. Failure to enjoin Teva's infringement of the '292 patent will substantially and irreparably damage GW.
 - 367. GW does not have an adequate remedy at law.

Count XVIII: Infringement of the '498 Patent by Teva

- 368. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 369. 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 '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.
- 370. A justiciable controversy exists between the parties hereto as to the infringement of the '498 patent.
- 371. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva 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 Teva's Proposed Product in the United States.
- 372. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva 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 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 '498 patent and knowledge that its acts are encouraging infringement.

- 373. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva 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 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 '498 patent, and Teva's Proposed Product lacks a substantial non-infringing use.
- 374. Failure to enjoin Teva's infringement of the '498 patent will substantially and irreparably damage GW.
 - 375. GW does not have an adequate remedy at law.

Count XIX: Infringement of the '741 Patent by Teva

- 376. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 377. 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 '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.
- 378. A justiciable controversy exists between the parties hereto as to the infringement of the '741 patent.
- 379. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva 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 Teva's Proposed Product in the United States.
- 380. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva 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 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 '741 patent and knowledge that its acts are encouraging infringement.
- 381. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva 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 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 '741 patent, and Teva's Proposed Product lacks a substantial non-infringing use.
- 382. Failure to enjoin Teva's infringement of the '741 patent will substantially and irreparably damage GW.
 - 383. GW does not have an adequate remedy at law.

Count XX: Infringement of the '258 Patent by Teva

- 384. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 385. 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 '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.

- 386. A justiciable controversy exists between the parties hereto as to the infringement of the '258 patent.
- 387. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva 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 Teva's Proposed Product in the United States.
- 388. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva 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 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 '258 patent and knowledge that its acts are encouraging infringement.
- 389. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva 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 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 '258 patent, and Teva's Proposed Product lacks a substantial non-infringing use.
- 390. Failure to enjoin Teva's infringement of the '258 patent will substantially and irreparably damage GW.
 - 391. GW does not have an adequate remedy at law.

Count XXI: Infringement of the '937 Patent by Apotex

- 392. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 393. 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 '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.
- 394. A justiciable controversy exists between the parties hereto as to the infringement of the '937 patent.
- 395. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex 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 Apotex's Proposed Product in the United States.
- 396. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex 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 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 '937 patent and knowledge that its acts are encouraging infringement.
- 397. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex 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 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 '937 patent, and Apotex's Proposed Product lacks a substantial non-infringing use.

- 398. Failure to enjoin Apotex's infringement of the '937 patent will substantially and irreparably damage GW.
 - 399. GW does not have an adequate remedy at law.

Count XXII: Infringement of the '183 Patent by Apotex

- 400. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 401. 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 '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.
- 402. A justiciable controversy exists between the parties hereto as to the infringement of the '183 patent.
- 403. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex 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 Apotex's Proposed Product in the United States.
- 404. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex 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 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 '183 patent and knowledge that its acts are encouraging infringement.

- 405. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex 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 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 '183 patent, and Apotex's Proposed Product lacks a substantial non-infringing use.
- 406. Failure to enjoin Apotex's infringement of the '183 patent will substantially and irreparably damage GW.
 - 407. GW does not have an adequate remedy at law.

Count XXIII: Infringement of the '184 Patent by Apotex

- 408. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 409. 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 '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.
- 410. A justiciable controversy exists between the parties hereto as to the infringement of the '184 patent.
- 411. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex 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 Apotex's Proposed Product in the United States.

- 412. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex 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 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 '184 patent and knowledge that its acts are encouraging infringement.
- 413. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex 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 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 '184 patent, and Apotex's Proposed Product lacks a substantial non-infringing use.
- 414. Failure to enjoin Apotex's infringement of the '184 patent will substantially and irreparably damage GW.
 - 415. GW does not have an adequate remedy at law.

Count XXIV: Infringement of the '185 Patent by Apotex

- 416. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 417. 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 '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.

- 418. A justiciable controversy exists between the parties hereto as to the infringement of the '185 patent.
- 419. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex 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 Apotex's Proposed Product in the United States.
- 420. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex 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 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 '185 patent and knowledge that its acts are encouraging infringement.
- 421. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex 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 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 '185 patent, and Apotex's Proposed Product lacks a substantial non-infringing use.
- 422. Failure to enjoin Apotex's infringement of the '185 patent will substantially and irreparably damage GW.
 - 423. GW does not have an adequate remedy at law.

Count XXV: Infringement of the '186 Patent by Apotex

- 424. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 425. 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 '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.
- 426. A justiciable controversy exists between the parties hereto as to the infringement of the '186 patent.
- 427. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex 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 Apotex's Proposed Product in the United States.
- 428. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex 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 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 '186 patent and knowledge that its acts are encouraging infringement.
- 429. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex 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 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 '186 patent, and Apotex's Proposed Product lacks a substantial non-infringing use.

- 430. Failure to enjoin Apotex's infringement of the '186 patent will substantially and irreparably damage GW.
 - 431. GW does not have an adequate remedy at law.

Count XXVI: Infringement of the '525 Patent by Apotex

- 432. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 433. 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 '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.
- 434. A justiciable controversy exists between the parties hereto as to the infringement of the '525 patent.
- 435. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex 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 Apotex's Proposed Product in the United States.
- 436. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex 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 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 '525 patent and knowledge that its acts are encouraging infringement.

- 437. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex 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 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 '525 patent, and Apotex's Proposed Product lacks a substantial non-infringing use.
- 438. Failure to enjoin Apotex's infringement of the '525 patent will substantially and irreparably damage GW.
 - 439. GW does not have an adequate remedy at law.

Count XXVII: Infringement of the '840 Patent by Apotex

- 440. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 441. 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 '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.
- 442. A justiciable controversy exists between the parties hereto as to the infringement of the '840 patent.
- 443. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex 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 Apotex's Proposed Product in the United States.

- 444. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex 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 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 '840 patent and knowledge that its acts are encouraging infringement.
- 445. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex 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 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 '840 patent, and Apotex's Proposed Product lacks a substantial non-infringing use.
- 446. Failure to enjoin Apotex's infringement of the '840 patent will substantially and irreparably damage GW.
 - 447. GW does not have an adequate remedy at law.

Count XXVIII: Infringement of the '095 Patent by Apotex

- 448. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 449. 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 '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.

- 450. A justiciable controversy exists between the parties hereto as to the infringement of the '095 patent.
- 451. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex 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 Apotex's Proposed Product in the United States.
- 452. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex 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 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 '095 patent and knowledge that its acts are encouraging infringement.
- 453. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex 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 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 '095 patent, and Apotex's Proposed Product lacks a substantial non-infringing use.
- 454. Failure to enjoin Apotex's infringement of the '095 patent will substantially and irreparably damage GW.
 - 455. GW does not have an adequate remedy at law.

Count XXIX: Infringement of the '288 Patent by Apotex

- 456. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 457. 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 '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.
- 458. A justiciable controversy exists between the parties hereto as to the infringement of the '288 patent.
- 459. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex 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 Apotex's Proposed Product in the United States.
- 460. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex 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 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 '288 patent and knowledge that its acts are encouraging infringement.
- 461. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex 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 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 '288 patent, and Apotex's Proposed Product lacks a substantial non-infringing use.

- 462. Failure to enjoin Apotex's infringement of the '288 patent will substantially and irreparably damage GW.
 - 463. GW does not have an adequate remedy at law.

Count XXX: Infringement of the '671 Patent by Apotex

- 464. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 465. 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 '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.
- 466. A justiciable controversy exists between the parties hereto as to the infringement of the '671 patent.
- 467. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex 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 Apotex's Proposed Product in the United States.
- 468. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex 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 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 '671 patent and knowledge that its acts are encouraging infringement.

- 469. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex 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 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 '671 patent, and Apotex's Proposed Product lacks a substantial non-infringing use.
- 470. Failure to enjoin Apotex's infringement of the '671 patent will substantially and irreparably damage GW.
 - 471. GW does not have an adequate remedy at law.

Count XXXI: Infringement of the '673 Patent by Apotex

- 472. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 473. 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 '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.
- 474. A justiciable controversy exists between the parties hereto as to the infringement of the '673 patent.
- 475. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex 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 Apotex's Proposed Product in the United States.

- 476. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex 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 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 '673 patent and knowledge that its acts are encouraging infringement.
- 477. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex 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 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 '673 patent, and Apotex's Proposed Product lacks a substantial non-infringing use.
- 478. Failure to enjoin Apotex's infringement of the '673 patent will substantially and irreparably damage GW.
 - 479. GW does not have an adequate remedy at law.

Count XXXII: Infringement of the '674 Patent by Apotex

- 480. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 481. 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 '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.

- 482. A justiciable controversy exists between the parties hereto as to the infringement of the '674 patent.
- 483. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex 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 Apotex's Proposed Product in the United States.
- 484. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex 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 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 '674 patent and knowledge that its acts are encouraging infringement.
- 485. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex 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 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 '674 patent, and Apotex's Proposed Product lacks a substantial non-infringing use.
- 486. Failure to enjoin Apotex's infringement of the '674 patent will substantially and irreparably damage GW.
 - 487. GW does not have an adequate remedy at law.

Count XXXIII: Infringement of the '860 Patent by Apotex

- 488. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 489. 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 '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.
- 490. A justiciable controversy exists between the parties hereto as to the infringement of the '860 patent.
- 491. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex 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 Apotex's Proposed Product in the United States.
- 492. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex 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 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 '860 patent and knowledge that its acts are encouraging infringement.
- 493. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex 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 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 '860 patent, and Apotex's Proposed Product lacks a substantial non-infringing use.

- 494. Failure to enjoin Apotex's infringement of the '860 patent will substantially and irreparably damage GW.
 - 495. GW does not have an adequate remedy at law.

Count XXXIV: Infringement of the '939 Patent by Apotex

- 496. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 497. 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 '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.
- 498. A justiciable controversy exists between the parties hereto as to the infringement of the '939 patent.
- 499. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex 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 Apotex's Proposed Product in the United States.
- 500. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex 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 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 '939 patent and knowledge that its acts are encouraging infringement.

- 501. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex 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 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 '939 patent, and Apotex's Proposed Product lacks a substantial non-infringing use.
- 502. Failure to enjoin Apotex's infringement of the '939 patent will substantially and irreparably damage GW.
 - 503. GW does not have an adequate remedy at law.

Count XXXV: Infringement of the '905 Patent by Apotex

- 504. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 505. 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 '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.
- 506. A justiciable controversy exists between the parties hereto as to the infringement of the '905 patent.
- 507. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex 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 Apotex's Proposed Product in the United States.

- 508. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex 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 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 '905 patent and knowledge that its acts are encouraging infringement.
- 509. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex 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 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 '905 patent, and Apotex's Proposed Product lacks a substantial non-infringing use.
- 510. Failure to enjoin Apotex's infringement of the '905 patent will substantially and irreparably damage GW.
 - 511. GW does not have an adequate remedy at law.

Count XXXVI: Infringement of the '516 Patent by Apotex

- 512. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 513. 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 '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.

- 514. A justiciable controversy exists between the parties hereto as to the infringement of the '516 patent.
- 515. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex 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 Apotex's Proposed Product in the United States.
- 516. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex 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 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 '516 patent and knowledge that its acts are encouraging infringement.
- 517. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex 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 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 '516 patent, and Apotex's Proposed Product lacks a substantial non-infringing use.
- 518. Failure to enjoin Apotex's infringement of the '516 patent will substantially and irreparably damage GW.
 - 519. GW does not have an adequate remedy at law.

Count XXXVII: Infringement of the '292 Patent by Apotex

- 520. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 521. 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 '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.
- 522. A justiciable controversy exists between the parties hereto as to the infringement of the '292 patent.
- 523. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex 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 Apotex's Proposed Product in the United States.
- 524. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex 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 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 '292 patent and knowledge that its acts are encouraging infringement.
- 525. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex 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 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 '292 patent, and Apotex's Proposed Product lacks a substantial non-infringing use.

- 526. Failure to enjoin Apotex's infringement of the '292 patent will substantially and irreparably damage GW.
 - 527. GW does not have an adequate remedy at law.

Count XXXVIII: Infringement of the '498 Patent by Apotex

- 528. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 529. 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 '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.
- 530. A justiciable controversy exists between the parties hereto as to the infringement of the '498 patent.
- 531. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex 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 Apotex's Proposed Product in the United States.
- 532. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex 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 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 '498 patent and knowledge that its acts are encouraging infringement.

- 533. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex 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 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 '498 patent, and Apotex's Proposed Product lacks a substantial non-infringing use.
- 534. Failure to enjoin Apotex's infringement of the '498 patent will substantially and irreparably damage GW.
 - 535. GW does not have an adequate remedy at law.

Count XXXIX: Infringement of the '741 Patent by Apotex

- 536. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 537. 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 '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.
- 538. A justiciable controversy exists between the parties hereto as to the infringement of the '741 patent.
- 539. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex 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 Apotex's Proposed Product in the United States.

- 540. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex 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 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 '741 patent and knowledge that its acts are encouraging infringement.
- 541. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex 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 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 '741 patent, and Apotex's Proposed Product lacks a substantial non-infringing use.
- 542. Failure to enjoin Apotex's infringement of the '741 patent will substantially and irreparably damage GW.
 - 543. GW does not have an adequate remedy at law.

Count XL: Infringement of the '258 Patent by Apotex

- 544. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 545. 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 '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.

- 546. A justiciable controversy exists between the parties hereto as to the infringement of the '258 patent.
- 547. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex 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 Apotex's Proposed Product in the United States.
- 548. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex 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 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 '258 patent and knowledge that its acts are encouraging infringement.
- 549. Unless enjoined by this Court, upon FDA approval of Apotex's ANDA, Apotex 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 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 '258 patent, and Apotex's Proposed Product lacks a substantial non-infringing use.
- 550. Failure to enjoin Apotex's infringement of the '258 patent will substantially and irreparably damage GW.
 - 551. GW does not have an adequate remedy at law.

Count XLI: Infringement of the '937 Patent by Padagis

- 552. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 553. 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 '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.
- 554. A justiciable controversy exists between the parties hereto as to the infringement of the '937 patent.
- 555. Unless enjoined by this Court, upon FDA approval of Padagis's ANDA, Padagis 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 Padagis's Proposed Product in the United States.
- 556. Unless enjoined by this Court, upon FDA approval of Padagis's ANDA, Padagis 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 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 '937 patent and knowledge that its acts are encouraging infringement.
- 557. Unless enjoined by this Court, upon FDA approval of Padagis's ANDA, Padagis 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 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 '937 patent, and Padagis's Proposed Product lacks a substantial non-infringing use.

- 558. Failure to enjoin Padagis's infringement of the '937 patent will substantially and irreparably damage GW.
 - 559. GW does not have an adequate remedy at law.

Count XLII: Infringement of the '183 Patent by Padagis

- 560. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 561. 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 '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.
- 562. A justiciable controversy exists between the parties hereto as to the infringement of the '183 patent.
- 563. Unless enjoined by this Court, upon FDA approval of Padagis's ANDA, Padagis 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 Padagis's Proposed Product in the United States.
- 564. Unless enjoined by this Court, upon FDA approval of Padagis's ANDA,

 Padagis 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

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

- 565. Unless enjoined by this Court, upon FDA approval of Padagis's ANDA,
 Padagis 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
 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 '183 patent, and Padagis's Proposed Product lacks a substantial non-infringing use.
- 566. Failure to enjoin Padagis's infringement of the '183 patent will substantially and irreparably damage GW.
 - 567. GW does not have an adequate remedy at law.

Count XLIII: Infringement of the '184 Patent by Padagis

- 568. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 569. 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 '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.
- 570. A justiciable controversy exists between the parties hereto as to the infringement of the '184 patent.
- 571. Unless enjoined by this Court, upon FDA approval of Padagis's ANDA,

 Padagis 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 Padagis's Proposed Product in the United States.

- 572. Unless enjoined by this Court, upon FDA approval of Padagis's ANDA,
 Padagis 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
 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 '184 patent and knowledge that its acts are encouraging infringement.
- 573. Unless enjoined by this Court, upon FDA approval of Padagis's ANDA,
 Padagis 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
 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 '184 patent, and Padagis's Proposed Product lacks a substantial non-infringing use.
- 574. Failure to enjoin Padagis's infringement of the '184 patent will substantially and irreparably damage GW.
 - 575. GW does not have an adequate remedy at law.

Count XLIV: Infringement of the '185 Patent by Padagis

- 576. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 577. 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 '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.

- 578. A justiciable controversy exists between the parties hereto as to the infringement of the '185 patent.
- 579. Unless enjoined by this Court, upon FDA approval of Padagis's ANDA,
 Padagis 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 Padagis's Proposed
 Product in the United States.
- 580. Unless enjoined by this Court, upon FDA approval of Padagis's ANDA,
 Padagis 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
 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 '185 patent and knowledge that its acts are encouraging infringement.
- Dalagis 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 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 '185 patent, and Padagis's Proposed Product lacks a substantial non-infringing use.
- 582. Failure to enjoin Padagis's infringement of the '185 patent will substantially and irreparably damage GW.
 - 583. GW does not have an adequate remedy at law.

Count XLV: Infringement of the '186 Patent by Padagis

- 584. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 585. 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 '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.
- 586. A justiciable controversy exists between the parties hereto as to the infringement of the '186 patent.
- 587. Unless enjoined by this Court, upon FDA approval of Padagis's ANDA, Padagis 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 Padagis's Proposed Product in the United States.
- 588. Unless enjoined by this Court, upon FDA approval of Padagis's ANDA,
 Padagis 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
 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 '186 patent and knowledge that its acts are encouraging infringement.
- 589. Unless enjoined by this Court, upon FDA approval of Padagis's ANDA,
 Padagis 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
 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 '186 patent, and Padagis's Proposed Product lacks a substantial non-infringing use.

- 590. Failure to enjoin Padagis's infringement of the '186 patent will substantially and irreparably damage GW.
 - 591. GW does not have an adequate remedy at law.

Count XLVI: Infringement of the '525 Patent by Padagis

- 592. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 593. 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 '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.
- 594. A justiciable controversy exists between the parties hereto as to the infringement of the '525 patent.
- 595. Unless enjoined by this Court, upon FDA approval of Padagis's ANDA, Padagis 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 Padagis's Proposed Product in the United States.
- 596. Unless enjoined by this Court, upon FDA approval of Padagis's ANDA,

 Padagis 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

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

- 597. Unless enjoined by this Court, upon FDA approval of Padagis's ANDA,
 Padagis 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
 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 '525 patent, and Padagis's Proposed Product lacks a substantial non-infringing use.
- 598. Failure to enjoin Padagis's infringement of the '525 patent will substantially and irreparably damage GW.
 - 599. GW does not have an adequate remedy at law.

Count XLVII: Infringement of the '840 Patent by Padagis

- 600. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 601. 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 '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.
- 602. A justiciable controversy exists between the parties hereto as to the infringement of the '840 patent.
- 603. Unless enjoined by this Court, upon FDA approval of Padagis's ANDA,

 Padagis 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 Padagis's Proposed Product in the United States.

- 604. Unless enjoined by this Court, upon FDA approval of Padagis's ANDA,
 Padagis 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
 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 '840 patent and knowledge that its acts are encouraging infringement.
- 605. Unless enjoined by this Court, upon FDA approval of Padagis's ANDA,
 Padagis 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
 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 '840 patent, and Padagis's Proposed Product lacks a substantial non-infringing use.
- 606. Failure to enjoin Padagis's infringement of the '840 patent will substantially and irreparably damage GW.
 - 607. GW does not have an adequate remedy at law.

Count XLVIII: Infringement of the '095 Patent by Padagis

- 608. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 609. 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 '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.

- 610. A justiciable controversy exists between the parties hereto as to the infringement of the '095 patent.
- Online the United States.

 Unless enjoined by this Court, upon FDA approval of Padagis's ANDA,

 Padagis 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 Padagis's Proposed Product in the United States.
- 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
 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 '095 patent and knowledge that its acts are encouraging infringement.
- On information and belief, Padagis's Proposed Product is designed for a use that infringes one or more claims of the '095 patent under 35 U.S.C. §
- 614. Failure to enjoin Padagis's infringement of the '095 patent will substantially and irreparably damage GW.
 - 615. GW does not have an adequate remedy at law.

Count XLIX: Infringement of the '288 Patent by Padagis

- 616. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 617. 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 '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.
- 618. A justiciable controversy exists between the parties hereto as to the infringement of the '288 patent.
- 619. Unless enjoined by this Court, upon FDA approval of Padagis's ANDA, Padagis 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 Padagis's Proposed Product in the United States.
- 620. Unless enjoined by this Court, upon FDA approval of Padagis's ANDA,
 Padagis 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
 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 '288 patent and knowledge that its acts are encouraging infringement.
- 621. Unless enjoined by this Court, upon FDA approval of Padagis's ANDA,
 Padagis 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
 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 '288 patent, and Padagis's Proposed Product lacks a substantial non-infringing use.

- 622. Failure to enjoin Padagis's infringement of the '288 patent will substantially and irreparably damage GW.
 - 623. GW does not have an adequate remedy at law.

Count L: Infringement of the '671 Patent by Padagis

- 624. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 625. 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 '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.
- 626. A justiciable controversy exists between the parties hereto as to the infringement of the '671 patent.
- 627. Unless enjoined by this Court, upon FDA approval of Padagis's ANDA, Padagis 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 Padagis's Proposed Product in the United States.
- 628. Unless enjoined by this Court, upon FDA approval of Padagis's ANDA,
 Padagis 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
 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 '671 patent and knowledge that its acts are encouraging infringement.

- 629. Unless enjoined by this Court, upon FDA approval of Padagis's ANDA,
 Padagis 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
 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 '671 patent, and Padagis's Proposed Product lacks a substantial non-infringing use.
- 630. Failure to enjoin Padagis's infringement of the '671 patent will substantially and irreparably damage GW.
 - 631. GW does not have an adequate remedy at law.

Count LI: Infringement of the '673 Patent by Padagis

- 632. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 633. 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 '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.
- 634. A justiciable controversy exists between the parties hereto as to the infringement of the '673 patent.
- 635. Unless enjoined by this Court, upon FDA approval of Padagis's ANDA, Padagis 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 Padagis's Proposed Product in the United States.

- 636. Unless enjoined by this Court, upon FDA approval of Padagis's ANDA,
 Padagis 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
 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 '673 patent and knowledge that its acts are encouraging infringement.
- 637. Unless enjoined by this Court, upon FDA approval of Padagis's ANDA, Padagis 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 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 '673 patent, and Padagis's Proposed Product lacks a substantial non-infringing use.
- 638. Failure to enjoin Padagis's infringement of the '673 patent will substantially and irreparably damage GW.
 - 639. GW does not have an adequate remedy at law.

Count LII: Infringement of the '674 Patent by Padagis

- 640. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 641. 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 '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.

- 642. A justiciable controversy exists between the parties hereto as to the infringement of the '674 patent.
- 643. Unless enjoined by this Court, upon FDA approval of Padagis's ANDA, Padagis 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 Padagis's Proposed Product in the United States.
- 644. Unless enjoined by this Court, upon FDA approval of Padagis's ANDA, Padagis 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 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 '674 patent and knowledge that its acts are encouraging infringement.
- 645. Unless enjoined by this Court, upon FDA approval of Padagis's ANDA, Padagis 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 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 '674 patent, and Padagis's Proposed Product lacks a substantial non-infringing use.
- 646. Failure to enjoin Padagis's infringement of the '674 patent will substantially and irreparably damage GW.
 - 647. GW does not have an adequate remedy at law.

Count LIII: Infringement of the '860 Patent by Padagis

- 648. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 649. 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 '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.
- 650. A justiciable controversy exists between the parties hereto as to the infringement of the '860 patent.
- 651. Unless enjoined by this Court, upon FDA approval of Padagis's ANDA, Padagis 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 Padagis's Proposed Product in the United States.
- 652. Unless enjoined by this Court, upon FDA approval of Padagis's ANDA, Padagis 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 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 '860 patent and knowledge that its acts are encouraging infringement.
- 653. Unless enjoined by this Court, upon FDA approval of Padagis's ANDA, Padagis 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 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 '860 patent, and Padagis's Proposed Product lacks a substantial non-infringing use.

- 654. Failure to enjoin Padagis's infringement of the '860 patent will substantially and irreparably damage GW.
 - 655. GW does not have an adequate remedy at law.

Count LIV: Infringement of the '939 Patent by Padagis

- 656. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 657. 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 '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.
- 658. A justiciable controversy exists between the parties hereto as to the infringement of the '939 patent.
- 659. Unless enjoined by this Court, upon FDA approval of Padagis's ANDA, Padagis 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 Padagis's Proposed Product in the United States.
- 660. Unless enjoined by this Court, upon FDA approval of Padagis's ANDA, Padagis 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 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 '939 patent and knowledge that its acts are encouraging infringement.

- 661. Unless enjoined by this Court, upon FDA approval of Padagis's ANDA, Padagis 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 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 '939 patent, and Padagis's Proposed Product lacks a substantial non-infringing use.
- 662. Failure to enjoin Padagis's infringement of the '939 patent will substantially and irreparably damage GW.
 - 663. GW does not have an adequate remedy at law.

Count LV: Infringement of the '905 Patent by Padagis

- 664. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 665. 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 '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.
- 666. A justiciable controversy exists between the parties hereto as to the infringement of the '905 patent.
- 667. Unless enjoined by this Court, upon FDA approval of Padagis's ANDA, Padagis 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 Padagis's Proposed Product in the United States.

- 668. Unless enjoined by this Court, upon FDA approval of Padagis's ANDA, Padagis 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 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 '905 patent and knowledge that its acts are encouraging infringement.
- 669. Unless enjoined by this Court, upon FDA approval of Padagis's ANDA, Padagis 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 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 '905 patent, and Padagis's Proposed Product lacks a substantial non-infringing use.
- 670. Failure to enjoin Padagis's infringement of the '905 patent will substantially and irreparably damage GW.
 - 671. GW does not have an adequate remedy at law.

Count LVI: Infringement of the '516 Patent by Padagis

- 672. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 673. 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 '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.

- 674. A justiciable controversy exists between the parties hereto as to the infringement of the '516 patent.
- 675. Unless enjoined by this Court, upon FDA approval of Padagis's ANDA, Padagis 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 Padagis's Proposed Product in the United States.
- 676. Unless enjoined by this Court, upon FDA approval of Padagis's ANDA, Padagis 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 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 '516 patent and knowledge that its acts are encouraging infringement.
- 677. Unless enjoined by this Court, upon FDA approval of Padagis's ANDA, Padagis 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 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 '516 patent, and Padagis's Proposed Product lacks a substantial non-infringing use.
- 678. Failure to enjoin Padagis's infringement of the '516 patent will substantially and irreparably damage GW.
 - 679. GW does not have an adequate remedy at law.

Count LVII: Infringement of the '292 Patent by Padagis

- 680. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 681. 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 '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.
- 682. A justiciable controversy exists between the parties hereto as to the infringement of the '292 patent.
- 683. Unless enjoined by this Court, upon FDA approval of Padagis's ANDA, Padagis 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 Padagis's Proposed Product in the United States.
- 684. Unless enjoined by this Court, upon FDA approval of Padagis's ANDA, Padagis 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 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 '292 patent and knowledge that its acts are encouraging infringement.
- 685. Unless enjoined by this Court, upon FDA approval of Padagis's ANDA, Padagis 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 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 '292 patent, and Padagis's Proposed Product lacks a substantial non-infringing use.

- 686. Failure to enjoin Padagis's infringement of the '292 patent will substantially and irreparably damage GW.
 - 687. GW does not have an adequate remedy at law.

Count LVIII: Infringement of the '498 Patent by Padagis

- 688. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 689. 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 '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.
- 690. A justiciable controversy exists between the parties hereto as to the infringement of the '498 patent.
- 691. Unless enjoined by this Court, upon FDA approval of Padagis's ANDA, Padagis 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 Padagis's Proposed Product in the United States.
- 692. Unless enjoined by this Court, upon FDA approval of Padagis's ANDA, Padagis 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 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 '498 patent and knowledge that its acts are encouraging infringement.

- 693. Unless enjoined by this Court, upon FDA approval of Padagis's ANDA, Padagis 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 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 '498 patent, and Padagis's Proposed Product lacks a substantial non-infringing use.
- 694. Failure to enjoin Padagis's infringement of the '498 patent will substantially and irreparably damage GW.
 - 695. GW does not have an adequate remedy at law.

Count LIX: Infringement of the '741 Patent by Padagis

- 696. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 697. 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 '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.
- 698. A justiciable controversy exists between the parties hereto as to the infringement of the '741 patent.
- 699. Unless enjoined by this Court, upon FDA approval of Padagis's ANDA, Padagis 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 Padagis's Proposed Product in the United States.

- 700. Unless enjoined by this Court, upon FDA approval of Padagis's ANDA, Padagis 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 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 '741 patent and knowledge that its acts are encouraging infringement.
- 701. Unless enjoined by this Court, upon FDA approval of Padagis's ANDA, Padagis 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 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 '741 patent, and Padagis's Proposed Product lacks a substantial non-infringing use.
- 702. Failure to enjoin Padagis's infringement of the '741 patent will substantially and irreparably damage GW.
 - 703. GW does not have an adequate remedy at law.

Count LX: Infringement of the '258 Patent by Padagis

- 704. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 705. 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 '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.

- 706. A justiciable controversy exists between the parties hereto as to the infringement of the '258 patent.
- 707. Unless enjoined by this Court, upon FDA approval of Padagis's ANDA, Padagis 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 Padagis's Proposed Product in the United States.
- 708. Unless enjoined by this Court, upon FDA approval of Padagis's ANDA, Padagis 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 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 '258 patent and knowledge that its acts are encouraging infringement.
- 709. Unless enjoined by this Court, upon FDA approval of Padagis's ANDA, Padagis 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 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 '258 patent, and Padagis's Proposed Product lacks a substantial non-infringing use.
- 710. Failure to enjoin Padagis's infringement of the '258 patent will substantially and irreparably damage GW.
 - 711. GW does not have an adequate remedy at law.

Count LXI: Infringement of the '937 Patent by InvaGen, Cipla and API Pharma

- 712. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 713. 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.
- 714. A justiciable controversy exists between the parties hereto as to the infringement of the '937 patent.
- 715. 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.
- 716. 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.
- 717. 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.

- 718. Failure to enjoin InvaGen, Cipla, and API Pharma's infringement of the '937 patent will substantially and irreparably damage GW.
 - 719. GW does not have an adequate remedy at law.

Count LXII: Infringement of the '183 Patent by InvaGen, Cipla and API Pharma

- 720. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 721. 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.
- 722. A justiciable controversy exists between the parties hereto as to the infringement of the '183 patent.
- 723. 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.
- 724. 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.

- 725. 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.
- 726. Failure to enjoin InvaGen, Cipla, and API Pharma's infringement of the '183 patent will substantially and irreparably damage GW.
 - 727. GW does not have an adequate remedy at law.

Count LXIII: Infringement of the '184 Patent by InvaGen, Cipla and API Pharma

- 728. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 729. 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.
- 730. A justiciable controversy exists between the parties hereto as to the infringement of the '184 patent.

- 731. 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.
- 732. 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.
- 733. 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.
- 734. Failure to enjoin InvaGen, Cipla, and API Pharma's infringement of the '184 patent will substantially and irreparably damage GW.
 - 735. GW does not have an adequate remedy at law.

Count LXIV: Infringement of the '185 Patent by InvaGen, Cipla and API Pharma

- 736. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 737. 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.
- 738. A justiciable controversy exists between the parties hereto as to the infringement of the '185 patent.
- 739. 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.
- 740. 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.
- 741. 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.

- 742. Failure to enjoin InvaGen, Cipla, and API Pharma's infringement of the '185 patent will substantially and irreparably damage GW.
 - 743. GW does not have an adequate remedy at law.

Count LXV: Infringement of the '186 Patent by InvaGen, Cipla and API Pharma

- 744. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 745. 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.
- 746. A justiciable controversy exists between the parties hereto as to the infringement of the '186 patent.
- 747. 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.
- 748. 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.

- 749. 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.
- 750. Failure to enjoin InvaGen, Cipla, and API Pharma's infringement of the '186 patent will substantially and irreparably damage GW.
 - 751. GW does not have an adequate remedy at law.

Count LXVI: Infringement of the '525 Patent by InvaGen, Cipla and API Pharma

- 752. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 753. 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.
- 754. A justiciable controversy exists between the parties hereto as to the infringement of the '525 patent.

- 755. 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.
- 756. 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.
- 757. 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.
- 758. Failure to enjoin InvaGen, Cipla, and API Pharma's infringement of the '525 patent will substantially and irreparably damage GW.
 - 759. GW does not have an adequate remedy at law.

Count LXVII: Infringement of the '840 Patent by InvaGen, Cipla and API Pharma

- 760. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 761. 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.
- 762. A justiciable controversy exists between the parties hereto as to the infringement of the '840 patent.
- 763. 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.
- 764. 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.
- 765. 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.

- 766. Failure to enjoin InvaGen, Cipla, and API Pharma's infringement of the '840 patent will substantially and irreparably damage GW.
 - 767. GW does not have an adequate remedy at law.

Count LXVIII: Infringement of the '095 Patent by InvaGen, Cipla and API Pharma

- 768. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 769. 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.
- 770. A justiciable controversy exists between the parties hereto as to the infringement of the '095 patent.
- 771. 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.
- 772. 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.

- 773. 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.
- 774. Failure to enjoin InvaGen, Cipla, and API Pharma's infringement of the '095 patent will substantially and irreparably damage GW.
 - 775. GW does not have an adequate remedy at law

Count LXIX: Infringement of the '288 Patent by InvaGen, Cipla and API Pharma

- 776. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 777. 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.
- 778. A justiciable controversy exists between the parties hereto as to the infringement of the '288 patent.

- 779. 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.
- 780. 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.
- 781. 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.
- 782. Failure to enjoin InvaGen, Cipla, and API Pharma's infringement of the '288 patent will substantially and irreparably damage GW.
 - 783. GW does not have an adequate remedy at law.

Count LXX: Infringement of the '671 Patent by InvaGen, Cipla and API Pharma

- 784. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 785. 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.
- 786. A justiciable controversy exists between the parties hereto as to the infringement of the '671 patent.
- 787. 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.
- 788. 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.
- 789. 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.

- 790. Failure to enjoin InvaGen, Cipla, and API Pharma's infringement of the '671 patent will substantially and irreparably damage GW.
 - 791. GW does not have an adequate remedy at law.

Count LXXI: Infringement of the '673 Patent by InvaGen, Cipla and API Pharma

- 792. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 793. 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.
- 794. A justiciable controversy exists between the parties hereto as to the infringement of the '673 patent.
- 795. 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.
- 796. 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.

- 797. 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.
- 798. Failure to enjoin InvaGen, Cipla, and API Pharma's infringement of the '673 patent will substantially and irreparably damage GW.
 - 799. GW does not have an adequate remedy at law.

Count LXXII: Infringement of the '674 Patent by InvaGen, Cipla and API Pharma

- 800. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 801. 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.
- 802. A justiciable controversy exists between the parties hereto as to the infringement of the '674 patent.

- 803. 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.
- 804. 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.
- 805. 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.
- 806. Failure to enjoin InvaGen, Cipla, and API Pharma's infringement of the '674 patent will substantially and irreparably damage GW.
 - 807. GW does not have an adequate remedy at law.

Count LXXIII: Infringement of the '860 Patent by InvaGen, Cipla and API Pharma

- 808. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 809. 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.
- 810. A justiciable controversy exists between the parties hereto as to the infringement of the '860 patent.
- 811. 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.
- 812. 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.
- 813. 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.

- 814. Failure to enjoin InvaGen, Cipla, and API Pharma's infringement of the '860 patent will substantially and irreparably damage GW.
 - 815. GW does not have an adequate remedy at law.

Count LXXIV: Infringement of the '939 Patent by InvaGen, Cipla and API Pharma

- 816. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 817. 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.
- 818. A justiciable controversy exists between the parties hereto as to the infringement of the '939 patent.
- 819. 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.
- 820. 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.

- 821. 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.
- 822. Failure to enjoin InvaGen, Cipla, and API Pharma's infringement of the '939 patent will substantially and irreparably damage GW.
 - 823. GW does not have an adequate remedy at law.

Count LXXV: Infringement of the '905 Patent by InvaGen, Cipla and API Pharma

- 824. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 825. 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.
- 826. A justiciable controversy exists between the parties hereto as to the infringement of the '905 patent.

- 827. 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.
- 828. 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.
- 829. 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.
- 830. Failure to enjoin InvaGen, Cipla, and API Pharma's infringement of the '905 patent will substantially and irreparably damage GW.
 - 831. GW does not have an adequate remedy at law.

Count LXXVI: Infringement of the '516 Patent by InvaGen, Cipla and API Pharma

- 832. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 833. 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.
- 834. A justiciable controversy exists between the parties hereto as to the infringement of the '516 patent.
- 835. 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.
- 836. 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.
- 837. 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.

- 838. Failure to enjoin InvaGen, Cipla, and API Pharma's infringement of the '516 patent will substantially and irreparably damage GW.
 - 839. GW does not have an adequate remedy at law.

Count LXXVII: Infringement of the '292 Patent by InvaGen, Cipla and API Pharma

- 840. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 841. 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.
- 842. A justiciable controversy exists between the parties hereto as to the infringement of the '292 patent.
- 843. 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.
- 844. 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.

- 845. 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.
- 846. Failure to enjoin InvaGen, Cipla, and API Pharma's infringement of the '292 patent will substantially and irreparably damage GW.
 - 847. GW does not have an adequate remedy at law.

Count LXXVIII: Infringement of the '498 Patent by InvaGen, Cipla and API Pharma

- 848. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 849. 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.
- 850. A justiciable controversy exists between the parties hereto as to the infringement of the '498 patent.

- 851. 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.
- 852. 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.
- 853. 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.
- 854. Failure to enjoin InvaGen, Cipla, and API Pharma's infringement of the '498 patent will substantially and irreparably damage GW.
 - 855. GW does not have an adequate remedy at law.

Count LXXIX: Infringement of the '741 Patent by InvaGen, Cipla and API Pharma

- 856. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 857. 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.
- 858. A justiciable controversy exists between the parties hereto as to the infringement of the '741 patent.
- 859. 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.
- 860. 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.
- 861. 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.

- 862. Failure to enjoin InvaGen, Cipla, and API Pharma's infringement of the '741 patent will substantially and irreparably damage GW.
 - 863. GW does not have an adequate remedy at law.

Count LXXX: Infringement of the '258 Patent by InvaGen, Cipla and API Pharma

- 864. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 865. 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.
- 866. A justiciable controversy exists between the parties hereto as to the infringement of the '258 patent.
- 867. 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.
- 868. 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.

- 869. 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.
- 870. Failure to enjoin InvaGen, Cipla, and API Pharma's infringement of the '258 patent will substantially and irreparably damage GW.
 - 871. GW does not have an adequate remedy at law.

Count LXXXI: Infringement of the '937 Patent by Lupin

- 872. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 873. 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 '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.
- 874. A justiciable controversy exists between the parties hereto as to the infringement of the '937 patent.

- 875. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin 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 Lupin's Proposed Product in the United States.
- 876. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin 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 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 '937 patent and knowledge that its acts are encouraging infringement.
- 877. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin 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 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 '937 patent, and Lupin's Proposed Product lacks a substantial non-infringing use.
- 878. Failure to enjoin Lupin's infringement of the '937 patent will substantially and irreparably damage GW.
 - 879. GW does not have an adequate remedy at law.

Count LXXXII: Infringement of the '183 Patent by Lupin

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

- 881. 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 '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.
- 882. A justiciable controversy exists between the parties hereto as to the infringement of the '183 patent.
- 883. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin 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 Lupin's Proposed Product in the United States.
- 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 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 '183 patent and knowledge that its acts are encouraging infringement.
- 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 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 '183 patent, and Lupin's Proposed Product lacks a substantial non-infringing use.

- 886. Failure to enjoin Lupin's infringement of the '183 patent will substantially and irreparably damage GW.
 - 887. GW does not have an adequate remedy at law.

Count LXXXIII: Infringement of the '184 Patent by Lupin

- 888. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 889. 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 '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.
- 890. A justiciable controversy exists between the parties hereto as to the infringement of the '184 patent.
- 891. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin 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 Lupin's Proposed Product in the United States.
- 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 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 '184 patent and knowledge that its acts are encouraging infringement.

- 893. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin 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 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 '184 patent, and Lupin's Proposed Product lacks a substantial non-infringing use.
- 894. Failure to enjoin Lupin's infringement of the '184 patent will substantially and irreparably damage GW.
 - 895. GW does not have an adequate remedy at law.

Count LXXXIV: Infringement of the '185 Patent by Lupin

- 896. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 897. 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 '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.
- 898. A justiciable controversy exists between the parties hereto as to the infringement of the '185 patent.
- 899. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin 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 Lupin's Proposed Product in the United States.

- 900. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin 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 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 '185 patent and knowledge that its acts are encouraging infringement.
- 901. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin 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 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 '185 patent, and Lupin's Proposed Product lacks a substantial non-infringing use.
- 902. Failure to enjoin Lupin's infringement of the '185 patent will substantially and irreparably damage GW.
 - 903. GW does not have an adequate remedy at law.

Count LXXXV: Infringement of the '186 Patent by Lupin

- 904. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 905. 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 '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.

- 906. A justiciable controversy exists between the parties hereto as to the infringement of the '186 patent.
- 907. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin 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 Lupin's Proposed Product in the United States.
- 908. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin 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 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 '186 patent and knowledge that its acts are encouraging infringement.
- 909. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin 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 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 '186 patent, and Lupin's Proposed Product lacks a substantial non-infringing use.
- 910. Failure to enjoin Lupin's infringement of the '186 patent will substantially and irreparably damage GW.
 - 911. GW does not have an adequate remedy at law.

Count LXXXVI: Infringement of the '525 Patent by Lupin

- 912. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 913. 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 '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.
- 914. A justiciable controversy exists between the parties hereto as to the infringement of the '525 patent.
- 915. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin 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 Lupin's Proposed Product in the United States.
- 916. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin 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 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 '525 patent and knowledge that its acts are encouraging infringement.
- 917. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin 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 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 '525 patent, and Lupin's Proposed Product lacks a substantial non-infringing use.

- 918. Failure to enjoin Lupin's infringement of the '525 patent will substantially and irreparably damage GW.
 - 919. GW does not have an adequate remedy at law.

Count LXXXVII: Infringement of the '840 Patent by Lupin

- 920. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 921. 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 '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.
- 922. A justiciable controversy exists between the parties hereto as to the infringement of the '840 patent.
- 923. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin 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 Lupin's Proposed Product in the United States.
- 924. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin 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 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 '840 patent and knowledge that its acts are encouraging infringement.

- 925. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin 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 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 '840 patent, and Lupin's Proposed Product lacks a substantial non-infringing use.
- 926. Failure to enjoin Lupin's infringement of the '840 patent will substantially and irreparably damage GW.
 - 927. GW does not have an adequate remedy at law.

Count LXXXVIII: Infringement of the '095 Patent by Lupin

- 928. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 929. 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 '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.
- 930. A justiciable controversy exists between the parties hereto as to the infringement of the '095 patent.
- 931. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin 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 Lupin's Proposed Product in the United States.

- 932. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin 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 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 '095 patent and knowledge that its acts are encouraging infringement.
- 933. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin 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 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 '095 patent, and Lupin's Proposed Product lacks a substantial non-infringing use.
- 934. Failure to enjoin Lupin's infringement of the '095 patent will substantially and irreparably damage GW.
 - 935. GW does not have an adequate remedy at law.

Count LXXXIX: Infringement of the '288 Patent by Lupin

- 936. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 937. 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 '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.

- 938. A justiciable controversy exists between the parties hereto as to the infringement of the '288 patent.
- 939. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin 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 Lupin's Proposed Product in the United States.
- 940. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin 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 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 '288 patent and knowledge that its acts are encouraging infringement.
- 941. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin 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 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 '288 patent, and Lupin's Proposed Product lacks a substantial non-infringing use.
- 942. Failure to enjoin Lupin's infringement of the '288 patent will substantially and irreparably damage GW.
 - 943. GW does not have an adequate remedy at law.

Count XC: Infringement of the '671 Patent by Lupin

- 944. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 945. 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 '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.
- 946. A justiciable controversy exists between the parties hereto as to the infringement of the '671 patent.
- 947. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin 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 Lupin's Proposed Product in the United States.
- 948. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin 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 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 '671 patent and knowledge that its acts are encouraging infringement.
- 949. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin 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 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 '671 patent, and Lupin's Proposed Product lacks a substantial non-infringing use.

- 950. Failure to enjoin Lupin's infringement of the '671 patent will substantially and irreparably damage GW.
 - 951. GW does not have an adequate remedy at law.

Count XCI: Infringement of the '673 Patent by Lupin

- 952. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 953. 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 '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.
- 954. A justiciable controversy exists between the parties hereto as to the infringement of the '673 patent.
- 955. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin 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 Lupin's Proposed Product in the United States.
- 956. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin 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 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 '673 patent and knowledge that its acts are encouraging infringement.

- 957. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin 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 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 '673 patent, and Lupin's Proposed Product lacks a substantial non-infringing use.
- 958. Failure to enjoin Lupin's infringement of the '673 patent will substantially and irreparably damage GW.
 - 959. GW does not have an adequate remedy at law.

Count XCII: Infringement of the '674 Patent by Lupin

- 960. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 961. 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 '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.
- 962. A justiciable controversy exists between the parties hereto as to the infringement of the '674 patent.
- 963. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin 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 Lupin's Proposed Product in the United States.
- 964. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin 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 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 '674 patent and knowledge that its acts are encouraging infringement.
- 965. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin 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 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 '674 patent, and Lupin's Proposed Product lacks a substantial non-infringing use.
- 966. Failure to enjoin Lupin's infringement of the '674 patent will substantially and irreparably damage GW.
 - 967. GW does not have an adequate remedy at law.

Count XCIII: Infringement of the '860 Patent by Lupin

- 968. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 969. 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 '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.

- 970. A justiciable controversy exists between the parties hereto as to the infringement of the '860 patent.
- 971. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin 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 Lupin's Proposed Product in the United States.
- 972. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin 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 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 '860 patent and knowledge that its acts are encouraging infringement.
- 973. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin 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 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 '860 patent, and Lupin's Proposed Product lacks a substantial non-infringing use.
- 974. Failure to enjoin Lupin's infringement of the '860 patent will substantially and irreparably damage GW.
 - 975. GW does not have an adequate remedy at law.

Count XCIV: Infringement of the '939 Patent by Lupin

- 976. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 977. 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 '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.
- 978. A justiciable controversy exists between the parties hereto as to the infringement of the '939 patent.
- 979. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin 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 Lupin's Proposed Product in the United States.
- 980. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin 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 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 '939 patent and knowledge that its acts are encouraging infringement.
- 981. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin 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 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 '939 patent, and Lupin's Proposed Product lacks a substantial non-infringing use.

- 982. Failure to enjoin Lupin's infringement of the '939 patent will substantially and irreparably damage GW.
 - 983. GW does not have an adequate remedy at law.

Count XCV: Infringement of the '905 Patent by Lupin

- 984. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 985. 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 '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.
- 986. A justiciable controversy exists between the parties hereto as to the infringement of the '905 patent.
- 987. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin 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 Lupin's Proposed Product in the United States.
- 988. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin 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 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 '905 patent and knowledge that its acts are encouraging infringement.

- 989. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin 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 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 '905 patent, and Lupin's Proposed Product lacks a substantial non-infringing use.
- 990. Failure to enjoin Lupin's infringement of the '905 patent will substantially and irreparably damage GW.
 - 991. GW does not have an adequate remedy at law.

Count XCVI: Infringement of the '516 Patent by Lupin

- 992. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 993. 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 '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.
- 994. A justiciable controversy exists between the parties hereto as to the infringement of the '516 patent.
- 995. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin 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 Lupin's Proposed Product in the United States.
- 996. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin 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 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 '516 patent and knowledge that its acts are encouraging infringement.
- 997. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin 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 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 '516 patent, and Lupin's Proposed Product lacks a substantial non-infringing use.
- 998. Failure to enjoin Lupin's infringement of the '516 patent will substantially and irreparably damage GW.
 - 999. GW does not have an adequate remedy at law.

Count XCVII: Infringement of the '292 Patent by Lupin

- 1000. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 1001. 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 '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.

- 1002. A justiciable controversy exists between the parties hereto as to the infringement of the '292 patent.
- 1003. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin 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 Lupin's Proposed Product in the United States.
- 1004. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin 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 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 '292 patent and knowledge that its acts are encouraging infringement.
- 1005. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin 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 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 '292 patent, and Lupin's Proposed Product lacks a substantial non-infringing use.
- 1006. Failure to enjoin Lupin's infringement of the '292 patent will substantially and irreparably damage GW.
 - 1007. GW does not have an adequate remedy at law.

Count XCVIII: Infringement of the '498 Patent by Lupin

- 1008. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 1009. 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 '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.
- 1010. A justiciable controversy exists between the parties hereto as to the infringement of the '498 patent.
- 1011. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin 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 Lupin's Proposed Product in the United States.
- 1012. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin 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 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 '498 patent and knowledge that its acts are encouraging infringement.
- 1013. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin 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 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 '498 patent, and Lupin's Proposed Product lacks a substantial non-infringing use.

- 1014. Failure to enjoin Lupin's infringement of the '498 patent will substantially and irreparably damage GW.
 - 1015. GW does not have an adequate remedy at law.

Count XCIX: Infringement of the '741 Patent by Lupin

- 1016. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 1017. 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 '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.
- 1018. A justiciable controversy exists between the parties hereto as to the infringement of the '741 patent.
- 1019. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin 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 Lupin's Proposed Product in the United States.
- 1020. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin 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 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 '741 patent and knowledge that its acts are encouraging infringement.

- 1021. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin 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 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 '741 patent, and Lupin's Proposed Product lacks a substantial non-infringing use.
- 1022. Failure to enjoin Lupin's infringement of the '741 patent will substantially and irreparably damage GW.
 - 1023. GW does not have an adequate remedy at law.

Count C: Infringement of the '258 Patent by Lupin

- 1024. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 1025. 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 '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.
- 1026. A justiciable controversy exists between the parties hereto as to the infringement of the '258 patent.
- 1027. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin 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 Lupin's Proposed Product in the United States.
- 1028. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin 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 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 '258 patent and knowledge that its acts are encouraging infringement.
- 1029. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA, Lupin 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 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 '258 patent, and Lupin's Proposed Product lacks a substantial non-infringing use.
- 1030. Failure to enjoin Lupin's infringement of the '258 patent will substantially and irreparably damage GW.
 - 1031. GW does not have an adequate remedy at law.

Count CI: Infringement of the '937 Patent by Alkem

- 1032. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 1033. 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 '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.

- 1034. A justiciable controversy exists between the parties hereto as to the infringement of the '937 patent.
- 1035. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem 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 Alkem's Proposed Product in the United States.
- 1036. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem 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 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 '937 patent and knowledge that its acts are encouraging infringement.
- 1037. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem 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 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 '937 patent, and Alkem's Proposed Product lacks a substantial non-infringing use.
- 1038. Failure to enjoin Alkem's infringement of the '937 patent will substantially and irreparably damage GW.
 - 1039. GW does not have an adequate remedy at law.

Count CII: Infringement of the '183 Patent by Alkem

- 1040. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 1041. 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 '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.
- 1042. A justiciable controversy exists between the parties hereto as to the infringement of the '183 patent.
- 1043. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem 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 Alkem's Proposed Product in the United States.
- 1044. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem 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 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 '183 patent and knowledge that its acts are encouraging infringement.
- 1045. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem 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 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 '183 patent, and Alkem's Proposed Product lacks a substantial non-infringing use.

- 1046. Failure to enjoin Alkem's infringement of the '183 patent will substantially and irreparably damage GW.
 - 1047. GW does not have an adequate remedy at law.

Count CIII: Infringement of the '184 Patent by Alkem

- 1048. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 1049. 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 '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.
- 1050. A justiciable controversy exists between the parties hereto as to the infringement of the '184 patent.
- 1051. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem 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 Alkem's Proposed Product in the United States.
- 1052. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem 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 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 '184 patent and knowledge that its acts are encouraging infringement.

- 1053. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem 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 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 '184 patent, and Alkem's Proposed Product lacks a substantial non-infringing use.
- 1054. Failure to enjoin Alkem's infringement of the '184 patent will substantially and irreparably damage GW.
 - 1055. GW does not have an adequate remedy at law.

Count CIV: Infringement of the '185 Patent by Alkem

- 1056. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 1057. 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 '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.
- 1058. A justiciable controversy exists between the parties hereto as to the infringement of the '185 patent.
- 1059. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem 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 Alkem's Proposed Product in the United States.

- 1060. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem 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 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 '185 patent and knowledge that its acts are encouraging infringement.
- 1061. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem 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 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 '185 patent, and Alkem's Proposed Product lacks a substantial non-infringing use.
- 1062. Failure to enjoin Alkem's infringement of the '185 patent will substantially and irreparably damage GW.
 - 1063. GW does not have an adequate remedy at law.

Count CV: Infringement of the '186 Patent by Alkem

- 1064. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 1065. 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 '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.

- 1066. A justiciable controversy exists between the parties hereto as to the infringement of the '186 patent.
- 1067. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem 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 Alkem's Proposed Product in the United States.
- 1068. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem 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 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 '186 patent and knowledge that its acts are encouraging infringement.
- 1069. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem 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 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 '186 patent, and Alkem's Proposed Product lacks a substantial non-infringing use.
- 1070. Failure to enjoin Alkem's infringement of the '186 patent will substantially and irreparably damage GW.
 - 1071. GW does not have an adequate remedy at law.

Count CVI: Infringement of the '525 Patent by Alkem

- 1072. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 1073. 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 '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.
- 1074. A justiciable controversy exists between the parties hereto as to the infringement of the '525 patent.
- 1075. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem 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 Alkem's Proposed Product in the United States.
- 1076. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem 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 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 '525 patent and knowledge that its acts are encouraging infringement.
- 1077. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem 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 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 '525 patent, and Alkem's Proposed Product lacks a substantial non-infringing use.

- 1078. Failure to enjoin Alkem's infringement of the '525 patent will substantially and irreparably damage GW.
 - 1079. GW does not have an adequate remedy at law.

Count CVII: Infringement of the '840 Patent by Alkem

- 1080. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 1081. 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 '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.
- 1082. A justiciable controversy exists between the parties hereto as to the infringement of the '840 patent.
- 1083. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem 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 Alkem's Proposed Product in the United States.
- 1084. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem 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 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 '840 patent and knowledge that its acts are encouraging infringement.

- 1085. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem 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 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 '840 patent, and Alkem's Proposed Product lacks a substantial non-infringing use.
- 1086. Failure to enjoin Alkem's infringement of the '840 patent will substantially and irreparably damage GW.
 - 1087. GW does not have an adequate remedy at law.

Count CVIII: Infringement of the '095 Patent by Alkem

- 1088. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 1089. 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 '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.
- 1090. A justiciable controversy exists between the parties hereto as to the infringement of the '095 patent.
- 1091. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem 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 Alkem's Proposed Product in the United States.

- 1092. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem 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 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 '095 patent and knowledge that its acts are encouraging infringement.
- 1093. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem 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 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 '095 patent, and Alkem's Proposed Product lacks a substantial non-infringing use.
- 1094. Failure to enjoin Alkem's infringement of the '095 patent will substantially and irreparably damage GW.
 - 1095. GW does not have an adequate remedy at law.

Count CIX: Infringement of the '288 Patent by Alkem

- 1096. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 1097. 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 '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.

- 1098. A justiciable controversy exists between the parties hereto as to the infringement of the '288 patent.
- 1099. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem 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 Alkem's Proposed Product in the United States.
- 1100. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem 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 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 '288 patent and knowledge that its acts are encouraging infringement.
- 1101. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem 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 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 '288 patent, and Alkem's Proposed Product lacks a substantial non-infringing use.
- 1102. Failure to enjoin Alkem's infringement of the '288 patent will substantially and irreparably damage GW.
 - 1103. GW does not have an adequate remedy at law.

Count CX: Infringement of the '671 Patent by Alkem

- 1104. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 1105. 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 '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.
- 1106. A justiciable controversy exists between the parties hereto as to the infringement of the '671 patent.
- 1107. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem 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 Alkem's Proposed Product in the United States.
- 1108. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem 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 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 '671 patent and knowledge that its acts are encouraging infringement.
- 1109. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem 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 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 '671 patent, and Alkem's Proposed Product lacks a substantial non-infringing use.

- 1110. Failure to enjoin Alkem's infringement of the '671 patent will substantially and irreparably damage GW.
 - 1111. GW does not have an adequate remedy at law.

Count CXI: Infringement of the '673 Patent by Alkem

- 1112. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 1113. 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 '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.
- 1114. A justiciable controversy exists between the parties hereto as to the infringement of the '673 patent.
- 1115. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem 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 Alkem's Proposed Product in the United States.
- 1116. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem 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 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 '673 patent and knowledge that its acts are encouraging infringement.

- 1117. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem 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 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 '673 patent, and Alkem's Proposed Product lacks a substantial non-infringing use.
- 1118. Failure to enjoin Alkem's infringement of the '673 patent will substantially and irreparably damage GW.
 - 1119. GW does not have an adequate remedy at law.

Count CXII: Infringement of the '674 Patent by Alkem

- 1120. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 1121. 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 '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.
- 1122. A justiciable controversy exists between the parties hereto as to the infringement of the '674 patent.
- 1123. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem 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 Alkem's Proposed Product in the United States.

- 1124. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem 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 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 '674 patent and knowledge that its acts are encouraging infringement.
- 1125. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem 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 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 '674 patent, and Alkem's Proposed Product lacks a substantial non-infringing use.
- 1126. Failure to enjoin Alkem's infringement of the '674 patent will substantially and irreparably damage GW.
 - 1127. GW does not have an adequate remedy at law.

Count CXIII: Infringement of the '860 Patent by Alkem

- 1128. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 1129. 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 '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.

- 1130. A justiciable controversy exists between the parties hereto as to the infringement of the '860 patent.
- 1131. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem 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 Alkem's Proposed Product in the United States.
- 1132. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem 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 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 '860 patent and knowledge that its acts are encouraging infringement.
- 1133. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem 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 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 '860 patent, and Alkem's Proposed Product lacks a substantial non-infringing use.
- 1134. Failure to enjoin Alkem's infringement of the '860 patent will substantially and irreparably damage GW.
 - 1135. GW does not have an adequate remedy at law.

Count CXIV: Infringement of the '939 Patent by Alkem

- 1136. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 1137. 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 '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.
- 1138. A justiciable controversy exists between the parties hereto as to the infringement of the '939 patent.
- 1139. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem 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 Alkem's Proposed Product in the United States.
- 1140. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem 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 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 '939 patent and knowledge that its acts are encouraging infringement.
- 1141. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem 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 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 '939 patent, and Alkem's Proposed Product lacks a substantial non-infringing use.

- 1142. Failure to enjoin Alkem's infringement of the '939 patent will substantially and irreparably damage GW.
 - 1143. GW does not have an adequate remedy at law.

Count CXV: Infringement of the '905 Patent by Alkem

- 1144. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 1145. 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 '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.
- 1146. A justiciable controversy exists between the parties hereto as to the infringement of the '905 patent.
- 1147. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem 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 Alkem's Proposed Product in the United States.
- 1148. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem 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 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 '905 patent and knowledge that its acts are encouraging infringement.

- 1149. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem 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 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 '905 patent, and Alkem's Proposed Product lacks a substantial non-infringing use.
- 1150. Failure to enjoin Alkem's infringement of the '905 patent will substantially and irreparably damage GW.
 - 1151. GW does not have an adequate remedy at law.

Count CXVI: Infringement of the '516 Patent by Alkem

- 1152. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 1153. 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 '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.
- 1154. A justiciable controversy exists between the parties hereto as to the infringement of the '516 patent.
- 1155. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem 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 Alkem's Proposed Product in the United States.

- 1156. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem 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 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 '516 patent and knowledge that its acts are encouraging infringement.
- 1157. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem 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 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 '516 patent, and Alkem's Proposed Product lacks a substantial non-infringing use.
- 1158. Failure to enjoin Alkem's infringement of the '516 patent will substantially and irreparably damage GW.
 - 1159. GW does not have an adequate remedy at law.

Count CXVII: Infringement of the '292 Patent by Alkem

- 1160. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 1161. 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 '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.

- 1162. A justiciable controversy exists between the parties hereto as to the infringement of the '292 patent.
- 1163. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem 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 Alkem's Proposed Product in the United States.
- 1164. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem 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 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 '292 patent and knowledge that its acts are encouraging infringement.
- 1165. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem 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 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 '292 patent, and Alkem's Proposed Product lacks a substantial non-infringing use.
- 1166. Failure to enjoin Alkem's infringement of the '292 patent will substantially and irreparably damage GW.
 - 1167. GW does not have an adequate remedy at law.

Count CXVIII: Infringement of the '498 Patent by Alkem

- 1168. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 1169. 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 '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.
- 1170. A justiciable controversy exists between the parties hereto as to the infringement of the '498 patent.
- 1171. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem 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 Alkem's Proposed Product in the United States.
- 1172. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem 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 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 '498 patent and knowledge that its acts are encouraging infringement.
- 1173. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem 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 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 '498 patent, and Alkem's Proposed Product lacks a substantial non-infringing use.

- 1174. Failure to enjoin Alkem's infringement of the '498 patent will substantially and irreparably damage GW.
 - 1175. GW does not have an adequate remedy at law.

Count CXIX: Infringement of the '741 Patent by Alkem

- 1176. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 1177. 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 '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.
- 1178. A justiciable controversy exists between the parties hereto as to the infringement of the '741 patent.
- 1179. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem 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 Alkem's Proposed Product in the United States.
- 1180. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem 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 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 '741 patent and knowledge that its acts are encouraging infringement.

- 1181. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem 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 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 '741 patent, and Alkem's Proposed Product lacks a substantial non-infringing use.
- 1182. Failure to enjoin Alkem's infringement of the '741 patent will substantially and irreparably damage GW.
 - 1183. GW does not have an adequate remedy at law.

Count CXX: Infringement of the '258 Patent by Alkem

- 1184. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 1185. 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 '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.
- 1186. A justiciable controversy exists between the parties hereto as to the infringement of the '258 patent.
- 1187. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem 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 Alkem's Proposed Product in the United States.

- 1188. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem 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 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 '258 patent and knowledge that its acts are encouraging infringement.
- 1189. Unless enjoined by this Court, upon FDA approval of Alkem's ANDA, Alkem 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 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 '258 patent, and Alkem's Proposed Product lacks a substantial non-infringing use.
- 1190. Failure to enjoin Alkem's infringement of the '258 patent will substantially and irreparably damage GW.
 - 1191. GW does not have an adequate remedy at law.

Count CXXI: Infringement of the '937 Patent by Taro

- 1192. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 1193. 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 '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.

- 1194. A justiciable controversy exists between the parties hereto as to the infringement of the '937 patent.
- 1195. Unless enjoined by this Court, upon FDA approval of Taro's ANDA, Taro 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 Taro's Proposed Product in the United States.
- 1196. Unless enjoined by this Court, upon FDA approval of Taro's ANDA, Taro 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 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 '937 patent and knowledge that its acts are encouraging infringement.
- 1197. Unless enjoined by this Court, upon FDA approval of Taro's ANDA, Taro 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 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 '937 patent, and Taro's Proposed Product lacks a substantial non-infringing use.
- 1198. Failure to enjoin Taro's infringement of the '937 patent will substantially and irreparably damage GW.
 - 1199. GW does not have an adequate remedy at law.

Count CXXII: Infringement of the '183 Patent by Taro

- 1200. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 1201. 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 '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.
- 1202. A justiciable controversy exists between the parties hereto as to the infringement of the '183 patent.
- 1203. Unless enjoined by this Court, upon FDA approval of Taro's ANDA, Taro 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 Taro's Proposed Product in the United States.
- 1204. Unless enjoined by this Court, upon FDA approval of Taro's ANDA, Taro 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 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 '183 patent and knowledge that its acts are encouraging infringement.
- 1205. Unless enjoined by this Court, upon FDA approval of Taro's ANDA, Taro 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 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 '183 patent, and Taro's Proposed Product lacks a substantial non-infringing use.

- 1206. Failure to enjoin Taro's infringement of the '183 patent will substantially and irreparably damage GW.
 - 1207. GW does not have an adequate remedy at law.

Count CXXIII: Infringement of the '184 Patent by Taro

- 1208. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 1209. 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 '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.
- 1210. A justiciable controversy exists between the parties hereto as to the infringement of the '184 patent.
- 1211. Unless enjoined by this Court, upon FDA approval of Taro's ANDA, Taro 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 Taro's Proposed Product in the United States.
- 1212. Unless enjoined by this Court, upon FDA approval of Taro's ANDA, Taro 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 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 '184 patent and knowledge that its acts are encouraging infringement.

- 1213. Unless enjoined by this Court, upon FDA approval of Taro's ANDA, Taro 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 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 '184 patent, and Taro's Proposed Product lacks a substantial non-infringing use.
- 1214. Failure to enjoin Taro's infringement of the '184 patent will substantially and irreparably damage GW.
 - 1215. GW does not have an adequate remedy at law.

Count CXXIV: Infringement of the '185 Patent by Taro

- 1216. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 1217. 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 '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.
- 1218. A justiciable controversy exists between the parties hereto as to the infringement of the '185 patent.
- 1219. Unless enjoined by this Court, upon FDA approval of Taro's ANDA, Taro 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 Taro's Proposed Product in the United States.
- 1220. Unless enjoined by this Court, upon FDA approval of Taro's ANDA, Taro 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 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 '185 patent and knowledge that its acts are encouraging infringement.
- 1221. Unless enjoined by this Court, upon FDA approval of Taro's ANDA, Taro 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 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 '185 patent, and Taro's Proposed Product lacks a substantial non-infringing use.
- 1222. Failure to enjoin Taro's infringement of the '185 patent will substantially and irreparably damage GW.
 - 1223. GW does not have an adequate remedy at law.

Count CXXV: Infringement of the '186 Patent by Taro

- 1224. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 1225. 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 '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.

- 1226. A justiciable controversy exists between the parties hereto as to the infringement of the '186 patent.
- 1227. Unless enjoined by this Court, upon FDA approval of Taro's ANDA, Taro 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 Taro's Proposed Product in the United States.
- 1228. Unless enjoined by this Court, upon FDA approval of Taro's ANDA, Taro 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 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 '186 patent and knowledge that its acts are encouraging infringement.
- 1229. Unless enjoined by this Court, upon FDA approval of Taro's ANDA, Taro 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 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 '186 patent, and Taro's Proposed Product lacks a substantial non-infringing use.
- 1230. Failure to enjoin Taro's infringement of the '186 patent will substantially and irreparably damage GW.
 - 1231. GW does not have an adequate remedy at law.

Count CXXVI: Infringement of the '525 Patent by Taro

- 1232. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 1233. 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 '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.
- 1234. A justiciable controversy exists between the parties hereto as to the infringement of the '525 patent.
- 1235. Unless enjoined by this Court, upon FDA approval of Taro's ANDA, Taro 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 Taro's Proposed Product in the United States.
- 1236. Unless enjoined by this Court, upon FDA approval of Taro's ANDA, Taro 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 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 '525 patent and knowledge that its acts are encouraging infringement.
- 1237. Unless enjoined by this Court, upon FDA approval of Taro's ANDA, Taro 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 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 '525 patent, and Taro's Proposed Product lacks a substantial non-infringing use.

- 1238. Failure to enjoin Taro's infringement of the '525 patent will substantially and irreparably damage GW.
 - 1239. GW does not have an adequate remedy at law.

Count CXXVII: Infringement of the '840 Patent by Taro

- 1240. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 1241. 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 '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.
- 1242. A justiciable controversy exists between the parties hereto as to the infringement of the '840 patent.
- 1243. Unless enjoined by this Court, upon FDA approval of Taro's ANDA, Taro 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 Taro's Proposed Product in the United States.
- 1244. Unless enjoined by this Court, upon FDA approval of Taro's ANDA, Taro 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 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 '840 patent and knowledge that its acts are encouraging infringement.

- 1245. Unless enjoined by this Court, upon FDA approval of Taro's ANDA, Taro 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 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 '840 patent, and Taro's Proposed Product lacks a substantial non-infringing use.
- 1246. Failure to enjoin Taro's infringement of the '840 patent will substantially and irreparably damage GW.
 - 1247. GW does not have an adequate remedy at law.

Count CXXVIII: Infringement of the '095 Patent by Taro

- 1248. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 1249. 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 '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.
- 1250. A justiciable controversy exists between the parties hereto as to the infringement of the '095 patent.
- 1251. Unless enjoined by this Court, upon FDA approval of Taro's ANDA, Taro 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 Taro's Proposed Product in the United States.
- 1252. Unless enjoined by this Court, upon FDA approval of Taro's ANDA, Taro 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 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 '095 patent and knowledge that its acts are encouraging infringement.
- 1253. Unless enjoined by this Court, upon FDA approval of Taro's ANDA, Taro 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 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 '095 patent, and Taro's Proposed Product lacks a substantial non-infringing use.
- 1254. Failure to enjoin Taro's infringement of the '095 patent will substantially and irreparably damage GW.
 - 1255. GW does not have an adequate remedy at law.

Count CXXIX: Infringement of the '288 Patent by Taro

- 1256. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 1257. 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 '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.

- 1258. A justiciable controversy exists between the parties hereto as to the infringement of the '288 patent.
- 1259. Unless enjoined by this Court, upon FDA approval of Taro's ANDA, Taro 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 Taro's Proposed Product in the United States.
- 1260. Unless enjoined by this Court, upon FDA approval of Taro's ANDA, Taro 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 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 '288 patent and knowledge that its acts are encouraging infringement.
- 1261. Unless enjoined by this Court, upon FDA approval of Taro's ANDA, Taro 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 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 '288 patent, and Taro's Proposed Product lacks a substantial non-infringing use.
- 1262. Failure to enjoin Taro's infringement of the '288 patent will substantially and irreparably damage GW.
 - 1263. GW does not have an adequate remedy at law.

Count CXXX: Infringement of the '671 Patent by Taro

- 1264. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 1265. 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 '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.
- 1266. A justiciable controversy exists between the parties hereto as to the infringement of the '671 patent.
- 1267. Unless enjoined by this Court, upon FDA approval of Taro's ANDA, Taro 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 Taro's Proposed Product in the United States.
- 1268. Unless enjoined by this Court, upon FDA approval of Taro's ANDA, Taro 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 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 '671 patent and knowledge that its acts are encouraging infringement.
- 1269. Unless enjoined by this Court, upon FDA approval of Taro's ANDA, Taro 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 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 '671 patent, and Taro's Proposed Product lacks a substantial non-infringing use.

- 1270. Failure to enjoin Taro's infringement of the '671 patent will substantially and irreparably damage GW.
 - 1271. GW does not have an adequate remedy at law.

Count CXXXI: Infringement of the '673 Patent by Taro

- 1272. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 1273. 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 '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.
- 1274. A justiciable controversy exists between the parties hereto as to the infringement of the '673 patent.
- 1275. Unless enjoined by this Court, upon FDA approval of Taro's ANDA, Taro 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 Taro's Proposed Product in the United States.
- 1276. Unless enjoined by this Court, upon FDA approval of Taro's ANDA, Taro 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 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 '673 patent and knowledge that its acts are encouraging infringement.

- 1277. Unless enjoined by this Court, upon FDA approval of Taro's ANDA, Taro 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 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 '673 patent, and Taro's Proposed Product lacks a substantial non-infringing use.
- 1278. Failure to enjoin Taro's infringement of the '673 patent will substantially and irreparably damage GW.
 - 1279. GW does not have an adequate remedy at law.

Count CXXXII: Infringement of the '674 Patent by Taro

- 1280. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 1281. 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 '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.
- 1282. A justiciable controversy exists between the parties hereto as to the infringement of the '674 patent.
- 1283. Unless enjoined by this Court, upon FDA approval of Taro's ANDA, Taro 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 Taro's Proposed Product in the United States.
- 1284. Unless enjoined by this Court, upon FDA approval of Taro's ANDA, Taro 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 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 '674 patent and knowledge that its acts are encouraging infringement.
- 1285. Unless enjoined by this Court, upon FDA approval of Taro's ANDA, Taro 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 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 '674 patent, and Taro's Proposed Product lacks a substantial non-infringing use.
- 1286. Failure to enjoin Taro's infringement of the '674 patent will substantially and irreparably damage GW.
 - 1287. GW does not have an adequate remedy at law.

Count CXXXIII: Infringement of the '860 Patent by Taro

- 1288. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 1289. 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 '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.

- 1290. A justiciable controversy exists between the parties hereto as to the infringement of the '860 patent.
- 1291. Unless enjoined by this Court, upon FDA approval of Taro's ANDA, Taro 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 Taro's Proposed Product in the United States.
- 1292. Unless enjoined by this Court, upon FDA approval of Taro's ANDA, Taro 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 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 '860 patent and knowledge that its acts are encouraging infringement.
- 1293. Unless enjoined by this Court, upon FDA approval of Taro's ANDA, Taro 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 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 '860 patent, and Taro's Proposed Product lacks a substantial non-infringing use.
- 1294. Failure to enjoin Taro's infringement of the '860 patent will substantially and irreparably damage GW.
 - 1295. GW does not have an adequate remedy at law.

Count CXXXIV: Infringement of the '939 Patent by Taro

- 1296. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 1297. 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 '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.
- 1298. A justiciable controversy exists between the parties hereto as to the infringement of the '939 patent.
- 1299. Unless enjoined by this Court, upon FDA approval of Taro's ANDA, Taro 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 Taro's Proposed Product in the United States.
- 1300. Unless enjoined by this Court, upon FDA approval of Taro's ANDA, Taro 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 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 '939 patent and knowledge that its acts are encouraging infringement.
- 1301. Unless enjoined by this Court, upon FDA approval of Taro's ANDA, Taro 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 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 '939 patent, and Taro's Proposed Product lacks a substantial non-infringing use.

- 1302. Failure to enjoin Taro's infringement of the '939 patent will substantially and irreparably damage GW.
 - 1303. GW does not have an adequate remedy at law.

Count CXXXV: Infringement of the '905 Patent by Taro

- 1304. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 1305. 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 '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.
- 1306. A justiciable controversy exists between the parties hereto as to the infringement of the '905 patent.
- 1307. Unless enjoined by this Court, upon FDA approval of Taro's ANDA, Taro 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 Taro's Proposed Product in the United States.
- 1308. Unless enjoined by this Court, upon FDA approval of Taro's ANDA, Taro 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 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 '905 patent and knowledge that its acts are encouraging infringement.

- 1309. Unless enjoined by this Court, upon FDA approval of Taro's ANDA, Taro 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 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 '905 patent, and Taro's Proposed Product lacks a substantial non-infringing use.
- 1310. Failure to enjoin Taro's infringement of the '905 patent will substantially and irreparably damage GW.
 - 1311. GW does not have an adequate remedy at law.

Count CXXXVI: Infringement of the '516 Patent by Taro

- 1312. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 1313. 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 '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.
- 1314. A justiciable controversy exists between the parties hereto as to the infringement of the '516 patent.
- 1315. Unless enjoined by this Court, upon FDA approval of Taro's ANDA, Taro 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 Taro's Proposed Product in the United States.
- 1316. Unless enjoined by this Court, upon FDA approval of Taro's ANDA, Taro 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 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 '516 patent and knowledge that its acts are encouraging infringement.
- 1317. Unless enjoined by this Court, upon FDA approval of Taro's ANDA, Taro 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 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 '516 patent, and Taro's Proposed Product lacks a substantial non-infringing use.
- 1318. Failure to enjoin Taro's infringement of the '516 patent will substantially and irreparably damage GW.
 - 1319. GW does not have an adequate remedy at law.

Count CXXXVII: Infringement of the '292 Patent by Taro

- 1320. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 1321. 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 '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.

- 1322. A justiciable controversy exists between the parties hereto as to the infringement of the '292 patent.
- 1323. Unless enjoined by this Court, upon FDA approval of Taro's ANDA, Taro 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 Taro's Proposed Product in the United States.
- 1324. Unless enjoined by this Court, upon FDA approval of Taro's ANDA, Taro 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 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 '292 patent and knowledge that its acts are encouraging infringement.
- 1325. Unless enjoined by this Court, upon FDA approval of Taro's ANDA, Taro 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 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 '292 patent, and Taro's Proposed Product lacks a substantial non-infringing use.
- 1326. Failure to enjoin Taro's infringement of the '292 patent will substantially and irreparably damage GW.
 - 1327. GW does not have an adequate remedy at law.

Count CXXXVIII: Infringement of the '498 Patent by Taro

- 1328. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 1329. 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 '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.
- 1330. A justiciable controversy exists between the parties hereto as to the infringement of the '498 patent.
- 1331. Unless enjoined by this Court, upon FDA approval of Taro's ANDA, Taro 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 Taro's Proposed Product in the United States.
- 1332. Unless enjoined by this Court, upon FDA approval of Taro's ANDA, Taro 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 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 '498 patent and knowledge that its acts are encouraging infringement.
- 1333. Unless enjoined by this Court, upon FDA approval of Taro's ANDA, Taro 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 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 '498 patent, and Taro's Proposed Product lacks a substantial non-infringing use.

- 1334. Failure to enjoin Taro's infringement of the '498 patent will substantially and irreparably damage GW.
 - 1335. GW does not have an adequate remedy at law.

Count CXXXIX: Infringement of the '741 Patent by Taro

- 1336. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 1337. 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 '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.
- 1338. A justiciable controversy exists between the parties hereto as to the infringement of the '741 patent.
- 1339. Unless enjoined by this Court, upon FDA approval of Taro's ANDA, Taro 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 Taro's Proposed Product in the United States.
- 1340. Unless enjoined by this Court, upon FDA approval of Taro's ANDA, Taro 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 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 '741 patent and knowledge that its acts are encouraging infringement.

- 1341. Unless enjoined by this Court, upon FDA approval of Taro's ANDA, Taro 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 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 '741 patent, and Taro's Proposed Product lacks a substantial non-infringing use.
- 1342. Failure to enjoin Taro's infringement of the '741 patent will substantially and irreparably damage GW.
 - 1343. GW does not have an adequate remedy at law.

Count CXL: Infringement of the '258 Patent by Taro

- 1344. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 1345. 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 '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.
- 1346. A justiciable controversy exists between the parties hereto as to the infringement of the '258 patent.
- 1347. Unless enjoined by this Court, upon FDA approval of Taro's ANDA, Taro 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 Taro's Proposed Product in the United States.
- 1348. Unless enjoined by this Court, upon FDA approval of Taro's ANDA, Taro 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 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 '258 patent and knowledge that its acts are encouraging infringement.
- 1349. Unless enjoined by this Court, upon FDA approval of Taro's ANDA, Taro 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 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 '258 patent, and Taro's Proposed Product lacks a substantial non-infringing use.
- 1350. Failure to enjoin Taro's infringement of the '258 patent will substantially and irreparably damage GW.
 - 1351. GW does not have an adequate remedy at law.

Count CXLI: Infringement of the '937 Patent by Ascent

- 1352. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 1353. 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 '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.

- 1354. A justiciable controversy exists between the parties hereto as to the infringement of the '937 patent.
- 1355. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent 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 Ascent's Proposed Product in the United States.
- 1356. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent 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 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 '937 patent and knowledge that its acts are encouraging infringement.
- 1357. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent 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 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 '937 patent, and Ascent's Proposed Product lacks a substantial non-infringing use.
- 1358. Failure to enjoin Ascent's infringement of the '937 patent will substantially and irreparably damage GW.
 - 1359. GW does not have an adequate remedy at law.

Count CXLII: Infringement of the '183 Patent by Ascent

- 1360. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 1361. 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 '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.
- 1362. A justiciable controversy exists between the parties hereto as to the infringement of the '183 patent.
- 1363. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent 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 Ascent's Proposed Product in the United States.
- 1364. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent 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 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 '183 patent and knowledge that its acts are encouraging infringement.
- 1365. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent 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 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 '183 patent, and Ascent's Proposed Product lacks a substantial non-infringing use.

- 1366. Failure to enjoin Ascent's infringement of the '183 patent will substantially and irreparably damage GW.
 - 1367. GW does not have an adequate remedy at law.

Count CXLIII: Infringement of the '184 Patent by Ascent

- 1368. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 1369. 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 '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.
- 1370. A justiciable controversy exists between the parties hereto as to the infringement of the '184 patent.
- 1371. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent 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 Ascent's Proposed Product in the United States.
- 1372. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent 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 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 '184 patent and knowledge that its acts are encouraging infringement.

- 1373. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent 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 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 '184 patent, and Ascent's Proposed Product lacks a substantial non-infringing use.
- 1374. Failure to enjoin Ascent's infringement of the '184 patent will substantially and irreparably damage GW.
 - 1375. GW does not have an adequate remedy at law.

Count CXLIV: Infringement of the '185 Patent by Ascent

- 1376. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 1377. 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 '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.
- 1378. A justiciable controversy exists between the parties hereto as to the infringement of the '185 patent.
- 1379. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent 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 Ascent's Proposed Product in the United States.

- 1380. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent 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 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 '185 patent and knowledge that its acts are encouraging infringement.
- 1381. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent 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 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 '185 patent, and Ascent's Proposed Product lacks a substantial non-infringing use.
- 1382. Failure to enjoin Ascent's infringement of the '185 patent will substantially and irreparably damage GW.
 - 1383. GW does not have an adequate remedy at law.

Count CXLV: Infringement of the '186 Patent by Ascent

- 1384. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 1385. 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 '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.

- 1386. A justiciable controversy exists between the parties hereto as to the infringement of the '186 patent.
- 1387. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent 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 Ascent's Proposed Product in the United States.
- 1388. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent 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 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 '186 patent and knowledge that its acts are encouraging infringement.
- 1389. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent 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 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 '186 patent, and Ascent's Proposed Product lacks a substantial non-infringing use.
- 1390. Failure to enjoin Ascent's infringement of the '186 patent will substantially and irreparably damage GW.
 - 1391. GW does not have an adequate remedy at law.

Count CXLVI: Infringement of the '525 Patent by Ascent

- 1392. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 1393. 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 '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.
- 1394. A justiciable controversy exists between the parties hereto as to the infringement of the '525 patent.
- 1395. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent 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 Ascent's Proposed Product in the United States.
- 1396. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent 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 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 '525 patent and knowledge that its acts are encouraging infringement.
- 1397. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent 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 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 '525 patent, and Ascent's Proposed Product lacks a substantial non-infringing use.

- 1398. Failure to enjoin Ascent's infringement of the '525 patent will substantially and irreparably damage GW.
 - 1399. GW does not have an adequate remedy at law.

Count CXLVII: Infringement of the '840 Patent by Ascent

- 1400. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 1401. 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 '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.
- 1402. A justiciable controversy exists between the parties hereto as to the infringement of the '840 patent.
- 1403. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent 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 Ascent's Proposed Product in the United States.
- 1404. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent 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 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 '840 patent and knowledge that its acts are encouraging infringement.

- 1405. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent 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 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 '840 patent, and Ascent's Proposed Product lacks a substantial non-infringing use.
- 1406. Failure to enjoin Ascent's infringement of the '840 patent will substantially and irreparably damage GW.
 - 1407. GW does not have an adequate remedy at law.

Count CXLVIII: Infringement of the '095 Patent by Ascent

- 1408. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 1409. 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 '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.
- 1410. A justiciable controversy exists between the parties hereto as to the infringement of the '095 patent.
- 1411. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent 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 Ascent's Proposed Product in the United States.

- 1412. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent 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 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 '095 patent and knowledge that its acts are encouraging infringement.
- 1413. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent 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 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 '095 patent, and Ascent's Proposed Product lacks a substantial non-infringing use.
- 1414. Failure to enjoin Ascent's infringement of the '095 patent will substantially and irreparably damage GW.
 - 1415. GW does not have an adequate remedy at law.

Count CXLIX: Infringement of the '288 Patent by Ascent

- 1416. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 1417. 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 '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.

- 1418. A justiciable controversy exists between the parties hereto as to the infringement of the '288 patent.
- 1419. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent 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 Ascent's Proposed Product in the United States.
- 1420. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent 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 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 '288 patent and knowledge that its acts are encouraging infringement.
- 1421. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent 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 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 '288 patent, and Ascent's Proposed Product lacks a substantial non-infringing use.
- 1422. Failure to enjoin Ascent's infringement of the '288 patent will substantially and irreparably damage GW.
 - 1423. GW does not have an adequate remedy at law.

Count CL: Infringement of the '671 Patent by Ascent

- 1424. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 1425. 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 '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.
- 1426. A justiciable controversy exists between the parties hereto as to the infringement of the '671 patent.
- 1427. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent 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 Ascent's Proposed Product in the United States.
- 1428. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent 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 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 '671 patent and knowledge that its acts are encouraging infringement.
- 1429. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent 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 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 '671 patent, and Ascent's Proposed Product lacks a substantial non-infringing use.

- 1430. Failure to enjoin Ascent's infringement of the '671 patent will substantially and irreparably damage GW.
 - 1431. GW does not have an adequate remedy at law.

Count CLI: Infringement of the '673 Patent by Ascent

- 1432. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 1433. 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 '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.
- 1434. A justiciable controversy exists between the parties hereto as to the infringement of the '673 patent.
- 1435. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent 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 Ascent's Proposed Product in the United States.
- 1436. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent 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 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 '673 patent and knowledge that its acts are encouraging infringement.

- 1437. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent 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 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 '673 patent, and Ascent's Proposed Product lacks a substantial non-infringing use.
- 1438. Failure to enjoin Ascent's infringement of the '673 patent will substantially and irreparably damage GW.
 - 1439. GW does not have an adequate remedy at law.

Count CLII: Infringement of the '674 Patent by Ascent

- 1440. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 1441. 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 '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.
- 1442. A justiciable controversy exists between the parties hereto as to the infringement of the '674 patent.
- 1443. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent 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 Ascent's Proposed Product in the United States.

- 1444. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent 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 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 '674 patent and knowledge that its acts are encouraging infringement.
- 1445. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent 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 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 '674 patent, and Ascent's Proposed Product lacks a substantial non-infringing use.
- 1446. Failure to enjoin Ascent's infringement of the '674 patent will substantially and irreparably damage GW.
 - 1447. GW does not have an adequate remedy at law.

Count CLIII: Infringement of the '860 Patent by Ascent

- 1448. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 1449. 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 '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.

- 1450. A justiciable controversy exists between the parties hereto as to the infringement of the '860 patent.
- 1451. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent 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 Ascent's Proposed Product in the United States.
- 1452. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent 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 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 '860 patent and knowledge that its acts are encouraging infringement.
- 1453. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent 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 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 '860 patent, and Ascent's Proposed Product lacks a substantial non-infringing use.
- 1454. Failure to enjoin Ascent's infringement of the '860 patent will substantially and irreparably damage GW.
 - 1455. GW does not have an adequate remedy at law.

Count CLIV: Infringement of the '608 Patent by Ascent

- 1456. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 1457. 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 '608 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.
- 1458. A justiciable controversy exists between the parties hereto as to the infringement of the '608 patent.
- 1459. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent will infringe one or more claims of the '608 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.
- 1460. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent will induce infringement of one or more claims of the '608 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 '608 patent and knowledge that its acts are encouraging infringement.
- 1461. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent will contributorily infringe one or more claims of the '608 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 '608 patent, and Ascent's Proposed Product lacks a substantial non-infringing use.

- 1462. Failure to enjoin Ascent's infringement of the '608 patent will substantially and irreparably damage GW.
 - 1463. GW does not have an adequate remedy at law.

Count CLV: Infringement of the '939 Patent by Ascent

- 1464. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 1465. 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 '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.
- 1466. A justiciable controversy exists between the parties hereto as to the infringement of the '939 patent.
- 1467. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent 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 Ascent's Proposed Product in the United States.
- 1468. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent 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 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 '939 patent and knowledge that its acts are encouraging infringement.

- 1469. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent 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 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 '939 patent, and Ascent's Proposed Product lacks a substantial non-infringing use.
- 1470. Failure to enjoin Ascent's infringement of the '939 patent will substantially and irreparably damage GW.
 - 1471. GW does not have an adequate remedy at law.

Count CLVI: Infringement of the '209 Patent by Ascent

- 1472. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 1473. 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 '209 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.
- 1474. A justiciable controversy exists between the parties hereto as to the infringement of the '209 patent.
- 1475. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent will infringe one or more claims of the '209 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.

- 1476. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent will induce infringement of one or more claims of the '209 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 '209 patent and knowledge that its acts are encouraging infringement.
- 1477. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent will contributorily infringe one or more claims of the '209 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 '209 patent, and Ascent's Proposed Product lacks a substantial non-infringing use.
- 1478. Failure to enjoin Ascent's infringement of the '209 patent will substantially and irreparably damage GW.
 - 1479. GW does not have an adequate remedy at law.

Count CLVII: Infringement of the '905 Patent by Ascent

- 1480. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 1481. 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 '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.

- 1482. A justiciable controversy exists between the parties hereto as to the infringement of the '905 patent.
- 1483. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent 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 Ascent's Proposed Product in the United States.
- 1484. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent 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 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 '905 patent and knowledge that its acts are encouraging infringement.
- 1485. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent 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 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 '905 patent, and Ascent's Proposed Product lacks a substantial non-infringing use.
- 1486. Failure to enjoin Ascent's infringement of the '905 patent will substantially and irreparably damage GW.
 - 1487. GW does not have an adequate remedy at law.

Count CLVIII: Infringement of the '516 Patent by Ascent

- 1488. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 1489. 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 '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.
- 1490. A justiciable controversy exists between the parties hereto as to the infringement of the '516 patent.
- 1491. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent 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 Ascent's Proposed Product in the United States.
- 1492. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent 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 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 '516 patent and knowledge that its acts are encouraging infringement.
- 1493. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent 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 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 '516 patent, and Ascent's Proposed Product lacks a substantial non-infringing use.

- 1494. Failure to enjoin Ascent's infringement of the '516 patent will substantially and irreparably damage GW.
 - 1495. GW does not have an adequate remedy at law.

Count CLIX: Infringement of the '795 Patent by Ascent

- 1496. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 1497. 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 '795 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.
- 1498. A justiciable controversy exists between the parties hereto as to the infringement of the '795 patent.
- 1499. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent will infringe one or more claims of the '795 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.
- 1500. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent will induce infringement of one or more claims of the '795 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 '795 patent and knowledge that its acts are encouraging infringement.

- 1501. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent will contributorily infringe one or more claims of the '795 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 '795 patent, and Ascent's Proposed Product lacks a substantial non-infringing use.
- 1502. Failure to enjoin Ascent's infringement of the '795 patent will substantially and irreparably damage GW.
 - 1503. GW does not have an adequate remedy at law.

Count CLX: Infringement of the '292 Patent by Ascent

- 1504. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 1505. 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 '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.
- 1506. A justiciable controversy exists between the parties hereto as to the infringement of the '292 patent.
- 1507. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent 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 Ascent's Proposed Product in the United States.

- 1508. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent 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 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 '292 patent and knowledge that its acts are encouraging infringement.
- 1509. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent 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 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 '292 patent, and Ascent's Proposed Product lacks a substantial non-infringing use.
- 1510. Failure to enjoin Ascent's infringement of the '292 patent will substantially and irreparably damage GW.
 - 1511. GW does not have an adequate remedy at law.

Count CLXI: Infringement of the '498 Patent by Ascent

- 1512. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 1513. 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 '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.

- 1514. A justiciable controversy exists between the parties hereto as to the infringement of the '498 patent.
- 1515. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent 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 Ascent's Proposed Product in the United States.
- 1516. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent 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 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 '498 patent and knowledge that its acts are encouraging infringement.
- 1517. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent 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 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 '498 patent, and Ascent's Proposed Product lacks a substantial non-infringing use.
- 1518. Failure to enjoin Ascent's infringement of the '498 patent will substantially and irreparably damage GW.
 - 1519. GW does not have an adequate remedy at law.

Count CLXII: Infringement of the '741 Patent by Ascent

- 1520. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 1521. 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 '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.
- 1522. A justiciable controversy exists between the parties hereto as to the infringement of the '741 patent.
- 1523. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent 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 Ascent's Proposed Product in the United States.
- 1524. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent 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 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 '741 patent and knowledge that its acts are encouraging infringement.
- 1525. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent 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 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 '741 patent, and Ascent's Proposed Product lacks a substantial non-infringing use.

- 1526. Failure to enjoin Ascent's infringement of the '741 patent will substantially and irreparably damage GW.
 - 1527. GW does not have an adequate remedy at law.

Count CLXIII: Infringement of the '055 Patent by Ascent

- 1528. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 1529. 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 '055 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.
- 1530. A justiciable controversy exists between the parties hereto as to the infringement of the '055 patent.
- 1531. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent will infringe one or more claims of the '055 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.
- 1532. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent will induce infringement of one or more claims of the '055 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 '055 patent and knowledge that its acts are encouraging infringement.

- 1533. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent will contributorily infringe one or more claims of the '055 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 '055 patent, and Ascent's Proposed Product lacks a substantial non-infringing use.
- 1534. Failure to enjoin Ascent's infringement of the '055 patent will substantially and irreparably damage GW.
 - 1535. GW does not have an adequate remedy at law.

Count CLXIV: Infringement of the '623 Patent by Ascent

- 1536. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 1537. 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 '623 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.
- 1538. A justiciable controversy exists between the parties hereto as to the infringement of the '623 patent.
- 1539. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent will infringe one or more claims of the '623 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.

- 1540. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent will induce infringement of one or more claims of the '623 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 '623 patent and knowledge that its acts are encouraging infringement.
- 1541. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent will contributorily infringe one or more claims of the '623 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 '623 patent, and Ascent's Proposed Product lacks a substantial non-infringing use.
- 1542. Failure to enjoin Ascent's infringement of the '623 patent will substantially and irreparably damage GW.
 - 1543. GW does not have an adequate remedy at law.

Count CLXV: Infringement of the '258 Patent by Ascent

- 1544. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 1545. 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 '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.

- 1546. A justiciable controversy exists between the parties hereto as to the infringement of the '258 patent.
- 1547. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent 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 Ascent's Proposed Product in the United States.
- 1548. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent 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 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 '258 patent and knowledge that its acts are encouraging infringement.
- 1549. Unless enjoined by this Court, upon FDA approval of Ascent's ANDA, Ascent 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 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 '258 patent, and Ascent's Proposed Product lacks a substantial non-infringing use.
- 1550. Failure to enjoin Ascent's infringement of the '258 patent will substantially and irreparably damage GW.
 - 1551. GW does not have an adequate remedy at law.

Count CLXVI: Infringement of the '183 Patent by MSN

- 1552. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 1553. 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 '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.
- 1554. A justiciable controversy exists between the parties hereto as to the infringement of the '183 patent.
- 1555. Unless enjoined by this Court, upon FDA approval of MSN's ANDA, MSN 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 MSN's Proposed Product in the United States.
- 1556. Unless enjoined by this Court, upon FDA approval of MSN's ANDA, MSN 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 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 '183 patent and knowledge that its acts are encouraging infringement.
- 1557. Unless enjoined by this Court, upon FDA approval of MSN's ANDA, MSN 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 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 '183 patent, and MSN's Proposed Product lacks a substantial non-infringing use.

- 1558. Failure to enjoin MSN's infringement of the '183 patent will substantially and irreparably damage GW.
 - 1559. GW does not have an adequate remedy at law.

Count CLXVII: Infringement of the '184 Patent by MSN

- 1560. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 1561. 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 '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.
- 1562. A justiciable controversy exists between the parties hereto as to the infringement of the '184 patent.
- 1563. Unless enjoined by this Court, upon FDA approval of MSN's ANDA, MSN 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 MSN's Proposed Product in the United States.
- 1564. Unless enjoined by this Court, upon FDA approval of MSN's ANDA, MSN 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 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 '184 patent and knowledge that its acts are encouraging infringement.

- 1565. Unless enjoined by this Court, upon FDA approval of MSN's ANDA, MSN 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 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 '184 patent, and MSN's Proposed Product lacks a substantial non-infringing use.
- 1566. Failure to enjoin MSN's infringement of the '184 patent will substantially and irreparably damage GW.
 - 1567. GW does not have an adequate remedy at law.

Count CLXVIII: Infringement of the '186 Patent by MSN

- 1568. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 1569. 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 '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.
- 1570. A justiciable controversy exists between the parties hereto as to the infringement of the '186 patent.
- 1571. Unless enjoined by this Court, upon FDA approval of MSN's ANDA, MSN 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 MSN's Proposed Product in the United States.
- 1572. Unless enjoined by this Court, upon FDA approval of MSN's ANDA, MSN 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 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 '186 patent and knowledge that its acts are encouraging infringement.
- 1573. Unless enjoined by this Court, upon FDA approval of MSN's ANDA, MSN 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 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 '186 patent, and MSN's Proposed Product lacks a substantial non-infringing use.
- 1574. Failure to enjoin MSN's infringement of the '186 patent will substantially and irreparably damage GW.
 - 1575. GW does not have an adequate remedy at law.

Count CLXIX: Infringement of the '840 Patent by MSN

- 1576. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 1577. 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 '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.

- 1578. A justiciable controversy exists between the parties hereto as to the infringement of the '840 patent.
- 1579. Unless enjoined by this Court, upon FDA approval of MSN's ANDA, MSN 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 MSN's Proposed Product in the United States.
- 1580. Unless enjoined by this Court, upon FDA approval of MSN's ANDA, MSN 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 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 '840 patent and knowledge that its acts are encouraging infringement.
- 1581. Unless enjoined by this Court, upon FDA approval of MSN's ANDA, MSN 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 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 '840 patent, and MSN's Proposed Product lacks a substantial non-infringing use.
- 1582. Failure to enjoin MSN's infringement of the '840 patent will substantially and irreparably damage GW.
 - 1583. GW does not have an adequate remedy at law.

Count CLXX: Infringement of the '095 Patent by MSN

- 1584. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 1585. 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 '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.
- 1586. A justiciable controversy exists between the parties hereto as to the infringement of the '095 patent.
- 1587. Unless enjoined by this Court, upon FDA approval of MSN's ANDA, MSN 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 MSN's Proposed Product in the United States.
- 1588. Unless enjoined by this Court, upon FDA approval of MSN's ANDA, MSN 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 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 '095 patent and knowledge that its acts are encouraging infringement.
- 1589. Unless enjoined by this Court, upon FDA approval of MSN's ANDA, MSN 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 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 '095 patent, and MSN's Proposed Product lacks a substantial non-infringing use.

- 1590. Failure to enjoin MSN's infringement of the '095 patent will substantially and irreparably damage GW.
 - 1591. GW does not have an adequate remedy at law.

Count CLXXI: Infringement of the '288 Patent by MSN

- 1592. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 1593. 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 '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.
- 1594. A justiciable controversy exists between the parties hereto as to the infringement of the '288 patent.
- 1595. Unless enjoined by this Court, upon FDA approval of MSN's ANDA, MSN 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 MSN's Proposed Product in the United States.
- 1596. Unless enjoined by this Court, upon FDA approval of MSN's ANDA, MSN 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 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 '288 patent and knowledge that its acts are encouraging infringement.

- 1597. Unless enjoined by this Court, upon FDA approval of MSN's ANDA, MSN 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 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 '288 patent, and MSN's Proposed Product lacks a substantial non-infringing use.
- 1598. Failure to enjoin MSN's infringement of the '288 patent will substantially and irreparably damage GW.
 - 1599. GW does not have an adequate remedy at law.

Count CLXXII: Infringement of the '673 Patent by MSN

- 1600. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 1601. 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 '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.
- 1602. A justiciable controversy exists between the parties hereto as to the infringement of the '673 patent.
- 1603. Unless enjoined by this Court, upon FDA approval of MSN's ANDA, MSN 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 MSN's Proposed Product in the United States.
- 1604. Unless enjoined by this Court, upon FDA approval of MSN's ANDA, MSN 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 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 '673 patent and knowledge that its acts are encouraging infringement.
- 1605. Unless enjoined by this Court, upon FDA approval of MSN's ANDA, MSN 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 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 '673 patent, and MSN's Proposed Product lacks a substantial non-infringing use.
- 1606. Failure to enjoin MSN's infringement of the '673 patent will substantially and irreparably damage GW.
 - 1607. GW does not have an adequate remedy at law.

Count CLXXIII: Infringement of the '674 Patent by MSN

- 1608. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 1609. 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 '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.

- 1610. A justiciable controversy exists between the parties hereto as to the infringement of the '674 patent.
- 1611. Unless enjoined by this Court, upon FDA approval of MSN's ANDA, MSN 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 MSN's Proposed Product in the United States.
- 1612. Unless enjoined by this Court, upon FDA approval of MSN's ANDA, MSN 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 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 '674 patent and knowledge that its acts are encouraging infringement.
- 1613. Unless enjoined by this Court, upon FDA approval of MSN's ANDA, MSN 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 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 '674 patent, and MSN's Proposed Product lacks a substantial non-infringing use.
- 1614. Failure to enjoin MSN's infringement of the '674 patent will substantially and irreparably damage GW.
 - 1615. GW does not have an adequate remedy at law.

Count CLXXIV: Infringement of the '860 Patent by MSN

- 1616. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 1617. 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 '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.
- 1618. A justiciable controversy exists between the parties hereto as to the infringement of the '860 patent.
- 1619. Unless enjoined by this Court, upon FDA approval of MSN's ANDA, MSN 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 MSN's Proposed Product in the United States.
- 1620. Unless enjoined by this Court, upon FDA approval of MSN's ANDA, MSN 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 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 '860 patent and knowledge that its acts are encouraging infringement.
- 1621. Unless enjoined by this Court, upon FDA approval of MSN's ANDA, MSN 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 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 '860 patent, and MSN's Proposed Product lacks a substantial non-infringing use.

- 1622. Failure to enjoin MSN's infringement of the '860 patent will substantially and irreparably damage GW.
 - 1623. GW does not have an adequate remedy at law.

Count CLXXV: Infringement of the '939 Patent by MSN

- 1624. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 1625. 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 '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.
- 1626. A justiciable controversy exists between the parties hereto as to the infringement of the '939 patent.
- 1627. Unless enjoined by this Court, upon FDA approval of MSN's ANDA, MSN 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 MSN's Proposed Product in the United States.
- 1628. Unless enjoined by this Court, upon FDA approval of MSN's ANDA, MSN 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 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 '939 patent and knowledge that its acts are encouraging infringement.

- 1629. Unless enjoined by this Court, upon FDA approval of MSN's ANDA, MSN 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 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 '939 patent, and MSN's Proposed Product lacks a substantial non-infringing use.
- 1630. Failure to enjoin MSN's infringement of the '939 patent will substantially and irreparably damage GW.
 - 1631. GW does not have an adequate remedy at law.

Count CLXXVI: Infringement of the '905 Patent by MSN

- 1632. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 1633. 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 '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.
- 1634. A justiciable controversy exists between the parties hereto as to the infringement of the '905 patent.
- 1635. Unless enjoined by this Court, upon FDA approval of MSN's ANDA, MSN 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 MSN's Proposed Product in the United States.
- 1636. Unless enjoined by this Court, upon FDA approval of MSN's ANDA, MSN 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 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 '905 patent and knowledge that its acts are encouraging infringement.
- 1637. Unless enjoined by this Court, upon FDA approval of MSN's ANDA, MSN 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 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 '905 patent, and MSN's Proposed Product lacks a substantial non-infringing use.
- 1638. Failure to enjoin MSN's infringement of the '905 patent will substantially and irreparably damage GW.
 - 1639. GW does not have an adequate remedy at law.

Count CLXXVII: Infringement of the '516 Patent by MSN

- 1640. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 1641. 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 '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.

- 1642. A justiciable controversy exists between the parties hereto as to the infringement of the '516 patent.
- 1643. Unless enjoined by this Court, upon FDA approval of MSN's ANDA, MSN 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 MSN's Proposed Product in the United States.
- 1644. Unless enjoined by this Court, upon FDA approval of MSN's ANDA, MSN 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 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 '516 patent and knowledge that its acts are encouraging infringement.
- 1645. Unless enjoined by this Court, upon FDA approval of MSN's ANDA, MSN 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 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 '516 patent, and MSN's Proposed Product lacks a substantial non-infringing use.
- 1646. Failure to enjoin MSN's infringement of the '516 patent will substantially and irreparably damage GW.
 - 1647. GW does not have an adequate remedy at law.

Count CLXXVIII: Infringement of the '292 Patent by MSN

- 1648. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 1649. 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 '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.
- 1650. A justiciable controversy exists between the parties hereto as to the infringement of the '292 patent.
- 1651. Unless enjoined by this Court, upon FDA approval of MSN's ANDA, MSN 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 MSN's Proposed Product in the United States.
- 1652. Unless enjoined by this Court, upon FDA approval of MSN's ANDA, MSN 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 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 '292 patent and knowledge that its acts are encouraging infringement.
- 1653. Unless enjoined by this Court, upon FDA approval of MSN's ANDA, MSN 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 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 '292 patent, and MSN's Proposed Product lacks a substantial non-infringing use.

- 1654. Failure to enjoin MSN's infringement of the '292 patent will substantially and irreparably damage GW.
 - 1655. GW does not have an adequate remedy at law.

Count CLXXIX: Infringement of the '498 Patent by MSN

- 1656. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 1657. 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 '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.
- 1658. A justiciable controversy exists between the parties hereto as to the infringement of the '498 patent.
- 1659. Unless enjoined by this Court, upon FDA approval of MSN's ANDA, MSN 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 MSN's Proposed Product in the United States.
- 1660. Unless enjoined by this Court, upon FDA approval of MSN's ANDA, MSN 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 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 '498 patent and knowledge that its acts are encouraging infringement.

- 1661. Unless enjoined by this Court, upon FDA approval of MSN's ANDA, MSN 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 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 '498 patent, and MSN's Proposed Product lacks a substantial non-infringing use.
- 1662. Failure to enjoin MSN's infringement of the '498 patent will substantially and irreparably damage GW.
 - 1663. GW does not have an adequate remedy at law.

Count CLXXX: Infringement of the '258 Patent by MSN

- 1664. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 1665. 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 '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.
- 1666. A justiciable controversy exists between the parties hereto as to the infringement of the '258 patent.
- 1667. Unless enjoined by this Court, upon FDA approval of MSN's ANDA, MSN 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 MSN's Proposed Product in the United States.

- 1668. Unless enjoined by this Court, upon FDA approval of MSN's ANDA, MSN 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 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 '258 patent and knowledge that its acts are encouraging infringement.
- 1669. Unless enjoined by this Court, upon FDA approval of MSN's ANDA, MSN 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 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 '258 patent, and MSN's Proposed Product lacks a substantial non-infringing use.
- 1670. Failure to enjoin MSN's infringement of the '258 patent will substantially and irreparably damage GW.
 - 1671. GW does not have an adequate remedy at law.

Count CLXXXI: Infringement of the '937 Patent by Biophore and Zenara

- 1672. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 1673. 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 '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.

- 1674. A justiciable controversy exists between the parties hereto as to the infringement of the '937 patent.
- 1675. 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 '937 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.
- 1676. 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 '937 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 '937 patent and knowledge that their acts are encouraging infringement.
- ANDA, Biophore and Zenara 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 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 '937 patent, and Biophore and Zenara's Proposed Product lacks a substantial non-infringing use.

- 1678. Failure to enjoin Biophore and Zenara's infringement of the '937 patent will substantially and irreparably damage GW.
 - 1679. GW does not have an adequate remedy at law.

Count CLXXXII: Infringement of the '183 Patent by Biophore and Zenara

- 1680. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 1681. 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 '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.
- 1682. A justiciable controversy exists between the parties hereto as to the infringement of the '183 patent.
- 1683. 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 '183 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.
- 1684. 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 '183 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 '183 patent and knowledge that their acts are encouraging infringement.

- ANDA, Biophore and Zenara 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 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 '183 patent, and Biophore and Zenara's Proposed Product lacks a substantial non-infringing use.
- 1686. Failure to enjoin Biophore and Zenara's infringement of the '183 patent will substantially and irreparably damage GW.
 - 1687. GW does not have an adequate remedy at law.

Count CLXXXIII: Infringement of the '184 Patent by Biophore and Zenara

- 1688. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 1689. 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 '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.
- 1690. A justiciable controversy exists between the parties hereto as to the infringement of the '184 patent.

- 1691. 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 '184 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.
- 1692. 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 '184 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 '184 patent and knowledge that their acts are encouraging infringement.
- ANDA, Biophore and Zenara 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 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 '184 patent, and Biophore and Zenara's Proposed Product lacks a substantial non-infringing use.
- 1694. Failure to enjoin Biophore and Zenara's infringement of the '184 patent will substantially and irreparably damage GW.
 - 1695. GW does not have an adequate remedy at law.

Count CLXXXIV: Infringement of the '185 Patent by Biophore and Zenara

- 1696. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 1697. 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 '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.
- 1698. A justiciable controversy exists between the parties hereto as to the infringement of the '185 patent.
- 1699. 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 '185 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.
- ANDA, Biophore and Zenara 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 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 '185 patent and knowledge that their acts are encouraging infringement.
- 1701. 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 '185 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 '185 patent, and Biophore and Zenara's Proposed Product lacks a substantial non-infringing use.

- 1702. Failure to enjoin Biophore and Zenara's infringement of the '185 patent will substantially and irreparably damage GW.
 - 1703. GW does not have an adequate remedy at law.

Count CLXXXV: Infringement of the '186 Patent by Biophore and Zenara

- 1704. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 1705. 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 '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.
- 1706. A justiciable controversy exists between the parties hereto as to the infringement of the '186 patent.
- 1707. 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 '186 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.

- ANDA, Biophore and Zenara 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 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 '186 patent and knowledge that their acts are encouraging infringement.
- 1709. 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 '186 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 '186 patent, and Biophore and Zenara's Proposed Product lacks a substantial non-infringing use.
- 1710. Failure to enjoin Biophore and Zenara's infringement of the '186 patent will substantially and irreparably damage GW.
 - 1711. GW does not have an adequate remedy at law.

Count CLXXXVI: Infringement of the '525 Patent by Biophore and Zenara

- 1712. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 1713. 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 '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.

- 1714. A justiciable controversy exists between the parties hereto as to the infringement of the '525 patent.
- 1715. 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 '525 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.
- 1716. 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 '525 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 '525 patent and knowledge that their acts are encouraging infringement.
- 1717. 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 '525 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 '525 patent, and Biophore and Zenara's Proposed Product lacks a substantial non-infringing use.

- 1718. Failure to enjoin Biophore and Zenara's infringement of the '525 patent will substantially and irreparably damage GW.
 - 1719. GW does not have an adequate remedy at law.

Count CLXXXVII: Infringement of the '840 Patent by Biophore and Zenara

- 1720. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 1721. 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 '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.
- 1722. A justiciable controversy exists between the parties hereto as to the infringement of the '840 patent.
- 1723. 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 '840 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.
- 1724. 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 '840 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 '840 patent and knowledge that their acts are encouraging infringement.

- 1725. 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 '840 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 '840 patent, and Biophore and Zenara's Proposed Product lacks a substantial non-infringing use.
- 1726. Failure to enjoin Biophore and Zenara's infringement of the '840 patent will substantially and irreparably damage GW.
 - 1727. GW does not have an adequate remedy at law.

Count CLXXXVIII: Infringement of the '095 Patent by Biophore and Zenara

- 1728. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 1729. 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 '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.
- 1730. A justiciable controversy exists between the parties hereto as to the infringement of the '095 patent.

- 1731. 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 '095 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.
- 1732. 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 '095 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 '095 patent and knowledge that their acts are encouraging infringement.
- ANDA, Biophore and Zenara 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 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 '095 patent, and Biophore and Zenara's Proposed Product lacks a substantial non-infringing use.
- 1734. Failure to enjoin Biophore and Zenara's infringement of the '095 patent will substantially and irreparably damage GW.
 - 1735. GW does not have an adequate remedy at law.

Count CLXXXIX: Infringement of the '288 Patent by Biophore and Zenara

- 1736. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 1737. 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 '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.
- 1738. A justiciable controversy exists between the parties hereto as to the infringement of the '288 patent.
- 1739. 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 '288 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.
- 1740. 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 '288 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 '288 patent and knowledge that their acts are encouraging infringement.
- 1741. 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 '288 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 '288 patent, and Biophore and Zenara's Proposed Product lacks a substantial non-infringing use.

- 1742. Failure to enjoin Biophore and Zenara's infringement of the '288 patent will substantially and irreparably damage GW.
 - 1743. GW does not have an adequate remedy at law.

Count CXC: Infringement of the '671 Patent by Biophore and Zenara

- 1744. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 1745. 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 '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.
- 1746. A justiciable controversy exists between the parties hereto as to the infringement of the '671 patent.
- 1747. 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 '671 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.

- 1748. 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 '671 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 '671 patent and knowledge that their acts are encouraging infringement.
- ANDA, Biophore and Zenara 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 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 '671 patent, and Biophore and Zenara's Proposed Product lacks a substantial non-infringing use.
- 1750. Failure to enjoin Biophore and Zenara's infringement of the '671 patent will substantially and irreparably damage GW.
 - 1751. GW does not have an adequate remedy at law.

Count CXCI: Infringement of the '673 Patent by Biophore and Zenara

- 1752. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 1753. 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 '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.

- 1754. A justiciable controversy exists between the parties hereto as to the infringement of the '673 patent.
- 1755. 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 '673 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.
- 1756. 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 '673 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 '673 patent and knowledge that their acts are encouraging infringement.
- 1757. 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 '673 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 '673 patent, and Biophore and Zenara's Proposed Product lacks a substantial non-infringing use.

- 1758. Failure to enjoin Biophore and Zenara's infringement of the '673 patent will substantially and irreparably damage GW.
 - 1759. GW does not have an adequate remedy at law.

Count CXCII: Infringement of the '674 Patent by Biophore and Zenara

- 1760. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 1761. 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 '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.
- 1762. A justiciable controversy exists between the parties hereto as to the infringement of the '674 patent.
- 1763. 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 '674 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.
- 1764. 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 '674 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 '674 patent and knowledge that their acts are encouraging infringement.

1765. 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 '674 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 '674 patent, and Biophore and Zenara's Proposed Product lacks a substantial non-infringing use.

1766. Failure to enjoin Biophore and Zenara's infringement of the '674 patent will substantially and irreparably damage GW.

1767. GW does not have an adequate remedy at law.

Count CXCIII: Infringement of the '860 Patent by Biophore and Zenara

- 1768. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 1769. 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 '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.
- 1770. A justiciable controversy exists between the parties hereto as to the infringement of the '860 patent.

- 1771. 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 '860 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.
- 1772. 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 '860 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 '860 patent and knowledge that their acts are encouraging infringement.
- 1773. 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 '860 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 '860 patent, and Biophore and Zenara's Proposed Product lacks a substantial non-infringing use.
- 1774. Failure to enjoin Biophore and Zenara's infringement of the '860 patent will substantially and irreparably damage GW.
 - 1775. GW does not have an adequate remedy at law.

Count CXCIV: Infringement of the '608 Patent by Biophore and Zenara

- 1776. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 1777. 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 '608 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.
- 1778. A justiciable controversy exists between the parties hereto as to the infringement of the '608 patent.
- 1779. 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 '608 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.
- 1780. 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 '608 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 '608 patent and knowledge that their acts are encouraging infringement.
- 1781. 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 '608 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 '608 patent, and Biophore and Zenara's Proposed Product lacks a substantial non-infringing use.

- 1782. Failure to enjoin Biophore and Zenara's infringement of the '608 patent will substantially and irreparably damage GW.
 - 1783. GW does not have an adequate remedy at law.

Count CXCV: Infringement of the '939 Patent by Biophore and Zenara

- 1784. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 1785. 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 '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.
- 1786. A justiciable controversy exists between the parties hereto as to the infringement of the '939 patent.
- 1787. 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 '939 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.

1788. 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 '939 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 '939 patent and knowledge that their acts are encouraging infringement.

1789. 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 '939 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 '939 patent, and Biophore and Zenara's Proposed Product lacks a substantial non-infringing use.

1790. Failure to enjoin Biophore and Zenara's infringement of the '939 patent will substantially and irreparably damage GW.

1791. GW does not have an adequate remedy at law.

Count CXCVI: Infringement of the '209 Patent by Biophore and Zenara

- 1792. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 1793. 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 '209 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.

- 1794. A justiciable controversy exists between the parties hereto as to the infringement of the '209 patent.
- 1795. 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 '209 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.
- 1796. 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 '209 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 '209 patent and knowledge that their acts are encouraging infringement.
- 1797. 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 '209 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 '209 patent, and Biophore and Zenara's Proposed Product lacks a substantial non-infringing use.

- 1798. Failure to enjoin Biophore and Zenara's infringement of the '209 patent will substantially and irreparably damage GW.
 - 1799. GW does not have an adequate remedy at law.

Count CXCVII: Infringement of the '905 Patent by Biophore and Zenara

- 1800. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 1801. 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 '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.
- 1802. A justiciable controversy exists between the parties hereto as to the infringement of the '905 patent.
- 1803. 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 '905 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.
- 1804. 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 '905 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 '905 patent and knowledge that their acts are encouraging infringement.

1805. 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 '905 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 '905 patent, and Biophore and Zenara's Proposed Product lacks a substantial non-infringing use.

1806. Failure to enjoin Biophore and Zenara's infringement of the '905 patent will substantially and irreparably damage GW.

1807. GW does not have an adequate remedy at law.

Count CXCVIII: Infringement of the '516 Patent by Biophore and Zenara

1808. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

1809. 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 '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.

1810. A justiciable controversy exists between the parties hereto as to the infringement of the '516 patent.

- 1811. 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 '516 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.
- 1812. 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 '516 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 '516 patent and knowledge that their acts are encouraging infringement.
- 1813. 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 '516 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 '516 patent, and Biophore and Zenara's Proposed Product lacks a substantial non-infringing use.
- 1814. Failure to enjoin Biophore and Zenara's infringement of the '516 patent will substantially and irreparably damage GW.
 - 1815. GW does not have an adequate remedy at law.

Count CXCIX: Infringement of the '795 Patent by Biophore and Zenara

- 1816. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 1817. 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 '795 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.
- 1818. A justiciable controversy exists between the parties hereto as to the infringement of the '795 patent.
- 1819. 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 '795 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.
- 1820. 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 '795 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 '795 patent and knowledge that their acts are encouraging infringement.
- 1821. 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 '795 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 '795 patent, and Biophore and Zenara's Proposed Product lacks a substantial non-infringing use.

- 1822. Failure to enjoin Biophore and Zenara's infringement of the '795 patent will substantially and irreparably damage GW.
 - 1823. GW does not have an adequate remedy at law.

Count CC: Infringement of the '292 Patent by Biophore and Zenara

- 1824. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 1825. 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 '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.
- 1826. A justiciable controversy exists between the parties hereto as to the infringement of the '292 patent.
- 1827. 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 '292 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.

- 1828. 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 '292 patent under 35 U.S.C. § 271(b), including at least claim 18, 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 '292 patent and knowledge that their acts are encouraging infringement.
- 1829. 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 '292 patent under 35 U.S.C. § 271(c), including at least claim 18, 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 '292 patent, and Biophore and Zenara's Proposed Product lacks a substantial non-infringing use.
- 1830. Failure to enjoin Biophore and Zenara's infringement of the '292 patent will substantially and irreparably damage GW.
 - 1831. GW does not have an adequate remedy at law.

Count CCI: Infringement of the '498 Patent by Biophore and Zenara

- 1832. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 1833. 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 '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.

- 1834. A justiciable controversy exists between the parties hereto as to the infringement of the '498 patent.
- 1835. 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 '498 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.
- 1836. 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 '498 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 '498 patent and knowledge that their acts are encouraging infringement.
- 1837. 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 '498 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 '498 patent, and Biophore and Zenara's Proposed Product lacks a substantial non-infringing use.

- 1838. Failure to enjoin Biophore and Zenara's infringement of the '498 patent will substantially and irreparably damage GW.
 - 1839. GW does not have an adequate remedy at law.

Count CCII: Infringement of the '741 Patent by Biophore and Zenara

- 1840. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 1841. 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 '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.
- 1842. A justiciable controversy exists between the parties hereto as to the infringement of the '741 patent.
- 1843. 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 '741 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.
- 1844. 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 '741 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 '741 patent and knowledge that their acts are encouraging infringement.

1845. 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 '741 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 '741 patent, and Biophore and Zenara's Proposed Product lacks a substantial non-infringing use.

1846. Failure to enjoin Biophore and Zenara's infringement of the '741 patent will substantially and irreparably damage GW.

1847. GW does not have an adequate remedy at law.

Count CCIII: Infringement of the '055 Patent by Biophore and Zenara

- 1848. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 1849. 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 '055 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.
- 1850. A justiciable controversy exists between the parties hereto as to the infringement of the '055 patent.

- 1851. 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 '055 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.
- 1852. 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 '055 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 '055 patent and knowledge that their acts are encouraging infringement.
- 1853. 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 '055 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 '055 patent, and Biophore and Zenara's Proposed Product lacks a substantial non-infringing use.
- 1854. Failure to enjoin Biophore and Zenara's infringement of the '055 patent will substantially and irreparably damage GW.
 - 1855. GW does not have an adequate remedy at law.

Count CCIV: Infringement of the '623 Patent by Biophore and Zenara

- 1856. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 1857. 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 '623 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.
- 1858. A justiciable controversy exists between the parties hereto as to the infringement of the '623 patent.
- 1859. 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 '623 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.
- ANDA, Biophore and Zenara will induce infringement of one or more claims of the '623 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 '623 patent and knowledge that their acts are encouraging infringement.
- 1861. 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 '623 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 '623 patent, and Biophore and Zenara's Proposed Product lacks a substantial non-infringing use.

- 1862. Failure to enjoin Biophore and Zenara's infringement of the '623 patent will substantially and irreparably damage GW.
 - 1863. GW does not have an adequate remedy at law.

Count CCV: Infringement of the '258 Patent by Biophore and Zenara

- 1864. GW repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.
- 1865. 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 '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.
- 1866. A justiciable controversy exists between the parties hereto as to the infringement of the '258 patent.
- 1867. 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 '258 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.

1868. 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 '258 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 '258 patent and knowledge that their acts are encouraging infringement.

1869. 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 '258 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 '258 patent, and Biophore and Zenara's Proposed Product lacks a substantial non-infringing use.

1870. Failure to enjoin Biophore and Zenara's infringement of the '258 patent will substantially and irreparably damage GW.

1871. GW does not have an adequate remedy at law.

PRAYER FOR RELIEF AGAINST TEVA

- (A) A Judgment that Teva infringed one or more claims of each of the patents-in-suit asserted against Teva 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 each of the patents-in-suit asserted against Teva;

- (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 each patent-in-suit asserted against Teva, 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 each of the patents-in-suit asserted against Teva, 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 patents-in-suit asserted against Teva, or from actively inducing or contributing to the infringement of any claim of the patents-in-suit asserted against Teva, until after the expiration of each such 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 Teva's Proposed Product will directly infringe, induce and/or contribute to infringement of one or more claims of each of the patents-in-suit asserted against Teva;
- (G) To the extent that Teva has committed any acts with respect to the methods claimed in the patents-in-suit asserted against Teva, 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 patents-in-suit asserted against Teva, a Judgment awarding damages to GW resulting from such infringement, together with interest;
- (I) A Judgment declaring that each patent-in-suit asserted against Teva 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

- (A) A Judgment that Apotex infringed one or more claims of each of the patents-insuit asserted against Apotex 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 each of the patents-in-suit asserted against Apotex;
- (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 each patent-in-suit asserted against Apotex, 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 each

of the patents-in-suit asserted against Apotex, 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 patents-in-suit asserted against Apotex, or from actively inducing or contributing to the infringement of any claim of the patents-in-suit asserted against Apotex, until after the expiration of each such 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 Apotex's Proposed Product will directly infringe, induce and/or contribute to infringement of one or more claims of each of the patents-in-suit asserted against Apotex;
- (G) To the extent that Apotex has committed any acts with respect to the methods claimed in the patents-in-suit asserted against Apotex, 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 patents-in-suit asserted against Apotex, a Judgment awarding damages to GW resulting from such infringement, together with interest;
- (I) A Judgment declaring that each patent-in-suit asserted against Apotex 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

- (A) A Judgment that Padagis infringed one or more claims of each of the patents-insuit asserted against Padagis 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 each of the patents-in-suit asserted against Padagis;
- (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 each patent-in-suit asserted against Padagis, 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 each patent-in-suit asserted against Padagis, 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 patents-in-suit asserted against Padagis, or from actively inducing or contributing to the infringement of any claim of the patents-in-suit asserted against Padagis, until after the expiration of each such 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 Padagis's Proposed Product will directly infringe, induce and/or contribute to infringement of one or more claims of each of the patents-in-suit asserted against Padagis;
- (G) To the extent that Padagis has committed any acts with respect to the methods claimed in the patents-in-suit asserted against Padagis, 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 patents-in-suit asserted against Padagis, a Judgment awarding damages to GW resulting from such infringement, together with interest;
- (I) A Judgment declaring that each patent-in-suit asserted against Padagis 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

- (A) A Judgment that InvaGen, Cipla, and/or API Pharma infringed one or more claims of each of the patents-in-suit asserted against InvaGen, Cipla, and API Pharma 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 each of the patents-in-suit asserted against InvaGen, Cipla, and API Pharma;

- (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 asserted against InvaGen, Cipla, and API Pharma, 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 of the patents-in-suit asserted against InvaGen, Cipla, and API Pharma, 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 patents-in-suit asserted against InvaGen, Cipla, and API Pharma, or from actively inducing or contributing to the infringement of any claim of the patents-in-suit asserted against InvaGen, Cipla, and API Pharma, until after the expiration of each such 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 the patents-in-suit asserted against InvaGen, Cipla, and API Pharma;

- (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 asserted against InvaGen, Cipla, and API Pharma, 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 each of the patents-in-suit asserted against InvaGen, Cipla, and API Pharma, a Judgment awarding damages to GW resulting from such infringement, together with interest;
- (I) A Judgment declaring that each patent-in-suit asserted against InvaGen, Cipla, and API Pharma 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

- (A) A Judgment that Lupin infringed one or more claims of each of the patents-in-suit asserted against Lupin 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 each of the patents-in-suit asserted against Lupin;
- (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 each

patent-in-suit asserted against Lupin, 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 each patent-in-suit asserted against Lupin, 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 patents-in-suit asserted against Lupin, or from actively inducing or contributing to the infringement of any claim of the patents-in-suit asserted against Lupin, until after the expiration of each such 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 Lupin's Proposed Product will directly infringe, induce and/or contribute to infringement of one or more claims of each of the patents-in-suit asserted against Lupin;
- (G) To the extent that Lupin has committed any acts with respect to the methods claimed in the patents-in-suit asserted against Lupin, 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

patents-in-suit asserted against Lupin, a Judgment awarding damages to GW resulting from such infringement, together with interest;

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

- (A) A Judgment that Alkem infringed one or more claims of each of the patents-insuit asserted against Alkem 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 each of the patents-in-suit asserted against Alkem;
- (C) An Order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of FDA approval of ANDA No. 217977 be a date no earlier than the later of the expiration of each patent-in-suit asserted against Alkem, or any later expiration of exclusivity to which 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 each of the patents-in-suit asserted against Alkem, 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 patents-in-suit asserted against Alkem, or from actively inducing or contributing to the infringement of any claim of the patents-in-suit asserted against Alkem, until after the expiration of each such patent-in-suit, or any later expiration of exclusivity to which 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 each of the patents-in-suit asserted against Alkem;
- (G) To the extent that Alkem has committed any acts with respect to the methods claimed in the patents-in-suit asserted against Alkem, other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), a Judgment awarding 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 patents-in-suit asserted against Alkem, a Judgment awarding damages to GW resulting from such infringement, together with interest;
- (I) A Judgment declaring that each patent-in-suit asserted against Alkem remains valid and enforceable;
- (J) A Judgment that this 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

- (A) A Judgment that Taro infringed one or more claims of each of the patents-in-suit asserted against Taro 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 each of the patents-in-suit asserted against Taro;
- (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 each patent-in-suit asserted against Taro, 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 each of the patents-in-suit asserted against Taro, 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 patents-in-suit asserted against Taro, or from actively inducing or contributing to the infringement of any claim of the patents-in-suit asserted against Taro, until after the expiration of each such 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 Taro's Proposed Product will directly infringe, induce and/or

contribute to infringement of one or more claims of each of the patents-in-suit asserted against Taro;

- (G) To the extent that Taro has committed any acts with respect to the methods claimed in the patents-in-suit asserted against Taro, 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 patents-in-suit asserted against Taro, a Judgment awarding damages to GW resulting from such infringement, together with interest;
- (I) A Judgment declaring that each patent-in-suit asserted against Taro 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

- (A) A Judgment that Ascent infringed one or more claims of each of the patents-insuit 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 each 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. 217994 be a date no earlier than the later of the expiration of each

patent-in-suit asserted against Ascent, 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 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 Ascent, its 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 Ascent's Proposed Product will directly infringe, induce and/or contribute to infringement of one or more claims of the patents-in-suit;
- (G) To the extent that Ascent has 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 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 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 asserted against Ascent 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

- (A) A Judgment that MSN infringed one or more claims of each of the patents-in-suit asserted against MSN 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 each of the patents-in-suit asserted against MSN;
- (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 each patent-in-suit asserted against MSN, 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 each of the patents-in-suit asserted against MSN, 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 patents-in-suit asserted against

MSN, or from actively inducing or contributing to the infringement of any claim of the patents-in-suit asserted against MSN, until after the expiration of each such 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 MSN's Proposed Product will directly infringe, induce and/or contribute to infringement of one or more claims of each of the patents-in-suit asserted against MSN;
- (G) To the extent that MSN has committed any acts with respect to the methods claimed in the patents-in-suit asserted against MSN, 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 patents-in-suit asserted against MSN, a Judgment awarding damages to GW resulting from such infringement, together with interest;
- (I) A Judgment declaring that each patent-in-suit asserted against MSN 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 each of the patents-in-suit 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 each 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. 217910 be a date no earlier than the later of the expiration of each patent-in-suit asserted against Biophore and Zenara, 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 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 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 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 Biophore and Zenara's Proposed Product will directly infringe, induce and/or contribute to infringement of one or more claims of the patents-in-suit;

- (G) To the extent that Biophore and Zenara 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;
- If Biophore and Zenara engage in the commercial manufacture, use, importation (H) into the United States, offer for sale, and/or sale of Biophore and Zenara'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;
- A Judgment declaring that each patent-in-suit asserted against Biophore and (I) Zenara remains valid and enforceable;
- A Judgment that this case is exceptional pursuant to 35 U.S.C. § 285 and **(J)** 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: January 3, 2023

By: s/ Charles M. Lizza

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CERTIFICATION PURSUANT TO L. CIV. R. 11.2 & 40.1

Pursuant to Local Civil Rules 11.2 and 40.1, I hereby certify that the matter in controversy is not related to any other matter currently pending in this Judicial District.

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: January 3, 2023 By: s/ Charles M. Lizza

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