IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GENENTECH, INC. and INTERMUNE, INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
CIPLA LIMITED, INVAGEN PHARMACEUTICALS, INC. and CIPLA USA, INC.,	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Genentech, Inc. ("Genentech") and InterMune, Inc. ("InterMune") (Genentech and InterMune, collectively, "Plaintiffs"), by their attorneys, for their Complaint against Defendants, Cipla Limited, InvaGen Pharmaceuticals, Inc. and Cipla USA, Inc. (collectively, "InvaGen" or "Defendants"), allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the Food and Drug Laws and Patent Laws of the United States, Titles 21 and 35 of the United States Code, respectively, concerning Defendants' submission of Abbreviated New Drug Application No. 212679, which seeks approval from the U.S. Food and Drug Administration ("FDA") to market a generic copy of Plaintiffs' drug Esbriet® (pirfenidone) 267 and 801 mg tablets, in violation of Plaintiffs' exclusive rights held under numerous patents that Plaintiffs have listed with the FDA for Esbriet®.

2. Plaintiffs seek a judgment of patent infringement under 35 U.S.C. § 271(e)(2)(A), and the remedies provided under the Hatch-Waxman Act specified in 35 U.S.C. § 271(e)(4),

including, but not limited to, the specific remedy provided in 35 U.S.C. § 271(e)(4)(A), which provides that the Court "shall order the effective date of any approval of the drug … involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed."

PARTIES

3. Plaintiff Genentech is a corporation organized and existing under the laws of Delaware, having its principal place of business at 1 DNA Way, South San Francisco, CA 94080. Genentech develops and commercializes pharmaceutical products throughout the United States, including within this judicial district, on its own behalf and on behalf of its affiliates within the Roche group of companies, including InterMune. Genentech holds New Drug Applications ("NDAs") in the United States for (i) Esbriet® capsules, 267 mg and (ii) Esbriet® tablets, 267, 534, and 801 mg. Genentech is also exclusively licensed by InterMune under the below-listed Asserted Patents, which cover Esbriet® FDA-approved formulations and its FDA-approved uses for safely and effectively treating Idiopathic Pulmonary Fibrosis.

4. Plaintiff InterMune is a corporation organized and existing under the laws of Delaware, having its principal place of business at 1 DNA Way, South San Francisco, CA 94080. InterMune owns the United States patents that have been listed with the FDA in connection with the NDAs held by Genentech for Esbriet®, including, but not limited to, all the Asserted Patents listed below.

5. On information and belief, Defendant Cipla Limited ("Cipla India") 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-400013, Maharashtra, India.

6. On information and belief, Cipla India controls and directs a wholly owned subsidiary in the United States named InvaGen Pharmaceuticals, Inc. ("InvaGen Inc."). On further information and belief, InvaGen Inc. is a New York corporation having a principal place of business at 7 Oser Ave., Hauppauge, New York 11788.

7. On information and belief, InvaGen Inc. controls and directs a wholly owned subsidiary in the United States named Cipla USA, Inc. ("Cipla USA"). On further information and belief, Cipla USA is a Delaware corporation having a principal place of business at 9100 S. Dadeland Blvd., Suite 1500, Miami, Florida 33156.

8. On information and belief, Cipla India, acting in concert with the other Defendants, is in the business of, among other things, developing, preparing, manufacturing, selling, marketing, and distributing generic drugs, including distributing, selling, and marketing generic drugs throughout the United States, including within the State of Delaware, through its own actions and through the actions of its agents and subsidiaries, including InvaGen Inc. and Cipla USA, from which Cipla India derives a substantial portion of its revenue.

9. On information and belief, InvaGen Inc. acted in concert with Cipla India and Cipla USA to prepare and submit ANDA No. 212679 (the "InvaGen ANDA") for InvaGen Inc.'s 267 and 801 mg pirfenidone tablets (the "InvaGen ANDA Product"), which was done at the direction of, under the control of, and for the direct benefit of Cipla India. On further information and belief, following FDA approval of the InvaGen ANDA, Cipla India will manufacture and supply to InvaGen Inc. and/ or Cipla USA the active ingredient pirfenidone in the approved generic product under Cipla India's Drug Master File ("DMF") No. 32423, and InvaGen Inc. and/ or Cipla USA will then market and sell the product throughout the United States at the direction, under the control, and for the direct benefit of Cipla India.

JURISDICTION AND VENUE

10. This is an action for patent infringement arising under the Patent Laws of the United States, 35 U.S.C. § 101, *et seq.,* seeking a finding and declaratory judgment of patent infringement under 35 U.S.C. § 271(e)(2)(A) and the remedies provided under the Hatch-Waxman Act specified in 35 U.S.C. § 271(e)(4). Jurisdiction exists under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202, and venue is proper in this Court under 28 U.S.C. §§ 1391(c) and 1400(b).

11. Venue is proper in this Court because, among other things, InvaGen Inc. consented to jurisdiction and venue in the United States District Court for the District of Delaware in this matter, through its counsel, by e-mail dated January 24, 2019. Cipla USA is incorporated in the State of Delaware and therefore "resides" in this judicial district. 28 U.S.C. § 1400(b). Cipla India is a foreign corporation not residing in any United States district and may be sued in any judicial district. 28 U.S.C. § 1391(c).

PERSONAL JURISDICTION OVER CIPLA INDIA

12. Plaintiffs reallege paragraphs 1-11 as if fully set forth herein.

13. On information and belief, Cipla India develops, manufactures, and/or distributes generic drugs for sale and use throughout the United States, including in this judicial district.

14. This Court has personal jurisdiction over Cipla India because, *inter alia*, Cipla India, on information and belief: (1) has substantial, continuous, and systematic contacts with this State, either directly or through at least one of its wholly-owned subsidiaries or agents; (2) intends to market, sell, and/or distribute the InvaGen ANDA Products to residents of this State upon approval of ANDA No. 212679, either directly or through at least one of its wholly-

owned subsidiaries or agents; (3) enjoys substantial income from sales of its generic pharmaceutical products in this State on its own and through InvaGen Inc., which is a New York corporation, and Cipla USA, which is a Delaware corporation; and (4) owns Cipla USA, which is a Delaware corporation.

15. Alternatively, to the extent the above facts do not establish personal jurisdiction over Cipla India, this Court may exercise jurisdiction over Cipla India pursuant to Fed. R. Civ. P. 4(k)(2) because: (a) Plaintiffs' claims arise under federal law; (b) Cipla India would be a foreign defendant not subject to personal jurisdiction in the courts of any State; and (c) Cipla India has sufficient contacts with the United States as a whole, including, but not limited to, filing ANDAs with the FDA and manufacturing and selling generic pharmaceutical products through its U.S. subsidiaries that are distributed throughout the United States, such that this Court's exercise of jurisdiction over Cipla India satisfies due process.

PERSONAL JURISDICTION OVER INVAGEN INC.

16. Plaintiffs reallege paragraphs 1-15 as if fully set forth herein.

17. On information and belief, InvaGen Inc. develops, manufactures, and/or distributes generic drugs for sale and use throughout the United States, including in this judicial district.

18. This Court has personal jurisdiction over InvaGen Inc. because InvaGen Inc. consented to jurisdiction and venue in the United States District Court for the District of Delaware in this matter, through its counsel, by e-mail dated January 24, 2019.

PERSONAL JURISDICTION OVER CIPLA USA

19. Plaintiffs reallege paragraphs 1-18 as if fully set forth herein.

20. On information and belief, Cipla USA develops, manufactures, and/or distributes generic drugs for sale and use throughout the United States, including in this judicial district.

21. This Court has personal jurisdiction over Cipla USA because, *inter alia*, Cipla USA, on information and belief: (1) is incorporated under the laws of the State of Delaware; (2) intends to market, sell, or distribute InvaGen's ANDA Products to residents of this State; (3) is controlled by Defendants Cipla India and InvaGen Inc.; (4) makes its generic drug products available in this State; and (5) enjoys substantial income from sales of its generic pharmaceutical products in this State.

BACKGROUND FACTS

22. Esbriet®, which contains pirfenidone as its active ingredient, is a drug used for treating patients afflicted with a rare, fatal lung disease called Idiopathic Pulmonary Fibrosis ("IPF").

23. IPF results in scarring of the lungs, which makes breathing difficult and prevents the heart, muscles, and vital organs from receiving enough oxygen to work properly. The disease can advance quickly or slowly, but eventually the lungs will harden and stop working altogether. The prognosis for IPF patients is extremely poor, with patients experiencing significant progressive worsening of disease, and median survival of 2-5 years after diagnosis. IPF is irreversible and fatal. The cause is unknown, and there is no cure.

24. Prior to Esbriet®, no drug had been approved in the United States as safe and effective for treating IPF. Approval in the United States came only after extensive clinical research by Plaintiff InterMune, which demonstrated that Esbriet® slows progression of the

disease. The FDA's approval of Esbriet® would not have been possible without the twelve years of effort by InterMune, a biopharmaceutical company that dedicated itself to developing medicines for treating IPF.

25. The FDA approved the first NDA for Esbriet® on October 15, 2014, shortly after Plaintiff InterMune was acquired by Plaintiff Genentech. This approval did not come easily. The FDA initially denied approval in 2010 following many years of research & development and multiple clinical trials. This necessitated further large-scale clinical trials and resubmission of the NDA in 2014. The clinical experimentation spanned over a decade and these combined results ultimately convinced the FDA that Esbriet® could be used safely and effectively to treat IPF patients.

26. When it first approved Esbriet®, the FDA accorded it status as a Breakthrough Therapy, and awarded Esbriet® Orphan Drug Exclusivity for treating IPF, which runs until October 15, 2021.

27. InvaGen now seeks to piggy-back on Plaintiffs' hard work by seeking FDA approval of the InvaGen ANDA that cross-references and relies upon Plaintiffs' clinical trial data. In so doing, InvaGen has not conducted any of the clinical trials needed to demonstrate effectiveness and safe conditions of use for its proposed InvaGen ANDA Product. Rather, InvaGen asks that the FDA permit the InvaGen ANDA to rely on proprietary clinical data submitted by Plaintiffs InterMune and Genentech.

28. This action arose when InvaGen sent a letter notifying Plaintiffs that (i) it had filed the InvaGen ANDA seeking to rely on Plaintiffs' safety and efficacy data without consent, and (ii) it is seeking FDA approval to commercially launch the InvaGen ANDA Product before Plaintiffs' exclusive patent rights to Esbriet® have expired.

THE ASSERTED PATENTS

- U.S. Patent No. 7,566,729

29. U.S. Patent No. 7,566,729 ("the '729 patent"), entitled "Modifying Pirfenidone Treatment for Patients with Atypical Liver Function," was duly and legally issued by the United States Patent & Trademark Office ("Patent Office") on July 28, 2009, and has not expired.

30. Plaintiffs have maintained the entire right, title, and interest in the '729 patent throughout the period of Defendants' infringement and have the exclusive right to sue for infringement. A copy of the '729 patent is attached as Exhibit 1.

- U.S. Patent No. 7,635,707

31. U.S. Patent No. 7,635,707 ("the '707 patent"), entitled "Pirfenidone Treatment for Patients with Atypical Liver Function," was duly and legally issued by the Patent Office on December 22, 2009, and has not expired.

32. Plaintiffs have maintained the entire right, title, and interest in the '707 patent throughout the period of Defendants' infringement and have the exclusive right to sue for infringement. A copy of the '707 patent is attached as Exhibit 2.

- U.S. Patent No. 7,767,700

33. U.S. Patent No. 7,767,700 ("the '700 patent"), entitled "Method of Providing Pirfenidone Therapy to a Patient," was duly and legally issued by the Patent Office on August 3, 2010, and has not expired.

34. Plaintiffs have maintained the entire right, title, and interest in the '700 patent throughout the period of Defendants' infringement and have the exclusive right to sue for infringement. A copy of the '700 patent is attached as Exhibit 3.

- U.S. Patent No. 7,816,383

35. U.S. Patent No. 7,816,383 ("the '383 patent"), entitled "Methods of Administering Pirfenidone Therapy," was duly and legally issued by the Patent Office on October 19, 2010, and has not expired.

36. Plaintiffs have maintained the entire right, title, and interest in the '383 patent throughout the period of Defendants' infringement and have the exclusive right to sue for infringement. A copy of the '383 patent is attached as Exhibit 4.

- U.S. Patent No. 7,910,610

37. U.S. Patent No. 7,910,610 ("the '610 patent"), entitled "Methods of Administering Pirfenidone Therapy," was duly and legally issued by the Patent Office on March 22, 2011, and has not expired.

38. Plaintiffs have maintained the entire right, title, and interest in the '610 patent throughout the period of Defendants' infringement and have the exclusive right to sue for infringement. A copy of the '610 patent is attached as Exhibit 5.

- U.S. Patent No. 8,013,002

39. U.S. Patent No. 8,013,002 ("the '002 patent"), entitled "Methods of Administering Pirfenidone Therapy," was duly and legally issued by the Patent Office on September 6, 2011, and has not expired.

40. Plaintiffs have maintained the entire right, title, and interest in the '002 patent throughout the period of Defendants' infringement and have the exclusive right to sue for infringement. A copy of the '002 patent is attached as Exhibit 6.

- U.S. Patent No. 8,084,475

41. U.S. Patent No. 8,084,475 ("the '475 patent"), entitled "Pirfenidone Therapy and Inducers of Cytochrome P450," was duly and legally issued by the Patent Office on December 27, 2011, and has not expired.

42. Plaintiffs have maintained the entire right, title, and interest in the '475 patent throughout the period of Defendants' infringement and have the exclusive right to sue for infringement. A copy of the '475 patent is attached as Exhibit 7.

- U.S. Patent No. 8,318,780

43. U.S. Patent No. 8,318,780 ("the '780 patent"), entitled "Methods of Administering Pirfenidone Therapy," was duly and legally issued by the Patent Office on November 27, 2012, and has not expired.

44. Plaintiffs have maintained the entire right, title, and interest in the '780 patent throughout the period of Defendants' infringement and have the exclusive right to sue for infringement. A copy of the '780 patent is attached as Exhibit 8.

- U.S. Patent No. 8,383,150

45. U.S. Patent No. 8,383,150 ("the '150 patent"), entitled "Granulate Formulation of Pirfenidone and Pharmaceutically Acceptable Excipients," was duly and legally issued by the Patent Office on February 26, 2013, and has not expired.

46. Plaintiffs have maintained the entire right, title, and interest in the '150 patent throughout the period of Defendants' infringement and have the exclusive right to sue for infringement. A copy of the '150 patent is attached as Exhibit 9.

- U.S. Patent No. 8,420,674

47. U.S. Patent No. 8,420,674 ("the '674 patent"), entitled "Method of Providing Pirfenidone Therapy to a Patient," was duly and legally issued by the Patent Office on April 16, 2013, and has not expired.

48. Plaintiffs have maintained the entire right, title, and interest in the '674 patent throughout the period of Defendants' infringement and have the exclusive right to sue for infringement. A copy of the '674 patent is attached as Exhibit 10.

- U.S. Patent No. 8,592,462

49. U.S. Patent No. 8,592,462 ("the '462 patent"), entitled "Pirfenidone Treatment for Patients with Atypical Liver Function," was duly and legally issued by the Patent Office on November 26, 2013, and has not expired.

50. Plaintiffs have maintained the entire right, title, and interest in the '462 patent throughout the period of Defendants' infringement. A copy of the '462 patent is attached as Exhibit 11.

- U.S. Patent No. 8,609,701

51. U.S. Patent No. 8,609,701 ("the '701 patent"), entitled "Pirfenidone Treatment for Patients with Atypical Liver Function," was duly and legally issued by the Patent Office on December 17, 2013, and has not expired.

52. Plaintiffs have maintained the entire right, title, and interest in the '701 patent throughout the period of Defendants' infringement and have the exclusive right to sue for infringement. A copy of the '701 patent is attached as Exhibit 12.

- U.S. Patent No. 8,648,098

53. U.S. Patent No. 8,648,098 ("the '098 patent"), entitled "Pirfenidone Therapy and Inducers of Cytochrome P450," was duly and legally issued by the Patent Office on February 11, 2014, and has not expired.

54. Plaintiffs have maintained the entire right, title, and interest in the '098 patent throughout the period of Defendants' infringement and have the exclusive right to sue for infringement. A copy of the '098 patent is attached as Exhibit 13.

- U.S. Patent No. 8,754,109

55. U.S. Patent No. 8,754,109 ("the '109 patent"), entitled "Pirfenidone Therapy and Inducers of Cytochrome P450," was duly and legally issued by the Patent Office on June 17, 2014, and has not expired.

56. Plaintiffs have maintained the entire right, title, and interest in the '109 patent throughout the period of Defendants' infringement and have the exclusive right to sue for infringement. A copy of the '109 patent is attached as Exhibit 14.

- U.S. Patent No. 8,778,947

57. U.S. Patent No. 8,778,947 ("the '947 patent"), entitled "Methods of Administering Pirfenidone Therapy," was duly and legally issued by the Patent Office on July 15, 2014, and has not expired.

58. Plaintiffs have maintained the entire right, title, and interest in the '947 patent throughout the period of Defendants' infringement and have the exclusive right to sue for infringement. A copy of the '947 patent is attached as Exhibit 15.

59. The '729, '707, '700, '383, '610, '002, '475, '780, '150, '674, '462, '701, '098, '109, and '947 patents are referred to collectively herein as the "Asserted Patents."

ACTS GIVING RISE TO THIS ACTION

60. Plaintiff Genentech is the holder of NDA No. 208780 (the "Genentech NDA") by which the FDA granted approval for 267, 534, and 801 mg pirfenidone tablets for treating IPF. Genentech holds the exclusive right to market these tablets in the United States under the trademark Esbriet®.

61. Esbriet® tablets and the use of Esbriet® tablets in accordance with its FDA-approved label are covered by one or more claims of the Asserted Patents.

62. The FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") lists the Asserted Patents in connection with Esbriet® tablets.

63. By letter dated December 21, 2018 (the "Notice Letter") InvaGen notified Plaintiffs that it had submitted the InvaGen ANDA to the FDA, seeking approval for commercial manufacture, use, and sale of the InvaGen ANDA Product in the United States prior to the expiration of the Asserted Patents.

64. In the Notice Letter, InvaGen notified Plaintiffs that, as a part of its ANDA, it had filed a certification under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the Asserted Patents (the "Paragraph IV Certification"), that those patents are allegedly invalid, unenforceable and/or will not be infringed by the commercial manufacture, use, and sale of the InvaGen ANDA Product in the United States.

65. By filing the InvaGen ANDA, InvaGen has necessarily represented to the FDA that the InvaGen ANDA Product will have the same pirfenidone active ingredient, route of administration, dosage form, and dosage strengths as Plaintiffs' FDA-approved Esbriet® tablets, and will be bioequivalent.

66. InvaGen's Notice Letter contained an offer of confidential access ("OCA"), the terms of which the parties attempted to negotiate in good faith in an effort to reach a mutually acceptable agreement, and under which the InvaGen ANDA would be provided to Plaintiffs. The parties were unable to reach an agreement on the OCA terms because InvaGen's proposed OCA contained unreasonable restrictions well beyond those that would apply under a protective order on who could view the ANDA. For example, the proposed InvaGen OCA contained a broad patent prosecution and regulatory work bar (including but not limited to a patent-related bar and an FDA bar), which, among other things, does not have a carve-out for inter partes reviews or other adversarial proceedings. The restrictions InvaGen placed on access to the InvaGen ANDA contravene 21 U.S.C. § 355(j)(5)(C)(i)(III), which states that an offer of confidential access "shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, **as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information**" (emphasis added). Plaintiffs have not been able to evaluate the InvaGen ANDA. Plaintiffs require discovery from InvaGen in this action.

67. This Complaint is being filed before the expiration of forty-five days from the date Plaintiffs received the Notice Letter.

COUNT I

INFRINGEMENT OF THE '729 PATENT

68. Plaintiffs reallege paragraphs 1 to 67 as if fully set forth herein.

69. InvaGen's Notice Letter regarding its Paragraph IV Certification does not deny that the InvaGen ANDA Product will infringe the '729 patent.

70. On information and belief, InvaGen does not deny that the InvaGen ANDA Product will infringe at least certain claims of the ’729 patent.

71. Defendants’ submission of the InvaGen ANDA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the InvaGen ANDA Product in the United States prior to the expiration of the ‘729 patent infringed at least one of the claims of the ‘729 patent, either literally or under the doctrine of equivalents under 35 U.S.C. § 271(e)(2)(A).

72. Defendants’ manufacture, use, offer to sell, or sale of the InvaGen ANDA Product in the United States or importation of the InvaGen ANDA Product into the United States during the term of the ‘729 patent would further infringe at least one claim of the ‘729 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

73. On information and belief, the InvaGen ANDA Product, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least one of the claims of the ‘729 patent either literally or under the doctrine of equivalents.

74. On information and belief, the use of the InvaGen ANDA Product constitutes a material part of at least one of the claims of the ‘729 patent; Defendants know that the InvaGen ANDA Product is especially made or adapted for use in infringing at least one of the claims of the ‘729 patent, either literally or under the doctrine of equivalents; and the InvaGen ANDA Product is not a staple article of commerce or commodity of commerce suitable for substantial noninfringing use.

75. On information and belief, the offering to sell, sale, and/or importation of the InvaGen ANDA Product would contributorily infringe at least one of the claims of the ‘729 patent, either literally or under the doctrine of equivalents.

76. On information and belief, InvaGen had knowledge of the '729 patent and, by its promotional activities and package inserts for the InvaGen ANDA Product, knows or should know that it will aid and abet others' direct infringement of at least one of the claims of the '729 patent, either literally or under the doctrine of equivalents, and specifically intends that those activities will infringe the '729 patent.

77. On information and belief, the offering to sell, sale, and/or importation of the InvaGen ANDA Product by Defendant would actively induce infringement of at least one of the claims of the '729 patent, either literally or under the doctrine of equivalents.

78. If Defendants' marketing and sale of the InvaGen ANDA Product prior to expiration of the '729 patent and all other relevant exclusivities are not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT II

INFRINGEMENT OF THE '707 PATENT

79. Plaintiffs reallege paragraphs 1 to 78 as if fully set forth herein.

80. InvaGen's Notice Letter regarding its Paragraph IV Certification does not deny that the InvaGen ANDA Product will infringe the '707 patent.

81. On information and belief, InvaGen does not deny that the InvaGen ANDA Product will infringe at least certain claims of the '707 patent.

82. Defendants' submission of the InvaGen ANDA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the InvaGen ANDA Product in the United States prior to the expiration of the '707 patent infringed at least one of the claims of the '707 patent, either literally or under the doctrine of equivalents under 35 U.S.C. § 271(e)(2)(A).

83. Defendants' manufacture, use, offer to sell, or sale of the InvaGen ANDA Product in the United States or importation of the InvaGen ANDA Product into the United States during the term of the '707 patent would further infringe at least one claim of the '707 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

84. On information and belief, the InvaGen ANDA Product, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least one of the claims of the '707 patent either literally or under the doctrine of equivalents.

85. On information and belief, the use of the InvaGen ANDA Product constitutes a material part of at least one of the claims of the '707 patent; Defendants know that the InvaGen ANDA Product is especially made or adapted for use in infringing at least one of the claims of the '707 patent, either literally or under the doctrine of equivalents; and the InvaGen ANDA Product is not a staple article of commerce or commodity of commerce suitable for substantial noninfringing use.

86. On information and belief, the offering to sell, sale, and/or importation of the InvaGen ANDA Product would contributorily infringe at least one of the claims of the '707 patent, either literally or under the doctrine of equivalents.

87. On information and belief, InvaGen had knowledge of the '707 patent and, by its promotional activities and package inserts for the InvaGen ANDA Product, knows or should know that it will aid and abet others' direct infringement of at least one of the claims of the '707 patent, either literally or under the doctrine of equivalents, and specifically intends that those activities will infringe the '707 patent.

88. On information and belief, the offering to sell, sale, and/or importation of the InvaGen ANDA Product by Defendant would actively induce infringement of at least one of the claims of the '707 patent, either literally or under the doctrine of equivalents.

89. If Defendants' marketing and sale of the InvaGen ANDA Product prior to expiration of the '707 patent and all other relevant exclusivities are not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT III

INFRINGEMENT OF THE '700 PATENT

90. Plaintiffs reallege paragraphs 1 to 89 as if fully set forth herein.

91. InvaGen's Notice Letter regarding its Paragraph IV Certification does not deny that the InvaGen ANDA Product will infringe claims 1-4, 7-10, 13-16, and 19 of the '700 patent.

92. On information and belief, InvaGen does not deny that the InvaGen ANDA Product will infringe at least certain claims of the '700 patent.

93. Defendants' submission of the InvaGen ANDA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the InvaGen ANDA Product in the United States prior to the expiration of the '700 patent infringed at least one of the claims of the '700 patent, including but not limited to claims 1-4, 7-10, 13-16, and 19, either literally or under the doctrine of equivalents under 35 U.S.C. § 271(e)(2)(A).

94. Defendants' manufacture, use, offer to sell, or sale of the InvaGen ANDA Product in the United States or importation of the InvaGen ANDA Product into the United States during the term of the '700 patent would further infringe at least one claim of the '700 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

95. On information and belief, the InvaGen ANDA Product, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least one of the claims of the '700 patent either literally or under the doctrine of equivalents.

96. On information and belief, the use of the InvaGen ANDA Product constitutes a material part of at least one of the claims of the '700 patent; Defendants know that the InvaGen ANDA Product is especially made or adapted for use in infringing at least one of the claims of the '700 patent, either literally or under the doctrine of equivalents; and the InvaGen ANDA Product is not a staple article of commerce or commodity of commerce suitable for substantial noninfringing use.

97. On information and belief, the offering to sell, sale, and/or importation of the InvaGen ANDA Product would contributorily infringe at least one of the claims of the '700 patent, either literally or under the doctrine of equivalents.

98. On information and belief, InvaGen had knowledge of the '700 patent and, by its promotional activities and package inserts for the InvaGen ANDA Product, knows or should know that it will aid and abet others' direct infringement of at least one of the claims of the '700 patent, either literally or under the doctrine of equivalents, and specifically intends that those activities will infringe the '700 patent.

99. On information and belief, the offering to sell, sale, and/or importation of the InvaGen ANDA Product by Defendant would actively induce infringement of at least one of the claims of the '700 patent, either literally or under the doctrine of equivalents.

100. If Defendants' marketing and sale of the InvaGen ANDA Product prior to expiration of the '700 patent and all other relevant exclusivities are not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT IV

INFRINGEMENT OF THE '383 PATENT

101. Plaintiffs reallege paragraphs 1 to 100 as if fully set forth herein.

102. InvaGen's Notice Letter regarding its Paragraph IV Certification does not deny that the InvaGen ANDA Product will infringe the '383 patent.

103. On information and belief, InvaGen does not deny that the InvaGen ANDA Product will infringe at least certain claims of the '383 patent.

104. Defendants' submission of the InvaGen ANDA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the InvaGen ANDA Product in the United States prior to the expiration of the '383 patent infringed at least one of the claims of the '383 patent, either literally or under the doctrine of equivalents under 35 U.S.C. § 271(e)(2)(A).

105. Defendants' manufacture, use, offer to sell, or sale of the InvaGen ANDA Product in the United States or importation of the InvaGen ANDA Product into the United States during the term of the '383 patent would further infringe at least one claim of the '383 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

106. On information and belief, the InvaGen ANDA Product, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least one of the claims of the '383 patent either literally or under the doctrine of equivalents.

107. On information and belief, the use of the InvaGen ANDA Product constitutes a material part of at least one of the claims of the '383 patent; Defendants know that the InvaGen ANDA Product is especially made or adapted for use in infringing at least one of the claims of the '383 patent, either literally or under the doctrine of equivalents; and the InvaGen ANDA Product is not a staple article of commerce or commodity of commerce suitable for substantial noninfringing use.

108. On information and belief, the offering to sell, sale, and/or importation of the InvaGen ANDA Product would contributorily infringe at least one of the claims of the '383 patent, either literally or under the doctrine of equivalents.

109. On information and belief, InvaGen had knowledge of the '383 patent and, by its promotional activities and package inserts for the InvaGen ANDA Product, knows or should know that it will aid and abet others' direct infringement of at least one of the claims of the '383 patent, either literally or under the doctrine of equivalents, and specifically intends that those activities will infringe the '383 patent.

110. On information and belief, the offering to sell, sale, and/or importation of the InvaGen ANDA Product by Defendant would actively induce infringement of at least one of the claims of the '383 patent, either literally or under the doctrine of equivalents.

111. If Defendants' marketing and sale of the InvaGen ANDA Product prior to expiration of the '383 patent and all other relevant exclusivities are not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT V

INFRINGEMENT OF THE '610 PATENT

112. Plaintiffs reallege paragraphs 1 to 111 as if fully set forth herein.

113. InvaGen's Notice Letter regarding its Paragraph IV Certification does not deny that the InvaGen ANDA Product will infringe the '610 patent.

114. On information and belief, InvaGen does not deny that the InvaGen ANDA Product will infringe at least certain claims of the '610 patent.

115. Defendants' submission of the InvaGen ANDA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the InvaGen ANDA Product in the United States prior to the expiration of the '610 patent infringed at least one of the claims of the '610 patent, either literally or under the doctrine of equivalents under 35 U.S.C. § 271(e)(2)(A).

116. Defendants' manufacture, use, offer to sell, or sale of the InvaGen ANDA Product in the United States or importation of the InvaGen ANDA Product into the United States during the term of the '610 patent would further infringe at least one claim of the '610 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

117. On information and belief, the InvaGen ANDA Product, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least one of the claims of the '610 patent either literally or under the doctrine of equivalents.

118. On information and belief, the use of the InvaGen ANDA Product constitutes a material part of at least one of the claims of the '610 patent; Defendants know that the InvaGen ANDA Product is especially made or adapted for use in infringing at least one of the claims of the '610 patent, either literally or under the doctrine of equivalents; and the InvaGen ANDA

Product is not a staple article of commerce or commodity of commerce suitable for substantial noninfringing use.

119. On information and belief, the offering to sell, sale, and/or importation of the InvaGen ANDA Product would contributorily infringe at least one of the claims of the '610 patent, either literally or under the doctrine of equivalents.

120. On information and belief, InvaGen had knowledge of the '610 patent and, by its promotional activities and package inserts for the InvaGen ANDA Product, knows or should know that it will aid and abet others' direct infringement of at least one of the claims of the '610 patent, either literally or under the doctrine of equivalents, and specifically intends that those activities will infringe the '610 patent.

121. On information and belief, the offering to sell, sale, and/or importation of the InvaGen ANDA Product by Defendant would actively induce infringement of at least one of the claims of the '610 patent, either literally or under the doctrine of equivalents.

122. If Defendants' marketing and sale of the InvaGen ANDA Product prior to expiration of the '610 patent and all other relevant exclusivities are not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT VI

INFRINGEMENT OF THE '002 PATENT

123. Plaintiffs reallege paragraphs 1 to 122 as if fully set forth herein.

124. InvaGen's Notice Letter regarding its Paragraph IV Certification does not deny that the InvaGen ANDA Product will infringe the '002 patent.

125. On information and belief, InvaGen does not deny that the InvaGen ANDA Product will infringe at least certain claims of the '002 patent.

126. Defendants' submission of the InvaGen ANDA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the InvaGen ANDA Product in the United States prior to the expiration of the '002 patent infringed at least one of the claims of the '002 patent, either literally or under the doctrine of equivalents under 35 U.S.C. § 271(e)(2)(A).

127. Defendants' manufacture, use, offer to sell, or sale of the InvaGen ANDA Product in the United States or importation of the InvaGen ANDA Product into the United States during the term of the '002 patent would further infringe at least one claim of the '002 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

128. On information and belief, the InvaGen ANDA Product, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least one of the claims of the '002 patent either literally or under the doctrine of equivalents.

129. On information and belief, the use of the InvaGen ANDA Product constitutes a material part of at least one of the claims of the '002 patent; Defendants know that the InvaGen ANDA Product is especially made or adapted for use in infringing at least one of the claims of the '002 patent, either literally or under the doctrine of equivalents; and the InvaGen ANDA Product is not a staple article of commerce or commodity of commerce suitable for substantial noninfringing use.

130. On information and belief, the offering to sell, sale, and/or importation of the InvaGen ANDA Product would contributorily infringe at least one of the claims of the '002 patent, either literally or under the doctrine of equivalents.

131. On information and belief, InvaGen had knowledge of the '002 patent and, by its promotional activities and package inserts for the InvaGen ANDA Product, knows or should

know that it will aid and abet others' direct infringement of at least one of the claims of the '002 patent, either literally or under the doctrine of equivalents, and specifically intends that those activities will infringe the '002 patent.

132. On information and belief, the offering to sell, sale, and/or importation of the InvaGen ANDA Product by Defendant would actively induce infringement of at least one of the claims of the '002 patent, either literally or under the doctrine of equivalents.

133. If Defendants' marketing and sale of the InvaGen ANDA Product prior to expiration of the '002 patent and all other relevant exclusivities are not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT VII

INFRINGEMENT OF THE '475 PATENT

134. Plaintiffs reallege paragraphs 1 to 133 as if fully set forth herein.

135. InvaGen's Notice Letter regarding its Paragraph IV Certification does not deny that the InvaGen ANDA Product will infringe the '475 patent.

136. On information and belief, InvaGen does not deny that the InvaGen ANDA Product will infringe at least certain claims of the '475 patent.

137. Defendants' submission of the InvaGen ANDA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the InvaGen ANDA Product in the United States prior to the expiration of the '475 patent infringed at least one of the claims of the '475 patent, either literally or under the doctrine of equivalents under 35 U.S.C. § 271(e)(2)(A).

138. Defendants' manufacture, use, offer to sell, or sale of the InvaGen ANDA Product in the United States or importation of the InvaGen ANDA Product into the United States during

the term of the ‘475 patent would further infringe at least one claim of the ‘475 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

139. On information and belief, the InvaGen ANDA Product, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least one of the claims of the ‘475 patent either literally or under the doctrine of equivalents.

140. On information and belief, the use of the InvaGen ANDA Product constitutes a material part of at least one of the claims of the ‘475 patent; Defendants know that the InvaGen ANDA Product is especially made or adapted for use in infringing at least one of the claims of the ‘475 patent, either literally or under the doctrine of equivalents; and the InvaGen ANDA Product is not a staple article of commerce or commodity of commerce suitable for substantial noninfringing use.

141. On information and belief, the offering to sell, sale, and/or importation of the InvaGen ANDA Product would contributorily infringe at least one of the claims of the ‘475 patent, either literally or under the doctrine of equivalents.

142. On information and belief, InvaGen had knowledge of the ‘475 patent and, by its promotional activities and package inserts for the InvaGen ANDA Product, knows or should know that it will aid and abet others’ direct infringement of at least one of the claims of the ‘475 patent, either literally or under the doctrine of equivalents, and specifically intends that those activities will infringe the ‘475 patent.

143. On information and belief, the offering to sell, sale, and/or importation of the InvaGen ANDA Product by Defendant would actively induce infringement of at least one of the claims of the ‘475 patent, either literally or under the doctrine of equivalents.

144. If Defendants' marketing and sale of the InvaGen ANDA Product prior to expiration of the '475 patent and all other relevant exclusivities are not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT VIII

INFRINGEMENT OF THE '780 PATENT

145. Plaintiffs reallege paragraphs 1 to 144 as if fully set forth herein.

146. InvaGen's Notice Letter regarding its Paragraph IV Certification does not deny that the InvaGen ANDA Product will infringe the '780 patent.

147. On information and belief, InvaGen does not deny that the InvaGen ANDA Product will infringe at least certain claims of the '780 patent.

148. Defendants' submission of the InvaGen ANDA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the InvaGen ANDA Product in the United States prior to the expiration of the '780 patent infringed at least one of the claims of the '780 patent, either literally or under the doctrine of equivalents under 35 U.S.C. § 271(e)(2)(A).

149. Defendants' manufacture, use, offer to sell, or sale of the InvaGen ANDA Product in the United States or importation of the InvaGen ANDA Product into the United States during the term of the '780 patent would further infringe at least one claim of the '780 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

150. On information and belief, the InvaGen ANDA Product, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least one of the claims of the '780 patent either literally or under the doctrine of equivalents.

151. On information and belief, the use of the InvaGen ANDA Product constitutes a material part of at least one of the claims of the '780 patent; Defendants know that the InvaGen ANDA Product is especially made or adapted for use in infringing at least one of the claims of the '780 patent, either literally or under the doctrine of equivalents; and the InvaGen ANDA Product is not a staple article of commerce or commodity of commerce suitable for substantial noninfringing use.

152. On information and belief, the offering to sell, sale, and/or importation of the InvaGen ANDA Product would contributorily infringe at least one of the claims of the '780 patent, either literally or under the doctrine of equivalents.

153. On information and belief, InvaGen had knowledge of the '780 patent and, by its promotional activities and package inserts for the InvaGen ANDA Product, knows or should know that it will aid and abet others' direct infringement of at least one of the claims of the '780 patent, either literally or under the doctrine of equivalents, and specifically intends that those activities will infringe the '780 patent.

154. On information and belief, the offering to sell, sale, and/or importation of the InvaGen ANDA Product by Defendant would actively induce infringement of at least one of the claims of the '780 patent, either literally or under the doctrine of equivalents.

155. If Defendants' marketing and sale of the InvaGen ANDA Product prior to expiration of the '780 patent and all other relevant exclusivities are not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT IX

INFRINGEMENT OF THE '150 PATENT

156. Plaintiffs reallege paragraphs 1 to 155 as if fully set forth herein.

157. Defendants' submission of the InvaGen ANDA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the InvaGen ANDA Product in the United States prior to the expiration of the '150 patent infringed at least one of the claims of the '150 patent, including but not limited to claims 1 and 27, either literally or under the doctrine of equivalents under 35 U.S.C. § 271(e)(2)(A).

158. Defendants' manufacture, use, offer to sell, or sale of the InvaGen ANDA Product in the United States or importation of the InvaGen ANDA Product into the United States during the term of the '150 patent would further infringe at least one claim of the '150 patent, including but not limited to claims 1 and 27, under 35 U.S.C. §§ 271 (a), (b), and/or (c).

159. On information and belief, the InvaGen ANDA Product, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least one of the claims of the '150 patent either literally or under the doctrine of equivalents.

160. On information and belief, the use of the InvaGen ANDA Product constitutes a material part of at least one of the claims of the '150 patent; Defendants know that the InvaGen ANDA Product is especially made or adapted for use in infringing at least one of the claims of the '150 patent, either literally or under the doctrine of equivalents; and the InvaGen ANDA Product is not a staple article of commerce or commodity of commerce suitable for substantial noninfringing use.

161. On information and belief, the offering to sell, sale, and/or importation of the InvaGen ANDA Product would contributorily infringe at least one of the claims of the '150 patent, either literally or under the doctrine of equivalents.

162. On information and belief, InvaGen had knowledge of the '150 patent and, by its promotional activities and package inserts for the InvaGen ANDA Product, knows or should know that it will aid and abet others' direct infringement of at least one of the claims of the '150 patent, either literally or under the doctrine of equivalents, and specifically intends that those activities will infringe the '150 patent.

163. On information and belief, the offering to sell, sale, and/or importation of the InvaGen ANDA Product by Defendant would actively induce infringement of at least one of the claims of the '150 patent, either literally or under the doctrine of equivalents.

164. If Defendants' marketing and sale of the InvaGen ANDA Product prior to expiration of the '150 patent and all other relevant exclusivities are not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT X

INFRINGEMENT OF THE '674 PATENT

165. Plaintiffs reallege paragraphs 1 to 164 as if fully set forth herein.

166. InvaGen's Notice Letter regarding its Paragraph IV Certification does not deny that the InvaGen ANDA Product will infringe claims 6-10 the '674 patent.

167. On information and belief, InvaGen does not deny that the InvaGen ANDA Product will infringe at least certain claims of the '674 patent.

168. Defendants' submission of the InvaGen ANDA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the InvaGen ANDA Product in the

United States prior to the expiration of the '674 patent infringed at least one of the claims of the '674 patent, including but not limited to claims 6-10, either literally or under the doctrine of equivalents under 35 U.S.C. § 271(e)(2)(A).

169. Defendants' manufacture, use, offer to sell, or sale of the InvaGen ANDA Product in the United States or importation of the InvaGen ANDA Product into the United States during the term of the '674 patent would further infringe at least one claim of the '674 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

170. On information and belief, the InvaGen ANDA Product, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least one of the claims of the '674 patent either literally or under the doctrine of equivalents.

171. On information and belief, the use of the InvaGen ANDA Product constitutes a material part of at least one of the claims of the '674 patent; Defendants know that the InvaGen ANDA Product is especially made or adapted for use in infringing at least one of the claims of the '674 patent, either literally or under the doctrine of equivalents; and the InvaGen ANDA Product is not a staple article of commerce or commodity of commerce suitable for substantial noninfringing use.

172. On information and belief, the offering to sell, sale, and/or importation of the InvaGen ANDA Product would contributorily infringe at least one of the claims of the '674 patent, either literally or under the doctrine of equivalents.

173. On information and belief, InvaGen had knowledge of the '674 patent and, by its promotional activities and package inserts for the InvaGen ANDA Product, knows or should know that it will aid and abet others' direct infringement of at least one of the claims of the '674

patent, either literally or under the doctrine of equivalents, and specifically intends that those activities will infringe the '674 patent.

174. On information and belief, the offering to sell, sale, and/or importation of the InvaGen ANDA Product by Defendant would actively induce infringement of at least one of the claims of the '674 patent, either literally or under the doctrine of equivalents.

175. If Defendants' marketing and sale of the InvaGen ANDA Product prior to expiration of the '674 patent and all other relevant exclusivities are not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT XI

INFRINGEMENT OF THE '462 PATENT

176. Plaintiffs reallege paragraphs 1 to 175 as if fully set forth herein.

177. InvaGen's Notice Letter regarding its Paragraph IV Certification does not deny that the InvaGen ANDA Product will infringe claims 1-4, 6-19 and 21-29 of the '462 patent.

178. On information and belief, InvaGen does not deny that the InvaGen ANDA Product will infringe at least certain claims of the '462 patent.

179. Defendants' submission of the InvaGen ANDA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the InvaGen ANDA Product in the United States prior to the expiration of the '462 patent infringed at least one of the claims of the '462 patent, including but not limited to claims 1-4, 6-19 and 21-29, either literally or under the doctrine of equivalents under 35 U.S.C. § 271(e)(2)(A).

180. Defendants' manufacture, use, offer to sell, or sale of the InvaGen ANDA Product in the United States or importation of the InvaGen ANDA Product into the United States during

the term of the ‘462 patent would further infringe at least one claim of the ‘462 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

181. On information and belief, the InvaGen ANDA Product, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least one of the claims of the ‘462 patent either literally or under the doctrine of equivalents.

182. On information and belief, the use of the InvaGen ANDA Product constitutes a material part of at least one of the claims of the ‘462 patent; Defendants know that the InvaGen ANDA Product is especially made or adapted for use in infringing at least one of the claims of the ‘462 patent, either literally or under the doctrine of equivalents; and the InvaGen ANDA Product is not a staple article of commerce or commodity of commerce suitable for substantial noninfringing use.

183. On information and belief, the offering to sell, sale, and/or importation of the InvaGen ANDA Product would contributorily infringe at least one of the claims of the ‘462 patent, either literally or under the doctrine of equivalents.

184. On information and belief, InvaGen had knowledge of the ‘462 patent and, by its promotional activities and package inserts for the InvaGen ANDA Product, knows or should know that it will aid and abet others’ direct infringement of at least one of the claims of the ‘462 patent, either literally or under the doctrine of equivalents, and specifically intends that those activities will infringe the ‘462 patent.

185. On information and belief, the offering to sell, sale, and/or importation of the InvaGen ANDA Product by Defendant would actively induce infringement of at least one of the claims of the ‘462 patent, either literally or under the doctrine of equivalents.

186. If Defendants' marketing and sale of the InvaGen ANDA Product prior to expiration of the '462 patent and all other relevant exclusivities are not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT XII

INFRINGEMENT OF THE '701 PATENT

187. Plaintiffs reallege paragraphs 1 to 186 as if fully set forth herein.

188. InvaGen's Notice Letter regarding its Paragraph IV Certification does not deny that the InvaGen ANDA Product will infringe claims 1-15, 17 and 19 of the '701 patent.

189. On information and belief, InvaGen does not deny that the InvaGen ANDA Product will infringe at least certain claims of the '701 patent.

190. Defendants' submission of the InvaGen ANDA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the InvaGen ANDA Product in the United States prior to the expiration of the '701 patent infringed at least one of the claims of the '701 patent, including but not limited to claims 1-15, 17 and 19, either literally or under the doctrine of equivalents under 35 U.S.C. § 271(e)(2)(A).

191. Defendants' manufacture, use, offer to sell, or sale of the InvaGen ANDA Product in the United States or importation of the InvaGen ANDA Product into the United States during the term of the '701 patent would further infringe at least one claim of the '701 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

192. On information and belief, the InvaGen ANDA Product, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least one of the claims of the '701 patent either literally or under the doctrine of equivalents.

193. On information and belief, the use of the InvaGen ANDA Product constitutes a material part of at least one of the claims of the '701 patent; Defendants know that the InvaGen ANDA Product is especially made or adapted for use in infringing at least one of the claims of the '701 patent, either literally or under the doctrine of equivalents; and the InvaGen ANDA Product is not a staple article of commerce or commodity of commerce suitable for substantial noninfringing use.

194. On information and belief, the offering to sell, sale, and/or importation of the InvaGen ANDA Product would contributorily infringe at least one of the claims of the '701 patent, either literally or under the doctrine of equivalents.

195. On information and belief, InvaGen had knowledge of the '701 patent and, by its promotional activities and package inserts for the InvaGen ANDA Product, knows or should know that it will aid and abet others' direct infringement of at least one of the claims of the '701 patent, either literally or under the doctrine of equivalents, and specifically intends that those activities will infringe the '701 patent.

196. On information and belief, the offering to sell, sale, and/or importation of the InvaGen ANDA Product by Defendant would actively induce infringement of at least one of the claims of the '701 patent, either literally or under the doctrine of equivalents.

197. If Defendants' marketing and sale of the InvaGen ANDA Product prior to expiration of the '701 patent and all other relevant exclusivities are not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT XIII

INFRINGEMENT OF THE '098 PATENT

198. Plaintiffs reallege paragraphs 1 to 197 as if fully set forth herein.

199. InvaGen's Notice Letter regarding its Paragraph IV Certification does not deny that the InvaGen ANDA Product will infringe the '098 patent.

200. On information and belief, InvaGen does not deny that the InvaGen ANDA Product will infringe at least certain claims of the '098 patent.

201. Defendants' submission of the InvaGen ANDA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the InvaGen ANDA Product in the United States prior to the expiration of the '098 patent infringed at least one of the claims of the '098 patent, either literally or under the doctrine of equivalents under 35 U.S.C. § 271(e)(2)(A).

202. Defendants' manufacture, use, offer to sell, or sale of the InvaGen ANDA Product in the United States or importation of the InvaGen ANDA Product into the United States during the term of the '098 patent would further infringe at least one claim of the '098 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

203. On information and belief, the InvaGen ANDA Product, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least one of the claims of the '098 patent either literally or under the doctrine of equivalents.

204. On information and belief, the use of the InvaGen ANDA Product constitutes a material part of at least one of the claims of the '098 patent; Defendants know that the InvaGen ANDA Product is especially made or adapted for use in infringing at least one of the claims of the '098 patent, either literally or under the doctrine of equivalents; and the InvaGen ANDA

Product is not a staple article of commerce or commodity of commerce suitable for substantial noninfringing use.

205. On information and belief, the offering to sell, sale, and/or importation of the InvaGen ANDA Product would contributorily infringe at least one of the claims of the '098 patent, either literally or under the doctrine of equivalents.

206. On information and belief, InvaGen had knowledge of the '098 patent and, by its promotional activities and package inserts for the InvaGen ANDA Product, knows or should know that it will aid and abet others' direct infringement of at least one of the claims of the '098 patent, either literally or under the doctrine of equivalents, and specifically intends that those activities will infringe the '098 patent.

207. On information and belief, the offering to sell, sale, and/or importation of the InvaGen ANDA Product by Defendant would actively induce infringement of at least one of the claims of the '098 patent, either literally or under the doctrine of equivalents.

208. If Defendants' marketing and sale of the InvaGen ANDA Product prior to expiration of the '098 patent and all other relevant exclusivities are not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT XIV

INFRINGEMENT OF THE '109 PATENT

209. Plaintiffs reallege paragraphs 1 to 208 as if fully set forth herein.

210. InvaGen's Notice Letter regarding its Paragraph IV Certification does not deny that the InvaGen ANDA Product will infringe the '109 patent.

211. On information and belief, InvaGen does not deny that the InvaGen ANDA Product will infringe at least certain claims of the '109 patent.

212. Defendants' submission of the InvaGen ANDA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the InvaGen ANDA Product in the United States prior to the expiration of the '109 patent infringed at least one of the claims of the '109 patent, either literally or under the doctrine of equivalents under 35 U.S.C. § 271(e)(2)(A).

213. Defendants' manufacture, use, offer to sell, or sale of the InvaGen ANDA Product in the United States or importation of the InvaGen ANDA Product into the United States during the term of the '109 patent would further infringe at least one claim of the '109 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

214. On information and belief, the InvaGen ANDA Product, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least one of the claims of the '109 patent either literally or under the doctrine of equivalents.

215. On information and belief, the use of the InvaGen ANDA Product constitutes a material part of at least one of the claims of the '109 patent; Defendants know that the InvaGen ANDA Product is especially made or adapted for use in infringing at least one of the claims of the '109 patent, either literally or under the doctrine of equivalents; and the InvaGen ANDA Product is not a staple article of commerce or commodity of commerce suitable for substantial noninfringing use.

216. On information and belief, the offering to sell, sale, and/or importation of the InvaGen ANDA Product would contributorily infringe at least one of the claims of the '109 patent, either literally or under the doctrine of equivalents.

217. On information and belief, InvaGen had knowledge of the '109 patent and, by its promotional activities and package inserts for the InvaGen ANDA Product, knows or should

know that it will aid and abet others' direct infringement of at least one of the claims of the '109 patent, either literally or under the doctrine of equivalents, and specifically intends that those activities will infringe the '109 patent.

218. On information and belief, the offering to sell, sale, and/or importation of the InvaGen ANDA Product by Defendant would actively induce infringement of at least one of the claims of the '109 patent, either literally or under the doctrine of equivalents.

219. If Defendants' marketing and sale of the InvaGen ANDA Product prior to expiration of the '109 patent and all other relevant exclusivities are not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT XV

INFRINGEMENT OF THE '947 PATENT

220. Plaintiffs reallege paragraphs 1 to 219 as if fully set forth herein.

221. InvaGen's Notice Letter regarding its Paragraph IV Certification does not deny that the InvaGen ANDA Product will infringe claims 1, 3 and 5-18 of the '947 patent.

222. On information and belief, InvaGen does not deny that the InvaGen ANDA Product will infringe at least certain claims of the '947 patent.

223. Defendants' submission of the InvaGen ANDA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the InvaGen ANDA Product in the United States prior to the expiration of the '947 patent infringed at least one of the claims of the '947 patent, including but not limited to claims 1, 3 and 5-18, either literally or under the doctrine of equivalents under 35 U.S.C. § 271(e)(2)(A).

224. Defendants' manufacture, use, offer to sell, or sale of the InvaGen ANDA Product in the United States or importation of the InvaGen ANDA Product into the United States during

the term of the '947 patent would further infringe at least one claim of the '947 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

225. On information and belief, the InvaGen ANDA Product, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least one of the claims of the '947 patent either literally or under the doctrine of equivalents.

226. On information and belief, the use of the InvaGen ANDA Product constitutes a material part of at least one of the claims of the '947 patent; Defendants know that the InvaGen ANDA Product is especially made or adapted for use in infringing at least one of the claims of the '947 patent, either literally or under the doctrine of equivalents; and the InvaGen ANDA Product is not a staple article of commerce or commodity of commerce suitable for substantial noninfringing use.

227. On information and belief, the offering to sell, sale, and/or importation of the InvaGen ANDA Product would contributorily infringe at least one of the claims of the '947 patent, either literally or under the doctrine of equivalents.

228. On information and belief, InvaGen had knowledge of the '947 patent and, by its promotional activities and package inserts for the InvaGen ANDA Product, knows or should know that it will aid and abet others' direct infringement of at least one of the claims of the '947 patent, either literally or under the doctrine of equivalents, and specifically intends that those activities will infringe the '947 patent.

229. On information and belief, the offering to sell, sale, and/or importation of the InvaGen ANDA Product by Defendant would actively induce infringement of at least one of the claims of the '947 patent, either literally or under the doctrine of equivalents.

230. If Defendants' marketing and sale of the InvaGen ANDA Product prior to expiration of the '947 patent and all other relevant exclusivities are not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

* * *

231. Defendants' activities, as alleged herein, were undertaken with knowledge of the Asserted Patents and without a good faith belief that they are not infringing those patents. This is an exceptional case.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray that this Court grant the following relief:

1. A judgment that the claims of the Asserted Patents were infringed by Defendants' submission of the InvaGen ANDA, either literally or under the doctrine of equivalents, and are not invalid or unenforceable, and that Defendants' making, using, offering to sell, or selling in the United States, or importing into the United States the InvaGen ANDA Product will infringe the claims of the Asserted Patents, either literally or under the doctrine of equivalents.

2. An Order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any approval of the InvaGen ANDA shall be a date which is not earlier than the latest expiration date of the Asserted Patents, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled.

3. An Order permanently enjoining Defendants, their affiliates, subsidiaries, and each of their officers, agents, servants and employees and those acting in privity or concert with them, from making, using, offering to sell, or selling in the United States, or importing into the United States the InvaGen ANDA Product until after the latest expiration date of the Asserted

Patents, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled.

4. Damages or other monetary relief, including costs, fees, pre- and post-judgment interest, to Plaintiffs if Defendants engage in commercial manufacture, use, offers to sell, sale, or importation in or into the United States of the InvaGen ANDA Product prior to the latest expiration date of the Asserted Patents, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled.

5. Such further and other relief as this Court deems proper and just, including any appropriate relief under 35 U.S.C. § 285.

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