IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GENENTECH, INC. and INTERMUNE, INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
SCIEGEN PHARMACEUTICALS INC. and BACTOLAC PHARMACEUTICAL 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, ScieGen Pharmaceuticals Inc. and Bactolac Pharmaceutical Inc. (collectively, "ScieGen" 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. 212077, which seeks approval from the U.S. Food and Drug Administration ("FDA") to market a generic copy of Plaintiffs' drug Esbriet® (pirfenidone) 267 mg capsules, 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 ScieGen Pharmaceuticals Inc. ("ScieGen Pharma.") is a private corporation organized and existing under the laws of New York, having its principal place of business at 20 Davids Drive, Hauppauge, New York 11788. Alternatively, on information and belief, ScieGen Pharma. has a place of business at 89 Arkay Drive, Hauppauge, New York, 11788.

6. On information and belief, ScieGen Pharma. is a wholly owned subsidiary of Bactolac Pharmaceutical Inc. ("Bactolac"). Bactolac is a Delaware corporation having a principal place of business at 7 Oser Avenue, Hauppauge, New York, 11788.

7. On information and belief, ScieGen Pharma. 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, subsidiaries and parent, including Bactolac, from which ScieGen Pharma. derives a substantial portion of its revenue.

8. On information and belief, ScieGen Pharma. acted in concert with Bactolac to prepare and submit ANDA No. 212077 (the "ScieGen ANDA") for ScieGen Pharma.'s 267 mg pirfenidone capsules (the "ScieGen ANDA Product"), which was done at the direction of, under the control of, and for the direct benefit of Bactolac.

JURISDICTION AND VENUE

9. 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).

10. Venue is proper in this Court under 28 U.S.C. §§ 1391(c) and/or 1400(b), and this Court has personal jurisdiction over ScieGen because, among other things, Bactolac is incorporated in the State of Delaware and therefore "resides" in this judicial district and ScieGen

Pharma., through its counsel, by e-mail dated January 16, 2019, agreed that it consents to and does not contest jurisdiction or venue in this Court in this matter.

PERSONAL JURISDICTION OVER SCIEGEN PHARMA.

11. Plaintiffs reallege paragraphs 1-10 as if fully set forth herein.

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

13. This Court has personal jurisdiction over ScieGen Pharma. because, *inter alia*, ScieGen Pharma., 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, its parent corporation, or agents; (2) intends to market, sell, and/or distribute the ScieGen ANDA Products to residents of this State upon approval of ANDA No. 212077, either directly or through at least one of its wholly-owned subsidiaries, its parent corporation, or agents; (3) enjoys substantial income from sales of its generic pharmaceutical products in this State on its own and through its parent, Bactolac, which is a Delaware corporation; and (4) is registered as a pharmacy wholesaler and controlled substance distributor/manufacturer with the Delaware Division of Professional Regulation.

14. Alternatively, to the extent the above facts do not establish personal jurisdiction over ScieGen Pharma., this Court may exercise jurisdiction over ScieGen Pharma. because it consented to jurisdiction in this matter, through its counsel, by e-mail dated January 16, 2019.

PERSONAL JURISDICTION OVER BACTOLAC

15. Plaintiffs reallege paragraphs 1-14 as if fully set forth herein.

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

17. This Court has personal jurisdiction over Bactolac because, *inter alia*, Bactolac, on information and belief: (1) is incorporated under the laws of the State of Delaware; (2) intends to market, sell, or distribute ScieGen's ANDA Products to residents of this State upon approval of ANDA No. 212077, either directly or through at least one of its wholly-owned subsidiaries or agents; and (3) enjoys substantial income from sales of its generic pharmaceutical products in this State.

BACKGROUND FACTS

18. 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").

19. 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.

20. 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.

21. 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.

22. 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.

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

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

THE ASSERTED PATENTS

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

25. 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.

26. 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 1.

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

27. 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.

28. 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 2.

- U.S. Patent No. 7,767,225

29. U.S. Patent No. 7,767,225 ("the '225 patent"), entitled "Capsule Formulation of Pirfenidone and Pharmaceutically Acceptable Excipients," was duly and legally issued by the Patent Office on August 3, 2010, and has not expired.

30. Plaintiffs have maintained the entire right, title, and interest in the '225 patent throughout the period of Defendants' infringement and have the exclusive right to sue for infringement. A copy of the '225 patent is attached as Exhibit 3.

- U.S. Patent No. 7,988,994

31. U.S. Patent No. 7,998,994 ("the '994 patent"), entitled "Capsule Formulation of Pirfenidone and Pharmaceutically Acceptable Excipients," was duly and legally issued by the Patent Office on August 2, 2011, and has not expired.

32. Plaintiffs have maintained the entire right, title, and interest in the '994 patent throughout the period of Defendants' infringement and have the exclusive right to sue for infringement. A copy of the '994 patent is attached as Exhibit 4.

- U.S. Patent No. 8,753,679

33. U.S. Patent No. 8,753,679 ("the '679 patent"), entitled "Capsule Formulation of Pirfenidone and Pharmaceutically Acceptable Excipients," was duly and legally issued by the Patent Office on June 17, 2014, and has not expired.

34. Plaintiffs have maintained the entire right, title, and interest in the '679 patent throughout the period of Defendants' infringement and have the exclusive right to sue for infringement. A copy of the '679 patent is attached as Exhibit 5.

35. The '150, '674, '225, '994 and '679 patents are referred to collectively herein as the "Asserted Patents."

ACTS GIVING RISE TO THIS ACTION

36. Plaintiff Genentech is the holder of NDA No. 022535 (the "Genentech NDA") by which the FDA granted approval for 267 mg pirfenidone capsules for treating IPF. Genentech holds the exclusive right to market these capsules in the United States under the trademark Esbriet®.

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

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

39. By letter dated December 10, 2018 (the "Notice Letter"), ScieGen notified Plaintiffs that it had submitted the ScieGen ANDA to the FDA, seeking approval for commercial manufacture, use, and sale of the ScieGen ANDA Product in the United States prior to the expiration of the Asserted Patents.

40. In the Notice Letter, ScieGen 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 ScieGen ANDA Product in the United States.

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

42. ScieGen'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 ScieGen ANDA would be provided to Plaintiffs. The parties reached agreement on the OCA terms, and ScieGen purported to have produced at least substantial portions of its ANDA. Plaintiffs have not been able to fully evaluate ScieGen's non-infringement assertions based, *inter alia*, on the time constraint of having to complete this evaluation within 45 days of Plaintiffs' receipt of the Notice Letter without the benefit of discovery. Plaintiffs require discovery from ScieGen in this action.

43. 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 '150 PATENT

44. Plaintiffs reallege paragraphs 1 to 43 as if fully set forth herein.

45. ScieGen's Notice Letter regarding its Paragraph IV Certification does not deny that the ScieGen ANDA Product will infringe claim 27 the '150 patent.

46. On information and belief, ScieGen does not deny that the ScieGen ANDA Product will infringe at least certain claims of the '150 patent.

47. Defendants' submission of the ScieGen ANDA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the ScieGen 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).

48. Defendants' manufacture, use, offer to sell, or sale of the ScieGen ANDA Product in the United States or importation of the ScieGen 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), either literally or under the doctrine of equivalents because, *inter alia*, the ScieGen ANDA Product contains the same components recited in claim 1 and use of the ScieGen ANDA product in accordance with its associated labeling would infringe at least claim 27.

49. On information and belief, the ScieGen 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.

50. On information and belief, the use of the ScieGen ANDA Product constitutes a material part of at least one of the claims of the '150 patent; Defendants know that the ScieGen 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 ScieGen ANDA Product is not a staple article of commerce or commodity of commerce suitable for substantial noninfringing use.

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

52. On information and belief, ScieGen had knowledge of the '150 patent and, by its promotional activities and package inserts for the ScieGen 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.

53. On information and belief, the offering to sell, sale, and/or importation of the ScieGen 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.

54. If Defendants' marketing and sale of the ScieGen 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 II

INFRINGEMENT OF THE '674 PATENT

55. Plaintiffs reallege paragraphs 1 to 54 as if fully set forth herein.

56. Defendants' submission of the ScieGen ANDA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the ScieGen 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 claim 6, either literally or under the doctrine of equivalents under 35 U.S.C. § 271(e)(2)(A).

57. Defendants' manufacture, use, offer to sell, or sale of the ScieGen ANDA Product in the United States or importation of the ScieGen ANDA Product into the United States during the term of the '674 patent would further infringe at least one claim of the '674 patent, including but not limited to claim 6, under 35 U.S.C. §§ 271 (a), (b), and/or (c) because, *inter alia*, the use of the ScieGen ANDA product in accordance with its associated labeling would infringe at least claim 6.

58. On information and belief, the ScieGen 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.

59. On information and belief, the use of the ScieGen ANDA Product constitutes a material part of at least one of the claims of the '674 patent; Defendants know that the ScieGen 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 ScieGen ANDA

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

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

61. On information and belief, ScieGen had knowledge of the '674 patent and, by its promotional activities and package inserts for the ScieGen 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.

62. On information and belief, the offering to sell, sale, and/or importation of the ScieGen 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.

63. If Defendants' marketing and sale of the ScieGen 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 III

INFRINGEMENT OF THE '225 PATENT

64. Plaintiffs reallege paragraphs 1 to 63 as if fully set forth herein.

65. Defendants' submission of the ScieGen ANDA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the ScieGen ANDA Product in the United States prior to the expiration of the '225 patent infringed at least one of the claims of the

‘225 patent, including but not limited to claims 1 and 11, either literally or under the doctrine of equivalents under 35 U.S.C. § 271(e)(2)(A).

66. Defendants’ manufacture, use, offer to sell, or sale of the ScieGen ANDA Product in the United States or importation of the ScieGen ANDA Product into the United States during the term of the ‘225 patent would further infringe at least one claim of the ‘225 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c), either literally or under the doctrine of equivalents because, *inter alia*, the ScieGen ANDA Product contains the same components recited in claim 1 and use of the ScieGen ANDA product in accordance with its associated labeling would infringe at least claim 11.

67. On information and belief, the ScieGen 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 ‘225 patent either literally or under the doctrine of equivalents.

68. On information and belief, the use of the ScieGen ANDA Product constitutes a material part of at least one of the claims of the ‘225 patent; Defendants know that the ScieGen ANDA Product is especially made or adapted for use in infringing at least one of the claims of the ‘225 patent, either literally or under the doctrine of equivalents; and the ScieGen ANDA Product is not a staple article of commerce or commodity of commerce suitable for substantial noninfringing use.

69. On information and belief, the offering to sell, sale, and/or importation of the ScieGen ANDA Product would contributorily infringe at least one of the claims of the ‘225 patent, either literally or under the doctrine of equivalents.

70. On information and belief, ScieGen had knowledge of the '225 patent and, by its promotional activities and package inserts for the ScieGen ANDA Product, knows or should know that it will aid and abet others' direct infringement of at least one of the claims of the '225 patent, either literally or under the doctrine of equivalents, and specifically intends that those activities will infringe the '225 patent.

71. On information and belief, the offering to sell, sale, and/or importation of the ScieGen ANDA Product by Defendant would actively induce infringement of at least one of the claims of the '225 patent, either literally or under the doctrine of equivalents.

72. If Defendants' marketing and sale of the ScieGen ANDA Product prior to expiration of the '225 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 '994 PATENT

73. Plaintiffs reallege paragraphs 1 to 72 as if fully set forth herein.

74. Defendants' submission of the ScieGen ANDA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the ScieGen ANDA Product in the United States prior to the expiration of the '994 patent infringed at least one of the claims of the '994 patent, including but not limited to claims 1 and 13, either literally or under the doctrine of equivalents under 35 U.S.C. § 271(e)(2)(A).

75. Defendants' manufacture, use, offer to sell, or sale of the ScieGen ANDA Product in the United States or importation of the ScieGen ANDA Product into the United States during the term of the '994 patent would further infringe at least one claim of the '994 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c), either literally or under the doctrine of equivalents because,

inter alia, the ScieGen ANDA Product contains the same components recited in claim 1 and use of the ScieGen ANDA product in accordance with its associated labeling would infringe at least claim 13.

76. On information and belief, the ScieGen 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 '994 patent either literally or under the doctrine of equivalents.

77. On information and belief, the use of the ScieGen ANDA Product constitutes a material part of at least one of the claims of the '994 patent; Defendants know that the ScieGen ANDA Product is especially made or adapted for use in infringing at least one of the claims of the '994 patent, either literally or under the doctrine of equivalents; and the ScieGen ANDA Product is not a staple article of commerce or commodity of commerce suitable for substantial noninfringing use.

78. On information and belief, the offering to sell, sale, and/or importation of the ScieGen ANDA Product would contributorily infringe at least one of the claims of the '994 patent, either literally or under the doctrine of equivalents.

79. On information and belief, ScieGen had knowledge of the '994 patent and, by its promotional activities and package inserts for the ScieGen ANDA Product, knows or should know that it will aid and abet others' direct infringement of at least one of the claims of the '994 patent, either literally or under the doctrine of equivalents, and specifically intends that those activities will infringe the '994 patent.

80. On information and belief, the offering to sell, sale, and/or importation of the ScieGen ANDA Product by Defendant would actively induce infringement of at least one of the claims of the '994 patent, either literally or under the doctrine of equivalents.

81. If Defendants' marketing and sale of the ScieGen ANDA Product prior to expiration of the '994 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 '679 PATENT

82. Plaintiffs reallege paragraphs 1 to 81 as if fully set forth herein.

83. Defendants' submission of the ScieGen ANDA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the ScieGen ANDA Product in the United States prior to the expiration of the '679 patent infringed at least one of the claims of the '679 patent, including but not limited to claims 1, 13 and 26, either literally or under the doctrine of equivalents under 35 U.S.C. § 271(e)(2)(A).

84. Defendants' manufacture, use, offer to sell, or sale of the ScieGen ANDA Product in the United States or importation of the ScieGen ANDA Product into the United States during the term of the '679 patent would further infringe at least one claim of the '679 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c) because, *inter alia*, the ScieGen ANDA Product contains the same components and has the properties recited in claims 1 and 26 and use of the ScieGen ANDA product in accordance with its associated labeling would infringe at least claim 13.

85. On information and belief, the ScieGen 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 '679 patent either literally or under the doctrine of equivalents.

86. On information and belief, the use of the ScieGen ANDA Product constitutes a material part of at least one of the claims of the '679 patent; Defendants know that the ScieGen ANDA Product is especially made or adapted for use in infringing at least one of the claims of the '679 patent, either literally or under the doctrine of equivalents; and the ScieGen ANDA Product is not a staple article of commerce or commodity of commerce suitable for substantial noninfringing use.

87. On information and belief, the offering to sell, sale, and/or importation of the ScieGen ANDA Product would contributorily infringe at least one of the claims of the '679 patent, either literally or under the doctrine of equivalents.

88. On information and belief, ScieGen had knowledge of the '679 patent and, by its promotional activities and package inserts for the ScieGen ANDA Product, knows or should know that it will aid and abet others' direct infringement of at least one of the claims of the '679 patent, either literally or under the doctrine of equivalents, and specifically intends that those activities will infringe the '679 patent.

89. On information and belief, the offering to sell, sale, and/or importation of the ScieGen ANDA Product by Defendant would actively induce infringement of at least one of the claims of the '679 patent, either literally or under the doctrine of equivalents.

90. If Defendants' marketing and sale of the ScieGen ANDA Product prior to expiration of the '679 patent and all other relevant exclusivities are not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

* * *

91. 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 ScieGen 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 ScieGen 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 ScieGen 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 ScieGen 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 ScieGen 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.

MORRIS NICHOLS ARSHT & TUNNELL LLP

/s/ Jack B. Blumenfeld

Jack B. Blumenfeld (#1014)
Karen Jacobs (#2881)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@mnat.com
kjacobs@mnat.com

Attorneys for Plaintiffs Genentech, Inc. and InterMune, Inc.

OF COUNSEL:

Mark E. Waddell
Warren K. MacRae
Ryan Hagglund
LOEB & LOEB LLP
345 Park Avenue
New York, NY 10154
(212) 407-4000

January 23, 2019