

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GENENTECH, INC. and)
INTERMUNE, INC.,)
)
Plaintiffs,)
)
v.) C.A. No. _____
)
MACLEODS PHARMACEUTICALS LTD.)
and MACLEODS PHARMA 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, Macleods Pharmaceuticals Ltd. and Macleods Pharma USA, Inc. (collectively, “Macleods” 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. 212748, 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 Macleods Pharmaceuticals Ltd. (“Macleods Ltd.”) is a corporation organized and existing under the laws of India, having a principal place of business at Atlanta Arcade, Marol Church Road, Andheri (east), Mumbai, India 400059.

6. On information and belief, Macleods Ltd. controls and directs a wholly owned subsidiary in the United States named Macleods Pharma USA, Inc. (“Macleods USA”).

Macleods USA is a Delaware corporation having a principal place of business at 666 Plainsboro Road, Building 200, Suite 230, Plainsboro, New Jersey 08536.

7. On information and belief, Macleods Ltd. 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 Macleods USA, from which Macleods Ltd. derives a substantial portion of its revenue.

8. On information and belief, Macleods Ltd. acted in concert with Macleods USA to prepare and submit ANDA No. 212748 (the “Macleods ANDA”) for Macleods Ltd.’s 267 mg pirfenidone capsules (the “Macleods ANDA Product”), which was done at the direction of, under the control of, and for the direct benefit of Macleods Ltd. Following FDA approval of the Macleods ANDA, Macleods Ltd. will manufacture and supply the approved generic product to Macleods USA, which will then market and sell the product throughout the United States at the direction, under the control, and for the direct benefit of Macleods Ltd.

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 because, among other things, Macleods USA is incorporated in the State of Delaware and therefore “resides” in this judicial district. 28 U.S.C. § 1400(b). Macleods Ltd. 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 MACLEODS LTD.

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

12. On information and belief, Macleods Ltd. 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 Macleods Ltd. because, *inter alia*, Macleods Ltd., 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 Macleods ANDA Products to residents of this State upon approval of ANDA No. 212748, 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 Macleods USA, which is a Delaware corporation; and (4) owns Macleods USA, which is a Delaware corporation.

14. Alternatively, to the extent the above facts do not establish personal jurisdiction over Macleods Ltd., this Court may exercise jurisdiction over Macleods Ltd. pursuant to Fed. R. Civ. P. 4(k)(2) because: (a) Plaintiffs’ claims arise under federal law; (b) Macleods Ltd. would be a foreign defendant not subject to personal jurisdiction in the courts of any State; and (c) Macleods Ltd. 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 Macleods Ltd. satisfies due process.

PERSONAL JURISDICTION OVER MACLEODS USA

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

16. On information and belief, Macleods USA 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 Macleods USA because, *inter alia*, Macleods USA, on information and belief: (1) is incorporated under the laws of the State of Delaware; (2) intends to market, sell, or distribute Macleods' ANDA Products to residents of this State; (3) is controlled by Defendant Macleods Ltd.; (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

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

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

THE ASSERTED PATENTS

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

25. 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.

26. 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

27. 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.

28. 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

29. 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.

30. 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

31. 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.

32. 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

33. 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.

34. 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

35. 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.

36. 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

37. 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.

38. 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

39. 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.

40. 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

41. 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.

42. 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

43. 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.

44. 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

45. 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.

46. 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

47. 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.

48. 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

49. 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.

50. 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

51. 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.

52. 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

53. 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.

54. 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.

- U.S. Patent No. 7,696,236

55. U.S. Patent No. 7,696,236 (“the ‘236 patent”), entitled “Method of Providing Pirfenidone Therapy to a Patient,” was duly and legally issued by the Patent Office on April 13, 2010, and has not expired.

56. Plaintiffs have maintained the entire right, title, and interest in the ‘236 patent throughout the period of Defendants’ infringement and have the exclusive right to sue for infringement. A copy of the ‘236 patent is attached as Exhibit 16.

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

57. 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.

58. 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 17.

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

59. 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.

60. 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 18.

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

61. 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.

62. 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 19.

63. The ‘729, ‘707, ‘700, ‘383, ‘610, ‘002, ‘475, ‘780, ‘150, ‘674, ‘462, ‘701, ‘098, ‘109, ‘947, ‘236, ‘225, ‘994 and ‘679 patents are referred to collectively herein as the “Asserted Patents.”

ACTS GIVING RISE TO THIS ACTION

64. 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[®].

65. 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.

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

67. By letter dated December 18, 2018 (the "Notice Letter"), Macleods notified Plaintiffs that it had submitted the Macleods ANDA to the FDA, seeking approval for commercial manufacture, use, and sale of the Macleods ANDA Product in the United States prior to the expiration of the Asserted Patents.

68. In the Notice Letter, Macleods 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 Macleods ANDA Product in the United States.

69. By filing the Macleods ANDA, Macleods has necessarily represented to the FDA that the Macleods 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.

70. Macleods' 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 Macleods ANDA would be provided to Plaintiffs. The parties were unable to reach an agreement on the OCA terms because Macleods' 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 Macleods OCA contained a

broad regulatory work bar (including but not limited to an FDA bar), which, among other things, does not have a carve-out for adversarial proceedings. The proposed Macleods OCA unreasonably restricted the ability of counsel to seek the opinions of Plaintiffs' in-house attorneys. The restrictions Macleods placed on access to the Macleods 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 Macleods' ANDA. Plaintiffs require discovery from Macleods in this action.

71. 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

72. Plaintiffs reallege paragraphs 1 to 71 as if fully set forth herein.

73. Macleods' Notice Letter regarding its Paragraph IV Certification does not provide a full and detailed explanation of why the Macleods ANDA Product will not infringe each claim of the '729 patent.

74. On information and belief, Macleods does not deny that the Macleods ANDA Product will infringe at least certain claims of the '729 patent.

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

76. Defendants' manufacture, use, offer to sell, or sale of the Macleods ANDA Product in the United States or importation of the Macleods 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).

77. On information and belief, the Macleods 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.

78. On information and belief, the use of the Macleods ANDA Product constitutes a material part of at least one of the claims of the '729 patent; Defendants know that the Macleods 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 Macleods ANDA Product is not a staple article of commerce or commodity of commerce suitable for substantial noninfringing use.

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

80. On information and belief, Macleods had knowledge of the '729 patent and, by its promotional activities and package inserts for the Macleods 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.

81. On information and belief, the offering to sell, sale, and/or importation of the Macleods 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.

82. If Defendants' marketing and sale of the Macleods 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

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

84. Macleods' Notice Letter regarding its Paragraph IV Certification does not provide a full and detailed explanation of why the Macleods ANDA Product will not infringe each claim of the '707 patent.

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

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

87. Defendants' manufacture, use, offer to sell, or sale of the Macleods ANDA Product in the United States or importation of the Macleods 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).

88. On information and belief, the Macleods 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.

89. On information and belief, the use of the Macleods ANDA Product constitutes a material part of at least one of the claims of the '707 patent; Defendants know that the Macleods 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 Macleods ANDA Product is not a staple article of commerce or commodity of commerce suitable for substantial noninfringing use.

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

91. On information and belief, Macleods had knowledge of the '707 patent and, by its promotional activities and package inserts for the Macleods 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.

92. On information and belief, the offering to sell, sale, and/or importation of the Macleods 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.

93. If Defendants' marketing and sale of the Macleods 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

94. Plaintiffs reallege paragraphs 1 to 93 as if fully set forth herein.

95. Macleods' Notice Letter regarding its Paragraph IV Certification does not provide a full and detailed explanation of why the Macleods ANDA Product will not infringe each claim of the '700 patent.

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

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

98. Defendants' manufacture, use, offer to sell, or sale of the Macleods ANDA Product in the United States or importation of the Macleods 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).

99. On information and belief, the Macleods 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.

100. On information and belief, the use of the Macleods ANDA Product constitutes a material part of at least one of the claims of the '700 patent; Defendants know that the Macleods 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 Macleods ANDA Product is not a staple article of commerce or commodity of commerce suitable for substantial noninfringing use.

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

102. On information and belief, Macleods had knowledge of the '700 patent and, by its promotional activities and package inserts for the Macleods 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.

103. On information and belief, the offering to sell, sale, and/or importation of the Macleods 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.

104. If Defendants' marketing and sale of the Macleods 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

105. Plaintiffs reallege paragraphs 1 to 104 as if fully set forth herein.

106. Macleods' Notice Letter regarding its Paragraph IV Certification does not provide a full and detailed explanation of why the Macleods ANDA Product will not infringe each claim of the '383 patent.

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

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

109. Defendants' manufacture, use, offer to sell, or sale of the Macleods ANDA Product in the United States or importation of the Macleods 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).

110. On information and belief, the Macleods 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.

111. On information and belief, the use of the Macleods ANDA Product constitutes a material part of at least one of the claims of the '383 patent; Defendants know that the Macleods 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 Macleods ANDA Product is not a staple article of commerce or commodity of commerce suitable for substantial noninfringing use.

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

113. On information and belief, Macleods had knowledge of the '383 patent and, by its promotional activities and package inserts for the Macleods 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.

114. On information and belief, the offering to sell, sale, and/or importation of the Macleods 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.

115. If Defendants' marketing and sale of the Macleods 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

116. Plaintiffs reallege paragraphs 1 to 115 as if fully set forth herein.

117. Macleods' Notice Letter regarding its Paragraph IV Certification does not provide a full and detailed explanation of why the Macleods ANDA Product will not infringe each claim of the '610 patent.

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

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

120. Defendants' manufacture, use, offer to sell, or sale of the Macleods ANDA Product in the United States or importation of the Macleods 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).

121. On information and belief, the Macleods 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.

122. On information and belief, the use of the Macleods ANDA Product constitutes a material part of at least one of the claims of the '610 patent; Defendants know that the Macleods 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 Macleods ANDA Product is not a staple article of commerce or commodity of commerce suitable for substantial noninfringing use.

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

124. On information and belief, Macleods had knowledge of the ‘610 patent and, by its promotional activities and package inserts for the Macleods 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.

125. On information and belief, the offering to sell, sale, and/or importation of the Macleods 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.

126. If Defendants’ marketing and sale of the Macleods 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

127. Plaintiffs reallege paragraphs 1 to 126 as if fully set forth herein.

128. Macleods’ Notice Letter regarding its Paragraph IV Certification does not provide a full and detailed explanation of why the Macleods ANDA Product will not infringe each claim of the ‘002 patent.

129. On information and belief, Macleods does not deny that the Macleods ANDA Product will infringe at least certain claims of the ‘002 patent.

130. Defendants’ submission of the Macleods ANDA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Macleods 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).

131. Defendants' manufacture, use, offer to sell, or sale of the Macleods ANDA Product in the United States or importation of the Macleods 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).

132. On information and belief, the Macleods 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.

133. On information and belief, the use of the Macleods ANDA Product constitutes a material part of at least one of the claims of the '002 patent; Defendants know that the Macleods 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 Macleods ANDA Product is not a staple article of commerce or commodity of commerce suitable for substantial noninfringing use.

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

135. On information and belief, Macleods had knowledge of the '002 patent and, by its promotional activities and package inserts for the Macleods 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.

136. On information and belief, the offering to sell, sale, and/or importation of the Macleods 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.

137. If Defendants' marketing and sale of the Macleods 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

138. Plaintiffs reallege paragraphs 1 to 137 as if fully set forth herein.

139. Macleods' Notice Letter regarding its Paragraph IV Certification does not provide a full and detailed explanation of why the Macleods ANDA Product will not infringe each claim of the '475 patent.

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

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

142. Defendants' manufacture, use, offer to sell, or sale of the Macleods ANDA Product in the United States or importation of the Macleods 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).

143. On information and belief, the Macleods 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.

144. On information and belief, the use of the Macleods ANDA Product constitutes a material part of at least one of the claims of the '475 patent; Defendants know that the Macleods 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 Macleods ANDA Product is not a staple article of commerce or commodity of commerce suitable for substantial noninfringing use.

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

146. On information and belief, Macleods had knowledge of the '475 patent and, by its promotional activities and package inserts for the Macleods 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.

147. On information and belief, the offering to sell, sale, and/or importation of the Macleods 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.

148. If Defendants' marketing and sale of the Macleods 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

149. Plaintiffs reallege paragraphs 1 to 148 as if fully set forth herein.

150. Macleods' Notice Letter regarding its Paragraph IV Certification does not provide a full and detailed explanation of why the Macleods ANDA Product will not infringe each claim of the '780 patent.

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

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

153. Defendants' manufacture, use, offer to sell, or sale of the Macleods ANDA Product in the United States or importation of the Macleods 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).

154. On information and belief, the Macleods 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.

155. On information and belief, the use of the Macleods ANDA Product constitutes a material part of at least one of the claims of the '780 patent; Defendants know that the Macleods 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 Macleods ANDA Product is not a staple article of commerce or commodity of commerce suitable for substantial noninfringing use.

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

157. On information and belief, Macleods had knowledge of the '780 patent and, by its promotional activities and package inserts for the Macleods 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.

158. On information and belief, the offering to sell, sale, and/or importation of the Macleods 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.

159. If Defendants' marketing and sale of the Macleods 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

160. Plaintiffs reallege paragraphs 1 to 159 as if fully set forth herein.

161. Macleods' Notice Letter regarding its Paragraph IV Certification does not provide a full and detailed explanation of why the Macleods ANDA Product will not infringe each claim of the '150 patent.

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

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

164. Defendants' manufacture, use, offer to sell, or sale of the Macleods ANDA Product in the United States or importation of the Macleods ANDA Product into the United States during the term of the '150 patent would further infringe at least one claim of the '150 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

165. On information and belief, the Macleods 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.

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

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

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

169. On information and belief, the offering to sell, sale, and/or importation of the Macleods 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.

170. If Defendants' marketing and sale of the Macleods 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

171. Plaintiffs reallege paragraphs 1 to 170 as if fully set forth herein.

172. Macleods' Notice Letter regarding its Paragraph IV Certification does not provide a full and detailed explanation of why the Macleods ANDA Product will not infringe each claim of the '674 patent.

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

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

175. Defendants' manufacture, use, offer to sell, or sale of the Macleods ANDA Product in the United States or importation of the Macleods 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).

176. On information and belief, the Macleods 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.

177. On information and belief, the use of the Macleods ANDA Product constitutes a material part of at least one of the claims of the '674 patent; Defendants know that the Macleods 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 Macleods ANDA Product is not a staple article of commerce or commodity of commerce suitable for substantial noninfringing use.

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

179. On information and belief, Macleods had knowledge of the ‘674 patent and, by its promotional activities and package inserts for the Macleods 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.

180. On information and belief, the offering to sell, sale, and/or importation of the Macleods 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.

181. If Defendants’ marketing and sale of the Macleods 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

182. Plaintiffs reallege paragraphs 1 to 181 as if fully set forth herein.

183. Macleods’ Notice Letter regarding its Paragraph IV Certification does not provide a full and detailed explanation of why the Macleods ANDA Product will not infringe each claim of the ‘462 patent.

184. On information and belief, Macleods does not deny that the Macleods ANDA Product will infringe at least certain claims of the ‘462 patent.

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

186. Defendants' manufacture, use, offer to sell, or sale of the Macleods ANDA Product in the United States or importation of the Macleods 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).

187. On information and belief, the Macleods 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.

188. On information and belief, the use of the Macleods ANDA Product constitutes a material part of at least one of the claims of the '462 patent; Defendants know that the Macleods 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 Macleods ANDA Product is not a staple article of commerce or commodity of commerce suitable for substantial noninfringing use.

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

190. On information and belief, Macleods had knowledge of the '462 patent and, by its promotional activities and package inserts for the Macleods 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.

191. On information and belief, the offering to sell, sale, and/or importation of the Macleods 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.

192. If Defendants' marketing and sale of the Macleods 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

193. Plaintiffs reallege paragraphs 1 to 192 as if fully set forth herein.

194. Macleods' Notice Letter regarding its Paragraph IV Certification does not provide a full and detailed explanation of why the Macleods ANDA Product will not infringe each claim of the '701 patent.

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

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

197. Defendants' manufacture, use, offer to sell, or sale of the Macleods ANDA Product in the United States or importation of the Macleods 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).

198. On information and belief, the Macleods 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.

199. On information and belief, the use of the Macleods ANDA Product constitutes a material part of at least one of the claims of the '701 patent; Defendants know that the Macleods 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 Macleods ANDA Product is not a staple article of commerce or commodity of commerce suitable for substantial noninfringing use.

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

201. On information and belief, Macleods had knowledge of the '701 patent and, by its promotional activities and package inserts for the Macleods 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.

202. On information and belief, the offering to sell, sale, and/or importation of the Macleods 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.

203. If Defendants' marketing and sale of the Macleods 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

204. Plaintiffs reallege paragraphs 1 to 203 as if fully set forth herein.

205. Macleods' Notice Letter regarding its Paragraph IV Certification does not provide a full and detailed explanation of why the Macleods ANDA Product will not infringe each claim of the '098 patent.

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

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

208. Defendants' manufacture, use, offer to sell, or sale of the Macleods ANDA Product in the United States or importation of the Macleods 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).

209. On information and belief, the Macleods 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.

210. On information and belief, the use of the Macleods ANDA Product constitutes a material part of at least one of the claims of the '098 patent; Defendants know that the Macleods 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 Macleods ANDA Product is not a staple article of commerce or commodity of commerce suitable for substantial noninfringing use.

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

212. On information and belief, Macleods had knowledge of the '098 patent and, by its promotional activities and package inserts for the Macleods 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.

213. On information and belief, the offering to sell, sale, and/or importation of the Macleods 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.

214. If Defendants' marketing and sale of the Macleods 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

215. Plaintiffs reallege paragraphs 1 to 214 as if fully set forth herein.

216. Macleods' Notice Letter regarding its Paragraph IV Certification does not provide a full and detailed explanation of why the Macleods ANDA Product will not infringe each claim of the '109 patent.

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

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

219. Defendants' manufacture, use, offer to sell, or sale of the Macleods ANDA Product in the United States or importation of the Macleods 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).

220. On information and belief, the Macleods 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.

221. On information and belief, the use of the Macleods ANDA Product constitutes a material part of at least one of the claims of the '109 patent; Defendants know that the Macleods 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 Macleods ANDA Product is not a staple article of commerce or commodity of commerce suitable for substantial noninfringing use.

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

223. On information and belief, Macleods had knowledge of the '109 patent and, by its promotional activities and package inserts for the Macleods 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.

224. On information and belief, the offering to sell, sale, and/or importation of the Macleods 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.

225. If Defendants' marketing and sale of the Macleods 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

226. Plaintiffs reallege paragraphs 1 to 225 as if fully set forth herein.

227. Macleods' Notice Letter regarding its Paragraph IV Certification does not provide a full and detailed explanation of why the Macleods ANDA Product will not infringe each claim of the '947 patent.

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

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

230. Defendants' manufacture, use, offer to sell, or sale of the Macleods ANDA Product in the United States or importation of the Macleods 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).

231. On information and belief, the Macleods 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.

232. On information and belief, the use of the Macleods ANDA Product constitutes a material part of at least one of the claims of the '947 patent; Defendants know that the Macleods 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 Macleods ANDA Product is not a staple article of commerce or commodity of commerce suitable for substantial noninfringing use.

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

234. On information and belief, Macleods had knowledge of the '947 patent and, by its promotional activities and package inserts for the Macleods 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.

235. On information and belief, the offering to sell, sale, and/or importation of the Macleods 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.

236. If Defendants' marketing and sale of the Macleods 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.

COUNT XVI

INFRINGEMENT OF THE '236 PATENT

237. Plaintiffs reallege paragraphs 1 to 236 as if fully set forth herein.

238. Macleods' Notice Letter regarding its Paragraph IV Certification does not provide a full and detailed explanation of why the Macleods ANDA Product will not infringe each claim of the '236 patent.

239. On information and belief, Macleods does not deny that the Macleods ANDA Product will infringe at least certain claims of the '236 patent.

240. Defendants' submission of the Macleods ANDA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Macleods ANDA Product in the United States prior to the expiration of the '236 patent infringed at least one of the claims of the '236 patent, either literally or under the doctrine of equivalents under 35 U.S.C. § 271(e)(2)(A).

241. Defendants' manufacture, use, offer to sell, or sale of the Macleods ANDA Product in the United States or importation of the Macleods ANDA Product into the United States during the term of the '236 patent would further infringe at least one claim of the '236 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

242. On information and belief, the Macleods 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 '236 patent either literally or under the doctrine of equivalents.

243. On information and belief, the use of the Macleods ANDA Product constitutes a material part of at least one of the claims of the '236 patent; Defendants know that the Macleods ANDA Product is especially made or adapted for use in infringing at least one of the claims of the '236 patent, either literally or under the doctrine of equivalents; and the Macleods ANDA Product is not a staple article of commerce or commodity of commerce suitable for substantial noninfringing use.

244. On information and belief, the offering to sell, sale, and/or importation of the Macleods ANDA Product would contributorily infringe at least one of the claims of the '236 patent, either literally or under the doctrine of equivalents.

245. On information and belief, Macleods had knowledge of the '236 patent and, by its promotional activities and package inserts for the Macleods ANDA Product, knows or should know that it will aid and abet others' direct infringement of at least one of the claims of the '236 patent, either literally or under the doctrine of equivalents, and specifically intends that those activities will infringe the '236 patent.

246. On information and belief, the offering to sell, sale, and/or importation of the Macleods ANDA Product by Defendant would actively induce infringement of at least one of the claims of the '236 patent, either literally or under the doctrine of equivalents.

247. If Defendants' marketing and sale of the Macleods ANDA Product prior to expiration of the '236 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 XVII

INFRINGEMENT OF THE '225 PATENT

248. Plaintiffs reallege paragraphs 1 to 247 as if fully set forth herein.

249. Macleods' Notice Letter regarding its Paragraph IV Certification does not provide a full and detailed explanation of why the Macleods ANDA Product will not infringe each claim of the '225 patent.

250. On information and belief, Macleods does not deny that the Macleods ANDA Product will infringe at least certain claims of the '225 patent.

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

252. Defendants' manufacture, use, offer to sell, or sale of the Macleods ANDA Product in the United States or importation of the Macleods 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).

253. On information and belief, the Macleods 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.

254. On information and belief, the use of the Macleods ANDA Product constitutes a material part of at least one of the claims of the '225 patent; Defendants know that the Macleods 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 Macleods ANDA Product is not a staple article of commerce or commodity of commerce suitable for substantial noninfringing use.

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

256. On information and belief, Macleods had knowledge of the '225 patent and, by its promotional activities and package inserts for the Macleods 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.

257. On information and belief, the offering to sell, sale, and/or importation of the Macleods 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.

258. If Defendants' marketing and sale of the Macleods 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 XVIII

INFRINGEMENT OF THE '994 PATENT

259. Plaintiffs reallege paragraphs 1 to 258 as if fully set forth herein.

260. Macleods' Notice Letter regarding its Paragraph IV Certification does not provide a full and detailed explanation of why the Macleods ANDA Product will not infringe each claim of the '994 patent.

261. On information and belief, Macleods does not deny that the Macleods ANDA Product will infringe at least certain claims of the '994 patent.

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

263. Defendants' manufacture, use, offer to sell, or sale of the Macleods ANDA Product in the United States or importation of the Macleods 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).

264. On information and belief, the Macleods 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.

265. On information and belief, the use of the Macleods ANDA Product constitutes a material part of at least one of the claims of the '994 patent; Defendants know that the Macleods 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 Macleods ANDA Product is not a staple article of commerce or commodity of commerce suitable for substantial noninfringing use.

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

267. On information and belief, Macleods had knowledge of the '994 patent and, by its promotional activities and package inserts for the Macleods 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.

268. On information and belief, the offering to sell, sale, and/or importation of the Macleods 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.

269. If Defendants' marketing and sale of the Macleods 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 XIX

INFRINGEMENT OF THE '679 PATENT

270. Plaintiffs reallege paragraphs 1 to 269 as if fully set forth herein.

271. Macleods' Notice Letter regarding its Paragraph IV Certification does not provide a full and detailed explanation of why the Macleods ANDA Product will not infringe each claim of the '679 patent.

272. On information and belief, Macleods does not deny that the Macleods ANDA Product will infringe at least certain claims of the '679 patent.

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

274. Defendants' manufacture, use, offer to sell, or sale of the Macleods ANDA Product in the United States or importation of the Macleods 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).

275. On information and belief, the Macleods 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.

276. On information and belief, the use of the Macleods ANDA Product constitutes a material part of at least one of the claims of the '679 patent; Defendants know that the Macleods 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 Macleods ANDA Product is not a staple article of commerce or commodity of commerce suitable for substantial noninfringing use.

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

278. On information and belief, Macleods had knowledge of the '679 patent and, by its promotional activities and package inserts for the Macleods 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.

279. On information and belief, the offering to sell, sale, and/or importation of the Macleods 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.

280. If Defendants' marketing and sale of the Macleods 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.

* * *

281. 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 Macleods 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 Macleods 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 Macleods 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 Macleods 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 Macleods 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

OF COUNSEL:

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

January 28, 2019

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.*