IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ABBVIE INC. and ABBVIE DEUTSCHLAND GMBH & CO. KG,	)	
Plaintiffs,	)	C.A. No. _____
v.	)	
MACLEODS PHARMACEUTICALS, LTD. and MACLEODS PHARMA USA, INC.,	)	
Defendants.	)	

COMPLAINT

Plaintiffs AbbVie Inc. ("AbbVie Inc.") and AbbVie Deutschland GmbH & Co. KG ("AbbVie Deutschland") (collectively "AbbVie") by way of complaint against Macleods Pharmaceuticals Ltd. and Macleods Pharma USA, Inc. (collectively, "Macleods" or "Defendants") states as follows:

THE PARTIES

1. AbbVie Inc. is a company organized and existing under the laws of Delaware with its principal place of business at 1 North Waukegan Road, North Chicago, Illinois 60064. AbbVie is a global biopharmaceutical research based biopharmaceutical company engaged in the business of research, development, manufacture, and sale of pharmaceutical products throughout the world.

2. AbbVie Deutschland GmbH & Co. KG is a limited partnership organized and existing under the laws of Germany with its registered address at Mainzer Straße 81, 65189 Wiesbaden, Germany. AbbVie Deutschland GmbH & Co. KG is governed by its General Partner, AbbVie Komplementär GmbH, and is a wholly-owned foreign subsidiary of AbbVie Inc.

3. On information and belief, Defendant Macleods Pharmaceuticals Ltd. ("Macleods

Pharmaceuticals") is a corporation organized and existing under the laws of India having a registered office at Atlanta Arcade, Marol Church Road, Andheri (East), Mumbai, 400 059, India.

4. On information and belief, Defendant Macleods Pharma USA, Inc. ("Macleods USA") is a Delaware corporation having a principal place of business at 666 Plainsboro Rd, Bldg. 200, Suite 230, Plainsboro, New Jersey 08536.

5. On information and belief, Macleods USA is registered to transact business in Delaware and has appointed a registered agent for service of process (Incorp Services, Inc., 919 North Market Street, Suite 950, Wilmington, Delaware 19801).

6. On information and belief, Macleods USA is a subsidiary of Macleods Pharmaceuticals.

NATURE OF THE ACTION

7. This is a civil action for patent infringement of: (1) United States Patent Number 7,148,359 B2 as amended by the Inter Partes Reexamination Certificate (1272nd), issued May 23, 2016, also known as United States Patent No. 7,148,359 C1 (together "the '359 Patent"); (2) United States Patent Number 7,364,752 B1 as amended by the Inter Partes Reexamination Certificate (1039th) issued January 23, 2015, also known as United States Patent No. 7,364,752 C1 (together "the '752 Patent"); (3) United States Patent Number 8,025,899 B2 ("the '899 Patent"); (4) United States Patent Number 8,268,349 B2 ("the '349 Patent"); (5) United States Patent Number 8,309,613 B2 ("the '613 Patent"); (6) United States Patent Number 8,377,952 B2 ("the '952 Patent"); (7) United States Patent Number 8,399,015 B2 ("the '015 Patent"); (8) United States Patent Number 8,470,347 B2 ("the '347 Patent"); and (9) United States Patent Number 8,691,878 B2 ("the '878 Patent") (collectively "the Patents-in-Suit"). This civil action arises under the United States Patent Laws, Title 35, United States Code, §§ 1 et seq., in particular under 35 U.S.C. § 271, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and

2202. This civil action relates to Abbreviated New Drug Application ("ANDA") No. 204739, which Macleods filed or caused to be filed under 21 U.S.C. § 355(j) with the United States Food and Drug Administration ("FDA") for approval to market generic copies of AbbVie's successful Kaletra® tablet products that are sold in the United States.

JURISDICTION AND VENUE

8. This is a civil action for patent infringement and declaratory judgment arising under the patent laws of the United States, 35 U.S.C. § 100 et seq., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

9. On information and belief, this Court has personal jurisdiction over Macleods because of, among other things, its marketing and sales activities in this judicial district, including but not limited to the substantial, continuous, and systematic distribution, marketing, and/or sales of pharmaceutical products in this judicial district; its plan to distribute and sell its infringing ANDA products in this judicial district coupled with its affirmative act of filing its ANDA for the purpose of engaging in that injury-causing and allegedly wrongful marketing conduct in this judicial district; and the fact that it has availed itself of the rights afforded in this judicial district.

10. On information and belief, Macleods develops, formulates, manufactures, imports, markets, and sells various generic pharmaceutical drug products, and regularly conducts business, throughout the United States, including in the State of Delaware, through various directly or indirectly-owned subsidiaries, including for example Macleods USA.

11. On information and belief, Macleods USA imports, markets, and sells various generic pharmaceutical drug products, and regularly conducts business, through the United States, including in the State of Delaware, for example on behalf of and at the direction of Macleods Pharmaceuticals.

12. On information and belief, Macleods has purposefully conducted and continues to conduct substantial business in this judicial district, from which it has derived, directly or indirectly, substantial revenue.

13. Upon information and belief, Macleods Pharmaceuticals has filed an ANDA, and/or been actively involved in the preparation and submission of an ANDA, for the purpose of seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the generic drug product described in ANDA No. 204739 in the United States, including Delaware.

14. Upon information and belief, Macleods USA has been actively involved in the preparation and submission of an ANDA, on behalf of Macleods Pharmaceuticals for the purpose of seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the generic drug product described in ANDA No. 204739 in the United States, including Delaware.

15. On information and belief, Macleods will act in concert, and intends to offer to sell and sell in this judicial district, the generic drug product that will be manufactured as a result of any FDA approval of Macleods' ANDA No. 204739, and based upon information and belief, this judicial district will be a destination of products that will be manufactured and sold as a result of any FDA approval of Macleods' ANDA No. 204739.

16. On information and belief, Macleods USA is qualified and registered to do business in the State of Delaware, has appointed a registered agent in Delaware, and holds current and valid "Pharmacy-Wholesale" and "Distributor/Manufacturer CSR" Licenses in Delaware.

17. On information and belief, Macleods Pharmaceuticals and/or Macleods USA have previously submitted to the jurisdiction of this Court and asserted counterclaims arising under

the Patent Laws of the United States in other civil actions initiated in this Court. *See, e.g.*, Answer at 5, 32–42, *Biogen International GmbH et al. v. Macleods Pharmaceuticals Ltd. et al.*, No. 17-cv-00857 (D. Del. July 17, 2017) (D.I. 7); Answer at 5–9, 19–23, *Bayer Pharma AG et al. v. Macleods Pharmaceuticals Ltd. et al.*, No. 15-cv-00464 (D. Del. Aug. 31, 2015) (D.I. 14).

18. Macleods is subject to specific personal jurisdiction in this District based on the filing of its ANDA with Paragraph IV certifications regarding the Patents-in-Suit with the intention of distributing and selling the products that are the subject of Macleods' ANDA No. 204739 in Delaware. *See Acorda Therapeutics Inc. v. Mylan Pharm. Inc.*, 817 F.3d 755 (Fed. Cir. 2016).

19. As in *Acorda Therapeutics*, Macleods "has taken the costly, significant step of applying to the FDA for approval to engage in future activities—including the marketing of its generic drugs—that will be purposefully directed at," on information and belief, this District and elsewhere. *Acorda Therapeutics*, 817 F.3d at 759.

20. Macleods' "ANDA filings constitute formal acts that reliably indicate plans to engage in marketing of the proposed generic drugs." *Acorda Therapeutics*, 817 F.3d at 760.

21. As in *Acorda Therapeutics*, on information and belief, Macleods "intends to direct sales of its drugs into [Delaware], among other places, once it has the requested FDA approval to market them." *Acorda Therapeutics*, 817 F.3d at 758.

22. On information and belief, Macleods will cause its proposed Generic Lopinavir/Ritonavir Tablets that are the subject of Macleods' ANDA No. 204739 to be sold in Delaware, upon approval of its ANDA.

23. Macleods' ANDA filing, including its Paragraph IV certifications regarding the Patents-in-Suit, is suit-related and has a substantial connection with this District because it reliably, non-speculatively predicts activities in this District by Macleods.

24. "[T]he minimum-contacts standard is satisfied by the particular actions [Macleods] has already taken—its ANDA filing[]—for the purpose of engaging in that injury-causing and allegedly wrongful marketing conduct in" this District. *Acorda Therapeutics*, 817 F.3d at 760.

25. This Court also has personal jurisdiction over Macleods by virtue of the fact that, among other things, Macleods has committed, or aided, abetted, contributed to, and/or participated in the commission of the tortious act of patent infringement that has led to foreseeable harm and injury to AbbVie, a Delaware corporation.

26. Exercising personal jurisdiction over Macleods in this District would not be unreasonable given Macleods' contacts in this District, the fact that AbbVie is a Delaware corporation, and the interest in this District of resolving disputes related to products to be sold herein.

27. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b).

28. Venue is proper in this judicial district because Macleods USA is incorporated in Delaware and Macleods Pharmaceuticals is incorporated in India, has its principal place of business in India, and has as its only U.S. subsidiary Macleods USA.

BACKGROUND

29. AbbVie is the holder of approved New Drug Application ("NDA") No. 21-906 for lopinavir/ritonavir tablets, 100 mg/25 mg and 200 mg/50 mg, which AbbVie markets and sells under the trademark Kaletra®. AbbVie manufactures and sells Kaletra® tablets in the United States under NDA No. 21-906.

30. Macleods filed with the FDA ANDA No. 204739 under 21 U.S.C. § 355(j)(1) and (2)(A), seeking FDA approval to market lopinavir/ritonavir tablets, 100 mg/25 mg and 200 mg/50 mg ("Macleods' Generic Lopinavir/Ritonavir Tablets"), which are generic copies of

AbbVie's Kaletra® tablets.

31. Upon information and belief, Macleods' ANDA No. 204739 seeks FDA approval of pharmaceutical compositions comprising lopinavir/ritonavir in 100 mg/25 mg and 200 mg/50 mg dosage strengths.

32. Upon information and belief, Macleods' ANDA No. 204739 seeks FDA approval to market Macleods' Generic Lopinavir/Ritonavir Tablets in the United States. On July 10, 2017, AbbVie received a letter on behalf of Macleods, dated July 7, 2017, purporting to be a "Notification of Certification of Invalidity, Unenforceability and/or Non-Infringement for U.S. Patent Nos. 7,148,359; 6,364,752[1]; 8,025,899; 8,268,349; 8,309,613; 8,377,952; 8,399,015; 8,470,347; and 8,691,878 Pursuant to Section 505(j)(2)(B)(iv) of the Federal Food, Drug and Cosmetic Act" ("Notice Letter"). Macleods' Notice Letter notified AbbVie that Macleods had filed ANDA No. 204739, seeking approval to market Macleods' Generic Lopinavir/Ritonavir Tablets. The Notice Letter also states that "Macleods has now certified to the FDA that to the best of its knowledge, the '359, '752, '899, '348, '613, '952, '015, '347, and '878 patents are invalid, unenforceable and/or will not be infringed by the commercial manufacture, use or sale of the drug product described in Macleods ANDA."

33. Macleods' Notice Letter purported to include an "Offer of Confidential Access" to to Macleods' ANDA. However, the proposed terms of Macleods' Offer of Confidential Access were unreasonable and Macleods' outside counsel refused to engage in discussions regarding the terms. Consequently, AbbVie was not provided a copy of ANDA No. 204739 prior to suit.

[1] MacLeods' Notice Letter refers in several places to U.S. Patent No. 6,364,752. U.S. Patent No. 6,364,752 is not listed in the Orange Book for any Kaletra® product. AbbVie understands all references in the Notice Letter to U.S. Patent No. 6,364,752 to be typographical errors intended to reference U.S. Patent No. 7,364,752. AbbVie does not assert infringement of U.S. Patent No. 6,364,752.

THE PATENTS-IN-SUIT

34. The ’359 Patent was originally duly and legally issued by the U.S. Patent and Trademark Office (“PTO”) on December 12, 2006. The ’359 Patent was the subject of a reexamination proceeding before the PTO. On May 23, 2016, after the conclusion of the reexamination proceeding, the PTO issued an Inter Partes Reexamination Certificate (1272nd), which amended the ’359 Patent as United States Patent No. 7,148,359 C1. AbbVie is the owner by assignment of the ’359 Patent and has the right to sue for infringement thereof. AbbVie lists the ’359 Patent in the Approved Drug Products with Therapeutic Equivalence Evaluations (“Orange Book”) for NDA No. 21-906, with an expiration date of January 19, 2020 (including pediatric exclusivity). A true and correct copy of the ’359 Patent is attached as Exhibit A.

35. The ’752 Patent was originally duly and legally issued by the PTO on April 29, 2008, as United States Patent No. 7,364,752 B1. The ’752 Patent was the subject of reexamination proceedings before the PTO. On January 23, 2015, after the conclusion of the reexamination proceedings, the PTO issued an Inter Partes Reexamination Certificate (1039th), which amended the ’752 Patent as United States Patent No. 7,364,752 C1. AbbVie Inc. is the owner by assignment of the ’752 Patent and has the right to sue for infringement thereof. AbbVie lists the ’752 Patent in the Orange Book for NDA 21-906, with an expiration date of May 10, 2021 (including pediatric exclusivity). A true and correct copy of the ’752 Patent is attached as Exhibit B.

36. The ’899 Patent was duly and legally issued by the PTO on September 27, 2011. AbbVie Inc. is the owner by assignment of the ’899 Patent and has the right to sue for infringement thereof. AbbVie lists the ’899 Patent in the Orange Book for NDA No. 21-906, with an expiration date of June 14, 2028 (including pediatric exclusivity). A true and correct copy of the ’899 Patent is attached as Exhibit C.

37. The ’349 Patent was duly and legally issued by the PTO on September 18, 2012.

AbbVie Inc. is the owner by assignment of the ’349 Patent and has the right to sue for infringement thereof. AbbVie lists the ’349 Patent in the Orange Book for NDA No. 21-906, with an expiration date of February 25, 2025 (including pediatric exclusivity). A true and correct copy of the ’349 Patent is attached as Exhibit D.

38. The ’613 Patent was duly and legally issued by the PTO on November 13, 2012. AbbVie Inc. is the owner by assignment of the ’613 Patent and has the right to sue for infringement thereof. AbbVie lists the ’613 Patent in the Orange Book for NDA No. 21-906, with an expiration date of June 24, 2025 (including pediatric exclusivity). A true and correct copy of the ’613 Patent is attached as Exhibit E.

39. The ’952 Patent was duly and legally issued by the PTO on February 19, 2013. AbbVie Inc. is the owner by assignment of the ’952 Patent and has the right to sue for infringement thereof. AbbVie lists the ’952 Patent in the Orange Book for NDA 21-906, with an expiration date of April 22, 2028 (including pediatric exclusivity). A true and correct copy of the ’952 Patent is attached as Exhibit F.

40. The ’015 Patent was duly and legally issued by the PTO on March 19, 2013. AbbVie Inc. is the owner by assignment of the ’015 Patent and has the right to sue for infringement thereof. AbbVie lists the ’015 Patent in the Orange Book for NDA No. 21-906, with an expiration date of February 25, 2025 (including pediatric exclusivity). A true and correct copy of the ’015 Patent is attached as Exhibit G.

41. The ’347 Patent was duly and legally issued by the PTO on June 25, 2013. AbbVie Deutschland GmbH & Co. KG is the owner by assignment of the ’347 Patent and has the right to sue for infringement thereof. AbbVie lists the ’347 Patent in the Orange Book for NDA No. 21-906, with an expiration date of March 17, 2027 (including pediatric exclusivity). A

true and correct copy of the ’347 Patent is attached as Exhibit H.

42. The ’878 Patent was duly and legally issued by the PTO on April 8, 2014. AbbVie Inc. is the owner by assignment of the ’878 Patent and has the right to sue for infringement thereof. AbbVie lists the ’878 Patent in the Orange Book for NDA 21-906, with an expiration date of February 25, 2025 (including pediatric exclusivity). A true and correct copy of the ’878 Patent is attached as Exhibit I.

FIRST COUNT
FOR PATENT INFRINGEMENT OF THE ’359 PATENT

43. Paragraphs 1–42 are incorporated herein by reference.

44. On information and belief, Defendants acted in concert to file and have maintained ANDA No. 204739 in order to obtain approval to manufacture, use, offer to sell, and sell Macleods’ Generic Lopinavir/Ritonavir Tablets in the United States before the expiration of the ’359 Patent.

45. On information and belief, Defendants acted in concert to file with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the ’359 Patent are purportedly invalid and/or not infringed.

46. On information and belief, Macleods has represented to the FDA in Macleods’ ANDA No. 204739 that Macleods’ Generic Lopinavir/Ritonavir Tablets are bioequivalent, therapeutically equivalent, and pharmaceutically equivalent to AbbVie’s Kaletra® tablets.

47. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 204739 seeking approval for the commercial manufacture, use, or sale of Macleods’ Generic Lopinavir/Ritonavir Tablets before the expiration date of the ’359 Patent constitutes infringement of one or more claims of the ’359 Patent, either literally or under the doctrine of equivalents.

48. Based on information and belief, including based on a review of Macleods' Notice Letter, Defendants will infringe, under § 271(a), either literally or under the doctrine of equivalents, at least independent claim 1 and dependent claim 8 of the '359 patent. Upon information and belief, including based on a review of Macleods' Notice Letter, which, *inter alia*, indicates that Macleods' Generic Lopinavir/Ritonavir Tablets are in the form of a solid solution or glassy solution and are bioequivalent, therapeutically equivalent, and pharmaceutically equivalent to AbbVie's Kaletra® tablets, Defendants will infringe, under § 271(a), either literally or under the doctrine of equivalents, Macleods' Generic Lopinavir/Ritonavir Tablets comprise "substantially pure amorphous ritonavir" as required by claim 1. On information and belief, including Macleods' failure to contest infringement of any remaining limitations of claim 1, Macleods' Generic Lopinavir/Ritonavir Tablets satisfy any remaining limitations of claim 1. Upon information and belief, Macleods' Generic Lopinavir/Ritonavir Tablets comprise substantially pure amorphous ritonavir that "does not contain more than about 10% of any other compound" as required by claim 1 and as further required by claim 8. On information and belief, including Macleods' failure to contest infringement of the remaining limitations of claim 8, Macleods' Generic Lopinavir/Ritonavir Tablets satisfy the remaining limitations of claim 8.

49. AbbVie will be irreparably harmed if Defendants are permitted to make, use, sell, offer to sell, and/or import their Macleods' Generic Lopinavir/Ritonavir Tablets in or into the United States, and are not enjoined from doing so. Pursuant to 35 U.S.C. §§ 271(e)(4) and/or 283, AbbVie is entitled to an order that the effective date of any approval of ANDA No. 204739 for Macleods' Generic Lopinavir/Ritonavir Tablets shall be a date which is not earlier than the date of expiration of the '359 Patent (and any additional dates of exclusivity), and an injunction against such infringement. AbbVie does not have an adequate remedy at law.

SECOND COUNT
FOR PATENT INFRINGEMENT OF THE '752 PATENT

50. Paragraphs 1–49 are incorporated herein by reference.

51. On information and belief, Defendants acted in concert to file and have maintained ANDA No. 204739 in order to obtain approval to manufacture, use, offer to sell, and sell Macleods' Generic Lopinavir/Ritonavir Tablets in the United States before the expiration of the '752 Patent.

52. On information and belief, Defendants acted in concert to file with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the '752 Patent are purportedly invalid and/or not infringed.

53. On information and belief, Macleods has represented to the FDA in Macleods' ANDA No. 204739 that Macleods' Generic Lopinavir/Ritonavir Tablets are bioequivalent, therapeutically equivalent, and pharmaceutically equivalent to AbbVie's Kaletra® tablets.

54. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 204739 seeking approval for the commercial manufacture, use, or sale of Macleods' Generic Lopinavir/Ritonavir Tablets before the expiration date of the '752 Patent constitutes infringement of one or more claims of the '752 patent, either literally or under the doctrine of equivalents.

55. Under 35 U.S.C. §§ 271(b) and (e)(2)(A), the submission to the FDA of ANDA No. 204739 seeking approval for the commercial manufacture, use, or sale of Macleods' Generic Lopinavir/Ritonavir Tablets before the expiration date of the '752 Patent constitutes induced infringement of one or more claims of the '752 Patent, either literally or under the doctrine of equivalents.

56. On information and belief, Defendants are actively seeking FDA approval to sell

Macleods' Generic Lopinavir/Ritonavir Tablets for the same indication, the same dosages, and the same method of use as the Kaletra® products sold by AbbVie.

57. On information and belief, Defendants' offering to sell, sale, making, and/or importation of Macleods' Generic Lopinavir/Ritonavir Tablets, once ANDA No. 204739 is approved by the FDA, would actively induce infringement of at least one of the claims of the '752 Patent under 35 U.S.C. § 271(b), either literally or under the doctrine of equivalents.

58. Defendants have knowledge and are aware of AbbVie's '752 Patent, as evidenced by Macleods' Notice Letter.

59. On information and belief, by the filing of ANDA No. 204739 with a proposed package insert having directions that encourage patients to administer Macleods' Generic Lopinavir/Ritonavir Tablets to treat an HIV infection, Defendants have an affirmative intent to actively induce infringement by patients of one or more claims of the '752 Patent, either literally or under the doctrine of equivalents.

60. On information and belief, by the filing of ANDA No. 204739 with a proposed package insert having directions that encourage medical practitioners to administer Macleods' Generic Lopinavir/Ritonavir Tablets to treat an HIV infection, Defendants have an affirmative intent to actively induce infringement by medical practitioners of one or more claims of the '752 Patent, either literally or under the doctrine of equivalents.

61. On information and belief, Defendants are aware and intend that patients will administer Macleods' Generic Lopinavir/Ritonavir Tablets and directly infringe at least one claim of the '752 Patent, either literally or under the doctrine of equivalents.

62. On information and belief, Defendants are aware and intend that medical practitioners will administer Macleods' Generic Lopinavir/Ritonavir Tablets and directly infringe at

least one claim of the ’752 Patent, either literally or under the doctrine of equivalents.

63. On information and belief, Defendants are aware and intend that patients will administer Macleods’ Generic Lopinavir/Ritonavir Tablets in a method of treatment according to the directions and instructions in the proposed package insert that will directly infringe at least one claim of the ’752 Patent, either literally or under the doctrine of equivalents.

64. On information and belief, Defendants are aware and intend that medical practitioners will administer Macleods’ Generic Lopinavir/Ritonavir Tablets in a method of treatment according to the directions and instructions in the proposed package insert that will directly infringe at least one claim of the ’752 Patent, either literally or under the doctrine of equivalents.

65. On information and belief, Defendants know or should know that they will aid and abet another’s direct infringement of at least one of the claims of the ’752 Patent, either literally or under the doctrine of equivalents, by Defendants’ proposed package insert for Macleods’ Generic Lopinavir/Ritonavir Tablets.

66. On information and belief, therefore, Defendants’ offering to sell, sale, making, and/or importation of Macleods’ Generic Lopinavir/Ritonavir Tablets, once approved by the FDA, would actively, intentionally, and knowingly induce infringement of one or more claims of the ’752 Patent, either literally or under the doctrine of equivalents.

67. On information and belief, Macleods’ Generic Lopinavir/Ritonavir Tablets, if approved by the FDA, will be imported by Defendants into the United States, offered for sale, and sold in the United States by them or on their behalf, and will be administered by patients in the United States, and will be administered by medical practitioners in the United States, which will constitute direct infringement of at least one claim under 35 U.S.C. § 271(a) of the ’752 Patent by Macleods, patients, and medical practitioners. On information and belief, the administration

of Macleods' Generic Lopinavir/Ritonavir Tablets will occur with Defendants' specific intent and encouragement, and will be conduct that Defendants know or should know will occur. On information and belief, Defendants will actively induce, encourage, aid, and abet that conduct by patients or medical practitioners, with knowledge and specific intent that the conduct will be in contravention of AbbVie's rights under the '752 Patent.

68. Defendants' threatened actions in actively aiding, abetting, encouraging, and inducing sales of Macleods' Generic Lopinavir/Ritonavir Tablets will infringe one or more claims of the '752 Patent under § 271(b), either literally or under the doctrine of equivalents.

69. Based on information and belief, including based on a review of Macleods' Notice Letter, Defendants will infringe, under § 271(a), either literally or under the doctrine of equivalents, at least claim 8 and will induce infringement, under § 271(b), either literally or under the doctrine of equivalents, at least dependent claim 38 of the '752 patent. On information and belief, including based on a review of Macleods' Notice Letter, which, *inter alia*, indicates that Macleods' Generic Lopinavir/Ritonavir Tablets are in the form of a solid solution or glassy solution and are bioequivalent, therapeutically equivalent, and pharmaceutically equivalent to AbbVie's Kaletra® tablets, Macleods' Generic Lopinavir/Ritonavir Tablets are a "pharmaceutical composition comprising ritonavir, wherein ritonavir is said composition is formulated as a solid dispersion of amorphous ritonavir" as required by claim 1, from which claim 8 depends. On information and belief, including Macleods' failure to contest infringement of the remaining limitations of claim 1, Macleods' Generic Lopinavir/Ritonavir Tablets satisfy the remaining limitations of claim 1. In addition, on information and belief, including Macleods' failure to contest infringement of the remaining limitations of claim 8, Macleods' Generic Lopinavir/Ritonavir Tablets meet all remaining limitations of claim 8. On information and belief,

Macleods' Generic Lopinavir/Ritonavir Tablets will be approved for the same indication as Kaletra®, and such approved use will meet the requirement that the Tablets be used in a "method of treating an HIV infection," as required by claim 38. Macleods' Generic Lopinavir/Ritonavir Tablets further comprise ABT-378 ("lopinavir"), as required by claim 6, from which claim 38 depends. On information and belief, Macleods' Generic Lopinavir/Ritonavir Tablets satisfy all remaining limitations of claim 6, from which claim 38 depends. Upon information and belief, upon FDA approval of Macleods' Generic Lopinavir/Ritonavir Tablets, medical practitioners will administer the Generic Lopinavir/Ritonavir Tablets to humans (mammals) in order to treat an HIV infection in accordance with and pursuant to the directions in Macleods' product labeling for its Generic Lopinavir/Ritonavir Tablets, and at least such medical practitioners will thus directly infringe claim 10, from which claim 38 depends. Upon information and belief, including Macleods' failure to contest infringement of the remaining limitations of claim 38, Macleods' Generic Lopinavir/Ritonavir Tablets satisfy the remaining limitations of claim 38. Upon information and belief, the use of Macleods' Generic Lopinavir/Ritonavir Tablets by at least such medical practitioners will directly infringe claim 38. As discussed in more detail above, upon information and belief, Macleods knowingly and intentionally will induce medical practitioners to induce claim 38.

70. AbbVie will be irreparably harmed if Defendants are permitted to make, use, sell, offer to sell, and/or import Macleods' Generic Lopinavir/Ritonavir Tablets in or into the United States, and is not enjoined from doing so. Pursuant to 35 U.S.C. §§ 271(e)(4) and/or 283, AbbVie is entitled to an order that the effective date of any approval of ANDA No. 204739 for Macleods' Generic Lopinavir/Ritonavir Tablets shall be a date which is not earlier than the date of expiration of the '752 Patent (and any additional dates of exclusivity), and an injunction

against such infringement. AbbVie does not have an adequate remedy at law.

THIRD COUNT
FOR PATENT INFRINGEMENT OF THE '899 PATENT

71. Paragraphs 1–70 are incorporated herein by reference.

72. On information and belief, Defendants acted in concert to file and have maintained ANDA No. 204739 in order to obtain approval to manufacture, use, offer to sell, and sell Macleods' Generic Lopinavir/Ritonavir Tablets in the United States before the expiration of the '899 Patent.

73. On information and belief, Defendants acted in concert to file with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the '899 Patent are purportedly invalid and/or not infringed.

74. On information and belief, Macleods Pharmaceuticals has represented to the FDA in Macleods' ANDA No. 204739 that Macleods' Generic Lopinavir/Ritonavir Tablets are bioequivalent, therapeutically equivalent, and pharmaceutically equivalent to AbbVie's Kaletra® tablets.

75. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 204739 seeking approval for the commercial manufacture, use, or sale of Macleods' Generic Lopinavir/Ritonavir Tablets before the expiration date of the '899 Patent constitutes infringement of one or more claims of the '899 Patent, either literally or under the doctrine of equivalents.

76. Based on information and belief, including based on a review of Macleods' Notice Letter, Defendants will infringe, under § 271(a), either literally or under the doctrine of equivalents, at least independent claim 1 and dependent claim 4 of the '899 Patent. Macleods' Generic Lopinavir/Ritonavir Tablets are a "solid pharmaceutical dosage form" that contains

lopinavir and ritonavir as required by claim 1. On information and belief, Macleods' Generic Lopinavir/Ritonavir Tablets meet all remaining limitations of claim 1. On information and belief, Macleods' Generic Lopinavir/Ritonavir Tablets also satisfy all the further limitations of claim 4.

77. In its Notice Letter, Macleods did not assert any basis for noninfringement for any claim of the '899 Patent.

78. AbbVie will be irreparably harmed if Defendants are permitted to make, use, sell, offer to sell, and/or import Macleods' Generic Lopinavir/Ritonavir Tablets in or into the United States, and are not enjoined from doing so. Pursuant to 35 U.S.C. §§ 271(e)(4) and/or 283, AbbVie is entitled to an order that the effective date of any approval of ANDA No. 204739 for Macleods' Generic Lopinavir/Ritonavir Tablets shall be a date which is not earlier than the date of expiration of the '899 Patent (and any additional dates of exclusivity), and an injunction against such infringement. AbbVie does not have an adequate remedy at law.

FOURTH COUNT
FOR PATENT INFRINGEMENT OF THE '349 PATENT

79. Paragraphs 1–78 are incorporated herein by reference.

80. On information and belief, Defendants acted in concert to file and have maintained ANDA No. 204739 in order to obtain approval to manufacture, use, offer to sell, and sell Macleods' Generic Lopinavir/Ritonavir Tablets in the United States before the expiration of the '349 Patent.

81. On information and belief, Defendants filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the '349 Patent are purportedly invalid and/or not infringed.

82. On information and belief, Macleods Pharmaceuticals has represented to the FDA in Macleods' ANDA No. 204739 that Macleods' Generic Lopinavir/Ritonavir Tablets are bioe-

quivalent, therapeutically equivalent, and pharmaceutically equivalent to AbbVie's Kaletra® tablets.

83. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 204739 seeking approval for the commercial manufacture, use, or sale of Macleods' Generic Lopinavir/Ritonavir Tablets before the expiration date of the '349 Patent constitutes infringement of one or more claims of the '349 Patent, either literally or under the doctrine of equivalents.

84. Based on information and belief, including based on a review of Macleods' Notice Letter, Defendants will infringe, under § 271(a), either literally or under the doctrine of equivalents, at least independent claim 1 and dependent claim 6 of the '349 Patent. Macleods' Generic Lopinavir/Ritonavir Tablets are a "solid pharmaceutical dosage form" that contains ritonavir as required by claim 1. On information and belief, Macleods' Generic Lopinavir/Ritonavir Tablets meet all additional limitations of claim 1. On information and belief, Macleods' Generic Lopinavir/Ritonavir Tablets also satisfy all the further limitations of claim 6.

85. In its Notice Letter, Macleods did not assert any basis for noninfringement for any claim of the '349 Patent.

86. AbbVie will be irreparably harmed if Defendants are permitted to make, use, sell, offer to sell, and/or import Macleods' Generic Lopinavir/Ritonavir Tablets in or into the United States, and are not enjoined from doing so. Pursuant to 35 U.S.C. §§ 271(e)(4) and/or 283, AbbVie is entitled to an order that the effective date of any approval of ANDA No. 204739 for Macleods' Generic Lopinavir/Ritonavir Tablets shall be a date which is not earlier than the date of expiration of the '349 Patent (and any additional dates of exclusivity), and an injunction against such infringement. AbbVie does not have an adequate remedy at law.

FIFTH COUNT
FOR PATENT INFRINGEMENT OF THE '613 PATENT

87. Paragraphs 1–86 are incorporated herein by reference.

88. On information and belief, Defendants acted in concert to file and have maintained ANDA No. 204739 in order to obtain approval to manufacture, use, offer to sell, and sell Macleods' Generic Lopinavir/Ritonavir Tablets in the United States before the expiration of the '613 Patent.

89. On information and belief, Defendants acted in concert to file with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the '613 Patent are purportedly invalid and/or not infringed.

90. On information and belief, Macleods Pharmaceuticals has represented to the FDA in Macleods' ANDA No. 204739 that Macleods' Generic Lopinavir/Ritonavir Tablets are bioequivalent, therapeutically equivalent, and pharmaceutically equivalent to AbbVie's Kaletra® tablets.

91. Under 35 U.S.C. §§ 271(b) and (e)(2)(A), the submission to the FDA of ANDA No. 204739 seeking approval for the commercial manufacture, use, or sale of Macleods' Generic Lopinavir/Ritonavir Tablets before the expiration date of the '613 Patent constitutes induced infringement of one or more claims of the '613 Patent, either literally or under the doctrine of equivalents.

92. On information and belief, Defendants are actively seeking FDA approval to sell Macleods' Generic Lopinavir/Ritonavir Tablets for the same indication, the same dosages, and the same method of use as the Kaletra® products sold by AbbVie.

93. On information and belief, Defendants' offering to sell, sale, making, and/or importation of Macleods' Generic Lopinavir/Ritonavir Tablets, once ANDA No. 204739 is

approved by the FDA, would actively induce infringement of at least one of the claims of the '613 Patent under 35 U.S.C. § 271(b), either literally or under the doctrine of equivalents.

94. Defendants have knowledge and are aware of AbbVie's '613 Patent, as evidenced by Macleods' Notice Letter.

95. On information and belief, by the filing of ANDA No. 204739 with a proposed package insert having directions that encourage patients to administer Macleods' Generic Lopinavir/Ritonavir Tablets to treat an HIV infection, Defendants have an affirmative intent to actively induce infringement by patients of one or more claims of the '613 Patent, either literally or under the doctrine of equivalents.

96. On information and belief, by the filing of ANDA No. 204739 with a proposed package insert having directions that encourage medical practitioners to administer Macleods' Generic Lopinavir/Ritonavir Tablets to treat an HIV infection, Defendants have an affirmative intent to actively induce infringement by medical practitioners of one or more claims of the '613 Patent, either literally or under the doctrine of equivalents.

97. On information and belief, Defendants are aware and intend that patients will administer Macleods' Generic Lopinavir/Ritonavir Tablets and directly infringe at least one claim of the '613 Patent, either literally or under the doctrine of equivalents.

98. On information and belief, Defendants are aware and intend that medical practitioners will administer Macleods' Generic Lopinavir/Ritonavir Tablets and directly infringe at least one claim of the '613 Patent, either literally or under the doctrine of equivalents.

99. On information and belief, Defendants are aware and intend that patients will administer Macleods' Generic Lopinavir/Ritonavir Tablets in a method of treatment according to the directions and instructions in the proposed package insert that will directly infringe at least

one claim of the '613 Patent, either literally or under the doctrine of equivalents.

100. On information and belief, Defendants are aware and intend that medical practitioners will administer Macleods' Generic Lopinavir/Ritonavir Tablets in a method of treatment according to the directions and instructions in the proposed package insert that will directly infringe at least one claim of the '613 Patent, either literally or under the doctrine of equivalents.

101. On information and belief, Defendants know or should know that they will aid and abet another's direct infringement of at least one of the claims of the '613 Patent, either literally or under the doctrine of equivalents, by Defendants' proposed package insert for Macleods' Generic Lopinavir/Ritonavir Tablets.

102. On information and belief, therefore, Defendants' offering to sell, sale, making, and/or importation of Macleods' Generic Lopinavir/Ritonavir Tablets, once approved by the FDA, would actively, intentionally, and knowingly induce infringement of one or more claims of the '613 Patent, either literally or under the doctrine of equivalents.

103. On information and belief, Macleods' Generic Lopinavir/Ritonavir Tablets, if approved by the FDA, will be imported by Defendants into the United States, offered for sale, and sold in the United States by them or on their behalf, and will be administered by patients in the United States, and will be administered by medical practitioners in the United States, which will constitute direct infringement of at least one claim under 35 U.S.C. § 271(a) of the '613 Patent by patients and medical practitioners. On information and belief, the administration, and prescription of Macleods' Generic Lopinavir/Ritonavir Tablets will occur with Defendants' specific intent and encouragement, and will be conduct that Defendants know or should know will occur. On information and belief, Defendants will actively induce, encourage, aid, and abet that conduct by patients or medical practitioners, with knowledge and specific intent that the conduct will be

in contravention of AbbVie's rights under the '613 Patent.

104. Defendants' threatened actions in actively aiding, abetting, encouraging, and inducing sales of Macleods' Generic Lopinavir/Ritonavir Tablets will infringe one or more claims of the '613 Patent under § 271(b), either literally or under the doctrine of equivalents.

105. Based on information and belief, including based on a review of Macleods' Notice Letter, Defendants will induce infringement under § 271(b), either literally or under the doctrine of equivalents, of at least independent claim 1 and dependent claim 3 of the '613 Patent. On information and belief, Macleods' Generic Lopinavir/Ritonavir Tablets will be approved for the same indication as Kaletra®, and such approved use will meet the requirement that the Tablets be used in a "method of treating an HIV infection," as required by claim 1. Macleods' Generic Lopinavir/Ritonavir Tablets are "solid pharmaceutical dosage form[s]" that comprise lopinavir and ritonavir, as required by claim 1. On information and belief, Macleods' Generic Lopinavir/Ritonavir Tablets satisfy all remaining limitations of claim 1. Upon information and belief, upon FDA approval of Macleods' Generic Lopinavir/Ritonavir Tablets, medical practitioners will administer the Generic Lopinavir/Ritonavir Tablets to humans (mammals) in order to treat an HIV infection in accordance with and pursuant to the directions in Macleods' product labeling for its Generic Lopinavir/Ritonavir Tablets, and will thus directly infringe claim 1. On information and belief, Macleods' Generic Lopinavir/Ritonavir Tablets satisfy all further limitations of claim 3. Upon information and belief, the use of Macleods' Generic Lopinavir/Ritonavir Tablets by medical practitioners is performed in such a manner that the Tablets satisfy the further limitations of claim 3, and at least such medical practitioners will directly infringe claims 1 and 3. As discussed in more detail above, upon information and belief, Macleods knowingly and intentionally will induce at least such medical practitioners to infringe claims 1 and 3.

106. In its Notice Letter, Macleods did not assert any basis for noninfringement for any claim of the ’613 Patent.

107. AbbVie will be irreparably harmed if Defendants are permitted to make, use, sell, offer to sell, and/or import Macleods’ Generic Lopinavir/Ritonavir Tablets in or into the United States, and is not enjoined from doing so. Pursuant to 35 U.S.C. §§ 271(e)(4) and/or 283, AbbVie is entitled to an order that the effective date of any approval of ANDA No. 204739 for Macleods’ Generic Lopinavir/Ritonavir Tablets shall be a date which is not earlier than the date of expiration of the ’613 Patent (and any additional dates of exclusivity), and an injunction against such infringement. AbbVie does not have an adequate remedy at law.

SIXTH COUNT
FOR PATENT INFRINGEMENT OF THE ’952 PATENT

108. Paragraphs 1–107 are incorporated herein by reference.

109. On information and belief, Defendants acted in concert to file and have maintained ANDA No. 204739 in order to obtain approval to manufacture, use, offer to sell, and sell Macleods’ Generic Lopinavir/Ritonavir Tablets in the United States before the expiration of the ’952 Patent.

110. On information and belief, Defendants acted in concert to file with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the ’878 Patent are purportedly invalid and/or not infringed.

111. On information and belief, Macleods Pharmaceuticals has represented to the FDA in Macleods’ ANDA No. 204739 that Macleods’ Generic Lopinavir/Ritonavir Tablets are bioequivalent, therapeutically equivalent, and pharmaceutically equivalent to AbbVie’s Kaletra® tablets.

112. Under 35 U.S.C. §§ 271(b) and (e)(2)(A), the submission to the FDA of ANDA

No. 204739 seeking approval for the commercial manufacture, use, or sale of Macleods' Generic Lopinavir/Ritonavir Tablets before the expiration date of the '952 Patent constitutes induced infringement of one or more claims of the '952 Patent, either literally or under the doctrine of equivalents.

113. On information and belief, Defendants are actively seeking FDA approval to sell Macleods' Generic Lopinavir/Ritonavir Tablets for the same indication, the same dosages, and the same method of use as the Kaletra® products sold by AbbVie.

114. On information and belief, Defendants' offering to sell, sale, making, and/or importation of Macleods' Generic Lopinavir/Ritonavir Tablets, once ANDA No. 204739 is approved by the FDA, would actively induce infringement of at least one of the claims of the '952 Patent under 35 U.S.C. § 271(b), either literally or under the doctrine of equivalents.

115. Defendants have knowledge and are aware of AbbVie's '952 Patent, as evidenced by Macleods' Notice Letter.

116. On information and belief, by the filing of ANDA No. 204739 with a proposed package insert having directions that encourage patients to administer Macleods' Generic Lopinavir/Ritonavir Tablets to treat HIV, Defendants have an affirmative intent to actively induce infringement by patients of one or more claims of the '952 Patent, either literally or under the doctrine of equivalents.

117. On information and belief, by the filing of ANDA No. 204739 with a proposed package insert having directions that encourage medical practitioners to administer Macleods' Generic Lopinavir/Ritonavir Tablets to treat HIV, Defendants have an affirmative intent to actively induce infringement by medical practitioners of one or more claims of the '952 Patent, either literally or under the doctrine of equivalents.

118. On information and belief, Defendants are aware and intend that patients will administer Macleods' Generic Lopinavir/Ritonavir Tablets and directly infringe at least one claim of the '952 Patent, either literally or under the doctrine of equivalents.

119. On information and belief, Defendants are aware and intend that medical practitioners will administer Macleods' Generic Lopinavir/Ritonavir Tablets and direct and control patients to take Macleods' Generic Lopinavir/Ritonavir Tablets in a way that will directly infringe at least one claim of the '952 Patent, either literally or under the doctrine of equivalents.

120. On information and belief, Defendants are aware and intend that patients will administer Macleods' Generic Lopinavir/Ritonavir Tablets in a method of treatment according to the directions and instructions in the proposed package insert that will directly infringe at least one claim of the '952 Patent, either literally or under the doctrine of equivalents.

121. On information and belief, Defendants are aware and intend that medical practitioners will administer Macleods' Generic Lopinavir/Ritonavir Tablets and direct patients to take them in a method of treatment according to the directions and instructions in the proposed package insert that will directly infringe at least one claim of the '952 Patent, either literally or under the doctrine of equivalents.

122. On information and belief, Defendants know or should know that they will aid and abet another's direct infringement of at least one of the claims of the '952 Patent, either literally or under the doctrine of equivalents, by Defendants' proposed package insert for Macleods' Generic Lopinavir/Ritonavir Tablets.

123. On information and belief, therefore, Defendants' offering to sell, sale, making, and/or importation of Macleods' Generic Lopinavir/Ritonavir Tablets, once approved by the FDA, would actively, intentionally, and knowingly induce infringement of one or more claims of

the ’952 Patent, either literally or under the doctrine of equivalents.

124. On information and belief, Macleods’ Generic Lopinavir/Ritonavir Tablets, if approved by the FDA, will be imported by Defendants into the United States, offered for sale, and sold in the United States by them or on their behalf, and will be administered by patients in the United States, and will be administered by medical practitioners in the United States, which will constitute direct infringement of at least one claim under 35 U.S.C. § 271(a) of the ’952 Patent by patients or medical practitioners. On information and belief, the administration of Macleods’ Generic Lopinavir/Ritonavir Tablets will occur with Defendants’ specific intent and encouragement, and will be conduct that Defendants know or should know will occur. On information and belief, Defendants will actively induce, encourage, aid, and abet that conduct by patients or medical practitioners, with knowledge and specific intent that the conduct will be in contravention of AbbVie’s rights under the ’952 Patent.

125. Defendants’ threatened actions in actively aiding, abetting, encouraging, and inducing sales of Macleods’ Generic Lopinavir/Ritonavir Tablets will infringe one or more claims of the ’952 Patent under § 271(b), either literally or under the doctrine of equivalents.

126. Based on information and belief, including based on a review of Macleods’ Notice Letter, Defendants will induce infringement, under § 271(b), either literally or under the doctrine of equivalents, of at least independent claim 1 and dependent claim 2 of the ’952 Patent. On information and belief, Macleods’ Generic Lopinavir/Ritonavir Tablets will be approved for the same indication as Kaletra®, and such approved use will meet the requirement that the Tablets be used in a “method of treating HIV,” as required by claim 1. On information and belief, medical practitioners will control and direct patients to take Macleods’ Generic Lopinavir/Ritonavir Tablets “without food or under a fasting condition,” as required by claim 1.

Macleods' Generic Lopinavir/Ritonavir Tablets are a "solid pharmaceutical dosage form" that contains lopinavir and ritonavir as required by claim 1. On information and belief, Macleods' Generic Lopinavir/Ritonavir Tablets satisfy all remaining limitations of claim 1. Upon information and belief, upon FDA approval of Macleods' Generic Lopinavir/Ritonavir Tablets, medical practitioners will administer the Generic Lopinavir/Ritonavir Tablets to humans (mammals) in order to treat an HIV infection in accordance with and pursuant to the directions in Macleods' product labeling for its Generic Lopinavir/Ritonavir Tablets, and will thus directly infringe claim 1. Upon information and belief, Macleods' Generic Lopinavir/Ritonavir Tablets satisfy the further limitations of claim 2. Upon information and belief, the use of Macleods' Generic Lopinavir/Ritonavir Tablets by medical practitioners is performed in such a manner to satisfy all remaining limitations of claim 2, and at least such medical practitioners will directly infringe claims 1 and 2. As discussed in more detail above, upon information and belief, Macleods knowingly and intentionally will induce at least such medical practitioners to infringe claims 1 and 2.

127. In its Notice Letter, Macleods did not assert any basis for noninfringement for any claim of the '952 Patent.

128. AbbVie will be irreparably harmed if Defendants are permitted to make, use, sell, offer to sell, and/or import Macleods' Generic Lopinavir/Ritonavir Tablets in or into the United States, and is not enjoined from doing so. Pursuant to 35 U.S.C. §§ 271(e)(4) and/or 283, AbbVie is entitled to an order that the effective date of any approval of ANDA No. 204739 for Macleods' Generic Lopinavir/Ritonavir Tablets shall be a date which is not earlier than the date of expiration of the '952 Patent (and any additional dates of exclusivity), and an injunction against such infringement. AbbVie does not have an adequate remedy at law.

SEVENTH COUNT
FOR PATENT INFRINGEMENT OF THE '015 PATENT

129. Paragraphs 1–128 are incorporated herein by reference.

130. On information and belief, Defendants acted in concert to file and have maintained ANDA No. 204739 in order to obtain approval to manufacture, use, offer to sell, and sell Macleods' Generic Lopinavir/Ritonavir Tablets in the United States before the expiration of the '015 Patent.

131. On information and belief, Defendants filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the '015 Patent are purportedly invalid and/or not infringed.

132. On information and belief, Macleods Pharmaceuticals has represented to the FDA in Macleods' ANDA No. 204739 that Macleods' Generic Lopinavir/Ritonavir Tablets are bioequivalent, therapeutically equivalent, and pharmaceutically equivalent to AbbVie's Kaletra® tablets.

133. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 204739 seeking approval for the commercial manufacture, use, or sale of Macleods' Generic Lopinavir/Ritonavir Tablets before the expiration date of the '015 Patent constitutes infringement of one or more claims of the '015 Patent, either literally or under the doctrine of equivalents.

134. Based on information and belief, including based on a review of Macleods' Notice Letter, Defendants will infringe, under § 271(a), either literally or under the doctrine of equivalents, at least independent claim 1 and dependent claim 4 of the '015 patent. Macleods' Generic Lopinavir/Ritonavir Tablets are a "solid pharmaceutical dosage form" that contains lopinavir and ritonavir, as required by claim 1. On information and belief, Macleods' Generic

Lopinavir/Ritonavir Tablets meet all remaining limitations of claim 1. On information and belief, Macleods' Generic Lopinavir/Ritonavir Tablets satisfy all the further limitations of claim 4.

135. In its Notice Letter, Macleods did not assert any basis for noninfringement for any claim of the '015 Patent.

136. AbbVie will be irreparably harmed if Defendants are permitted to make, use, sell, offer to sell, and/or import Macleods' Generic Lopinavir/Ritonavir Tablets in or into the United States, and are not enjoined from doing so. Pursuant to 35 U.S.C. §§ 271(e)(4) and/or 283, AbbVie is entitled to an order that the effective date of any approval of ANDA No. 204739 for Macleods' Generic Lopinavir/Ritonavir Tablets shall be a date which is not earlier than the date of expiration of the '015 Patent (and any additional dates of exclusivity), and an injunction against such infringement. AbbVie does not have an adequate remedy at law.

EIGHTH COUNT
FOR PATENT INFRINGEMENT OF THE '347 PATENT

137. Paragraphs 1–136 are incorporated herein by reference.

138. On information and belief, Defendants acted in concert to file and have maintained ANDA No. 204739 in order to obtain approval to manufacture, use, offer to sell, and sell Macleods' Generic Lopinavir/Ritonavir Tablets in the United States before the expiration of the '347 Patent.

139. On information and belief, Defendants filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the '347 Patent are purportedly invalid and/or not infringed.

140. On information and belief, Macleods Pharmaceuticals has represented to the FDA in Macleods' ANDA No. 204739 that Macleods' Generic Lopinavir/Ritonavir Tablets are bioequivalent, therapeutically equivalent, and pharmaceutically equivalent to AbbVie's Kaletra®

tablets.

141. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 204739 seeking approval for the commercial manufacture, use, or sale of Macleods' Generic Lopinavir/Ritonavir Tablets before the expiration date of the '347 Patent constitutes infringement of one or more claims of the '347 Patent, either literally or under the doctrine of equivalents.

142. Based on information and belief, including based on a review of Macleods' Notice Letter, Defendants will infringe, under § 271(a), either literally or under the doctrine of equivalents, at least independent claim 1 and dependent claim 2 of the '347 patent. Macleods' Generic Lopinavir/Ritonavir Tablets are a solid formulation, as required by claim 1. On information and belief, which, *inter alia*, indicates that Macleods' Generic Lopinavir/Ritonavir Tablets are in the form of a solid solution or glassy solution and are bioequivalent, therapeutically equivalent, and pharmaceutically equivalent to AbbVie's Kaletra® tablets, Macleods' Generic Lopinavir/Ritonavir Tablets are a solid formulation wherein the formulation is essentially free of lipid and active pharmaceutical ingredient crystals, as required by claim 1. On information and belief, including Macleods' failure to contest infringement of the remaining limitations of claim 1, Macleods' Generic Lopinavir/Ritonavir Tablets meet all remaining limitations of claim 1. On information and belief, including Macleods' failure to contest infringement of the remaining limitations of claim 2, Macleods' Generic Lopinavir/Ritonavir Tablets satisfy all the further limitations of claim 2.

143. AbbVie will be irreparably harmed if Defendants are permitted to make, use, sell, offer to sell, and/or import Macleods' Generic Lopinavir/Ritonavir Tablets in or into the United States, and are not enjoined from doing so. Pursuant to 35 U.S.C. §§ 271(e)(4) and/or 283,

AbbVie is entitled to an order that the effective date of any approval of ANDA No. 204739 for Macleods' Generic Lopinavir/Ritonavir Tablets shall be a date which is not earlier than the date of expiration of the '347 Patent (and any additional dates of exclusivity), and an injunction against such infringement. AbbVie does not have an adequate remedy at law.

NINTH COUNT
FOR PATENT INFRINGEMENT OF THE '878 PATENT

144. Paragraphs 1–143 are incorporated herein by reference.

145. On information and belief, Defendants acted in concert to file and have maintained ANDA No. 204739 in order to obtain approval to manufacture, use, offer to sell, and sell Macleods' Generic Lopinavir/Ritonavir Tablets in the United States before the expiration of the '878 Patent.

146. On information and belief, Defendants filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification that the claims of the '878 Patent are purportedly invalid and/or not infringed.

147. On information and belief, Macleods Pharmaceuticals has represented to the FDA in Macleods' ANDA No. 204739 that Macleods' Generic Lopinavir/Ritonavir Tablets are bioequivalent, therapeutically equivalent, and pharmaceutically equivalent to AbbVie's Kaletra® tablets.

148. Under 35 U.S.C. §§ 271(b) and (e)(2)(A), the submission to the FDA of ANDA No. 204739 seeking approval for the commercial manufacture, use, or sale of Macleods' Generic Lopinavir/Ritonavir Tablets before the expiration date of the '878 Patent constitutes induced infringement of one or more claims of the '878 Patent, either literally or under the doctrine of equivalents.

149. On information and belief, Defendants are actively seeking FDA approval to sell

Macleods' Generic Lopinavir/Ritonavir Tablets for the same indication, the same dosages, and the same method of use as the Kaletra® products sold by AbbVie.

150. On information and belief, Defendants' offering to sell, sale, making, and/or importation of Macleods' Generic Lopinavir/Ritonavir Tablets, once ANDA No. 204739 is approved by the FDA, would actively induce infringement of at least one of the claims of the '878 Patent under 35 U.S.C. § 271(b), either literally or under the doctrine of equivalents.

151. Defendants have knowledge and are aware of AbbVie's '878 Patent, as evidenced by Macleods' Notice Letter.

152. On information and belief, by the filing of ANDA No. 204739 with a proposed package insert having directions that encourage patients to administer Macleods' Generic Lopinavir/Ritonavir Tablets to treat HIV, Defendants have an affirmative intent to actively induce infringement by patients of one or more claims of the '878 Patent, either literally or under the doctrine of equivalents.

153. On information and belief, by the filing of ANDA No. 204739 with a proposed package insert having directions that encourage medical practitioners to administer Macleods' Generic Lopinavir/Ritonavir Tablets to treat HIV, Defendants have an affirmative intent to actively induce infringement by medical practitioners of one or more claims of the '878 Patent, either literally or under the doctrine of equivalents.

154. On information and belief, Defendants are aware and intend that patients will administer and/or use Macleods' Generic Lopinavir/Ritonavir Tablets and directly infringe at least one claim of the '878 Patent, either literally or under the doctrine of equivalents.

155. On information and belief, Defendants are aware and intend that medical practitioners will administer Macleods' Generic Lopinavir/Ritonavir Tablets and directly infringe at

least one claim of the ’878 Patent, either literally or under the doctrine of equivalents.

156. On information and belief, Defendants are aware and intend that patients will administer Macleods’ Generic Lopinavir/Ritonavir Tablets in a method of treatment according to the directions and instructions in the proposed package insert that will directly infringe at least one claim of the ’878 Patent, either literally or under the doctrine of equivalents.

157. On information and belief, Defendants are aware and intend that medical practitioners will administer Macleods’ Generic Lopinavir/Ritonavir Tablets in a method of treatment according to the directions and instructions in the proposed package insert that will directly infringe at least one claim of the ’878 Patent, either literally or under the doctrine of equivalents.

158. On information and belief, Defendants know or should know that they will aid and abet another’s direct infringement of at least one of the claims of the ’878 Patent, either literally or under the doctrine of equivalents, by Defendants’ proposed package insert for Macleods’ Generic Lopinavir/Ritonavir Tablets.

159. On information and belief, therefore, Defendants’ offering to sell, sale, making, and/or importation of Macleods’ Generic Lopinavir/Ritonavir Tablets, once approved by the FDA, would actively, intentionally, and knowingly induce infringement of one or more claims of the ’878 Patent, either literally or under the doctrine of equivalents.

160. On information and belief, Macleods’ Generic Lopinavir/Ritonavir Tablets, if approved by the FDA, will be imported by Defendants into the United States, offered for sale, and sold in the United States by them or on their behalf, and will be administered by patients in the United States, and will be administered by medical practitioners in the United States, which will constitute direct infringement of at least one claim under 35 U.S.C. § 271(a) of the ’878 Patent by patients and medical practitioners. On information and belief, the administration of Macleods’

Generic Lopinavir/Ritonavir Tablets will occur with Defendants' specific intent and encouragement, and will be conduct that Defendants know or should know will occur. On information and belief, Defendants will actively induce, encourage, aid, and abet that conduct by patients or medical practitioners, with knowledge and specific intent that the conduct will be in contravention of AbbVie's rights under the '878 Patent.

161. Defendants' threatened actions in actively aiding, abetting, encouraging, and inducing sales of Macleods' Generic Lopinavir/Ritonavir Tablets will infringe one or more claims of the '878 Patent under § 271(b), either literally or under the doctrine of equivalents.

162. Based on information and belief, including based on a review of Macleods' Notice Letter, Defendants will induce infringement, under § 271(b), either literally or under the doctrine of equivalents, of at least independent claim 1 and dependent claim 2 of the '878 Patent. On information and belief, Macleods' Generic Lopinavir/Ritonavir Tablets will be approved for the same indication as Kaletra®, and such approved use will meet the requirement that the Tablets be used in a "method of treating HIV," as required by claim 1. Macleods' Generic Lopinavir/Ritonavir Tablets are a "solid pharmaceutical dosage form" that comprise ritonavir as required by claim 1. On information and belief, Macleods' Generic Lopinavir/Ritonavir Tablets satisfy all remaining limitations of claim 1. Upon information and belief, upon FDA approval of Macleods' Generic Lopinavir/Ritonavir Tablets, medical practitioners will administer the Generic Lopinavir/Ritonavir Tablets to humans (mammals) in order to treat an HIV infection in accordance with and pursuant to the directions in Macleods' product labeling for its Generic Lopinavir/Ritonavir Tablets and will directly infringe claim 1. Upon information and belief, Macleods' Generic Lopinavir/Ritonavir Tablets satisfy all further limitations of claim 2. Upon information and belief, the use of Macleods' Generic Lopinavir/Ritonavir Tablets by medical

practitioners will satisfy the further limitations of claim 2, and at least such medical practitioners will directly infringe claims 1 and 2. As discussed in more detail above, upon information and belief, Macleods knowingly and intentionally will induce such medical practitioners to infringe claims 1 and 2.

163. In its Notice Letter, Macleods did not assert any basis for noninfringement for any claim of the ’878 Patent.

164. AbbVie will be irreparably harmed if Defendants are permitted to make, use, sell, offer to sell, and/or import Macleods’ Generic Lopinavir/Ritonavir Tablets in or into the United States and is not enjoined from doing so. Pursuant to 35 U.S.C. §§ 271(e)(4) and/or 283, AbbVie is entitled to an order that the effective date of any approval of ANDA No. 204739 for Macleods’ Generic Lopinavir/Ritonavir Tablets shall be a date which is not earlier than the date of expiration of the ’878 Patent (and any additional dates of exclusivity), and an injunction against such infringement. AbbVie does not have an adequate remedy at law.

TENTH COUNT
DECLARATORY JUDGMENT AS TO THE ’359 PATENT

165. Paragraphs 1–164 are incorporated herein by reference.

166. On information and belief, Defendants are actively seeking FDA approval to sell Macleods’ Generic Lopinavir/Ritonavir Tablets for the same indication, the same dosages, and the same method of use as the Kaletra® products sold by AbbVie.

167. On information and belief, upon FDA approval of ANDA No. 204739, Defendants will infringe one or more claims of the ’359 Patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing Macleods’ Generic Lopinavir/Ritonavir Tablets, unless this Court orders that the effective date of any FDA approval of ANDA No. 204739 shall be no earlier than the expiration date of the

'359 Patent and any additional periods of exclusivity.

168. On information and belief, Defendants intend to commence sales of Macleods' Generic Lopinavir/Ritonavir Tablets immediately upon receiving final approval from the FDA.

169. On information and belief, in Macleods' ANDA No. 204739, Macleods Pharmaceuticals has represented to the FDA that Macleods' Generic Lopinavir/Ritonavir Tablets are bioequivalent, therapeutically equivalent, and pharmaceutically equivalent to AbbVie's Kaletra® tablets.

170. On information and belief, therefore, Defendants' manufacture, importation, sale, and/or offer for sale of Macleods' Generic Lopinavir/Ritonavir Tablets, once approved by the FDA, would directly infringe one or more claims of the '359 Patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

171. Defendants have knowledge and are aware of AbbVie's '359 Patent, as evidenced by Macleods' Notice Letter.

172. A case or controversy exists between AbbVie and Defendants regarding the infringement and validity of the '359 Patent.

173. Under the totality of the circumstances, there is a substantial controversy between AbbVie and Defendants having sufficient immediacy and reality to establish declaratory judgment jurisdiction relating to Defendants' threatened infringement of the '359 Patent.

174. AbbVie will be substantially and irreparably damaged and harmed by the infringing activities described above unless those activities are enjoined by this Court. AbbVie does not have an adequate remedy at law.

175. In view of the foregoing, there exists a substantial controversy between AbbVie and Macleods, which have adverse legal interests, of sufficient immediacy and reality to warrant

the issuance of a declaratory judgment.

ELEVENTH COUNT
DECLARATORY JUDGMENT AS TO THE '752 PATENT

176. Paragraphs 1–175 are incorporated herein by reference.

177. On information and belief, Defendants are actively seeking FDA approval to sell Macleods' Generic Lopinavir/Ritonavir Tablets for the same indication, the same dosages, and the same method of use as the Kaletra® products sold by AbbVie.

178. On information and belief, upon FDA approval of ANDA No. 204739, Defendants will infringe one or more claims of the '359 Patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing Macleods' Generic Lopinavir/Ritonavir Tablets, unless this Court orders that the effective date of any FDA approval of ANDA No. 204739 shall be no earlier than the expiration date of the '752 Patent and any additional periods of exclusivity.

179. On information and belief, upon FDA approval of ANDA No. 204739, Defendants will infringe one or more claims of the '752 Patent under 35 U.S.C. § 271(b), by actively inducing direct infringement by others (for example, by medical practitioners or patients), unless this Court orders that the effective date of any FDA approval of ANDA No. 204739 shall be no earlier than the expiration date of the '752 Patent and any additional periods of exclusivity.

180. On information and belief, Defendants intend to commence sales of Macleods' Generic Lopinavir/Ritonavir Tablets immediately upon receiving final approval from the FDA.

181. On information and belief, in Macleods' ANDA No. 204739, Macleods Pharmaceuticals has represented to the FDA that Macleods' Generic Lopinavir/Ritonavir Tablets are bioequivalent, therapeutically equivalent, and pharmaceutically equivalent to AbbVie's Kaletra® tablets.

182. On information and belief, therefore, Defendants' manufacture, use, importation, sale, and/or offer for sale of Macleods' Generic Lopinavir/Ritonavir Tablets, once approved by the FDA, would directly infringe one or more claims of the '752 Patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

183. On information and belief, Defendants' offering to sell, sale, making, and/or importation of Macleods' Generic Lopinavir/Ritonavir Tablets, once approved by the FDA, would actively induce infringement under 35 U.S.C. § 271(b) of at least one of the claims of the '752 Patent, either literally or under the doctrine of equivalents.

184. A case or controversy exists between AbbVie and Defendants regarding the infringement and validity of the '752 Patent.

185. Under the totality of the circumstances, there is a substantial controversy between AbbVie and Defendants having sufficient immediacy and reality to establish declaratory judgment jurisdiction relating to Defendants' threatened infringement of the '752 Patent.

186. AbbVie will be substantially and irreparably damaged and harmed by the infringing activities described above unless those activities are enjoined by this Court. AbbVie does not have an adequate remedy at law.

187. In view of the foregoing, there exists a substantial controversy between AbbVie and Defendants, which have adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

TWELFTH COUNT
DECLARATORY JUDGMENT AS TO THE '899 PATENT

188. Paragraphs 1–187 are incorporated herein by reference.

189. On information and belief, Defendants are actively seeking FDA approval to sell Macleods' Generic Lopinavir/Ritonavir Tablets for the same indication, the same dosages, and

the same method of use as the Kaletra® products sold by AbbVie.

190. On information and belief, upon FDA approval of ANDA No. 204739, Defendants will infringe one or more claims of the '899 Patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing Macleods' Generic Lopinavir/Ritonavir Tablets, unless this Court orders that the effective date of any FDA approval of ANDA No. 204739 shall be no earlier than the expiration date of the '899 Patent and any additional periods of exclusivity.

191. On information and belief, Defendants intend to commence sales of Macleods' Generic Lopinavir/Ritonavir Tablets immediately upon receiving final approval from the FDA.

192. On information and belief, in Macleods' ANDA No. 204739, Macleods Pharmaceuticals has represented to the FDA that Macleods' Generic Lopinavir/Ritonavir Tablets are bioequivalent, therapeutically equivalent, and pharmaceutically equivalent to AbbVie's Kaletra® tablets.

193. On information and belief, therefore, Defendants' manufacture, importation, sale, and/or offer for sale of Macleods' Generic Lopinavir/Ritonavir Tablets, once approved by the FDA would directly infringe one or more claims of the '899 Patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

194. Defendants have knowledge and are aware of AbbVie's '899 Patent, as evidenced by Macleods' Notice Letter.

195. A case or controversy exists between AbbVie and Defendants regarding the infringement and validity of the '899 Patent.

196. Under the totality of the circumstances, there is a substantial controversy between AbbVie and Defendants having sufficient immediacy and reality to establish declaratory judg-

ment jurisdiction relating to Defendants' threatened infringement of the '899 Patent.

197. AbbVie will be substantially and irreparably damaged and harmed by the infringing activities described above unless those activities are enjoined by this Court. AbbVie does not have an adequate remedy at law.

198. In view of the foregoing, there exists a substantial controversy between AbbVie and Defendants, which have adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

THIRTEENTH COUNT
DECLARATORY JUDGMENT AS TO THE '349 PATENT

199. Paragraphs 1–198 are incorporated herein by reference.

200. On information and belief, Defendants are actively seeking FDA approval to sell Macleods' Generic Lopinavir/Ritonavir Tablets for the same indication, the same dosages, and the same method of use as the Kaletra® products sold by AbbVie.

201. On information and belief, upon FDA approval of ANDA No. 204739, Defendants will infringe one or more claims of the '349 Patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing Macleods' Generic Lopinavir/Ritonavir Tablets, unless this Court orders that the effective date of any FDA approval of ANDA No. 204739 shall be no earlier than the expiration date of the '349 Patent and any additional periods of exclusivity.

202. On information and belief, Defendants intend to commence sales of Macleods' Generic Lopinavir/Ritonavir Tablets immediately upon receiving final approval from the FDA.

203. On information and belief, in Macleods' ANDA No. 204739, Macleods Pharmaceuticals has represented to the FDA that Macleods' Generic Lopinavir/Ritonavir Tablets are bioequivalent, therapeutically equivalent, and pharmaceutically equivalent to AbbVie's Kaletra®

tablets.

204. On information and belief, therefore, Defendants' manufacture, importation, sale, and/or offer for sale of Macleods' Generic Lopinavir/Ritonavir Tablets, once approved by the FDA, would directly infringe one or more claims of the '349 Patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

205. Defendants have knowledge and are aware of AbbVie's '349 Patent, as evidenced by Macleods' Notice Letter.

206. A case or controversy exists between AbbVie and Defendants regarding the infringement and validity of the '349 Patent.

207. Under the totality of the circumstances, there is a substantial controversy between AbbVie and Defendants having sufficient immediacy and reality to establish declaratory judgment jurisdiction relating to Defendants' threatened infringement of the '349 Patent.

208. AbbVie will be substantially and irreparably damaged and harmed by the infringing activities described above unless those activities are enjoined by this Court. AbbVie does not have an adequate remedy at law.

209. In view of the foregoing, there exists a substantial controversy between AbbVie and Macleods, which have adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

FOURTEENTH COUNT
DECLARATORY JUDGMENT AS TO THE '613 PATENT

210. Paragraphs 1–209 are incorporated herein by reference.

211. On information and belief, Defendants are actively seeking FDA approval to sell Macleods' Generic Lopinavir/Ritonavir Tablets for the same indication, the same dosages, and the same method of use as the Kaletra® products sold by AbbVie.

212. On information and belief, upon FDA approval of ANDA No. 204739, Defendants will infringe one or more claims of the '613 Patent under 35 U.S.C. § 271(b), by actively inducing direct infringement by others (for example, by medical practitioners or patients), unless this Court orders that the effective date of any FDA approval of ANDA No. 204739 shall be no earlier than the expiration date of the '613 Patent and any additional periods of exclusivity.

213. On information and belief, Defendants intend to commence sales of Macleods' Generic Lopinavir/Ritonavir Tablets immediately upon receiving final approval from the FDA.

214. On information and belief, in Macleods' ANDA No. 204739, Macleods Pharmaceuticals has represented to the FDA that Macleods' Generic Lopinavir/Ritonavir Tablets are bioequivalent, therapeutically equivalent, and pharmaceutically equivalent to AbbVie's Kaletra® tablets.

215. On information and belief, Defendants' offering to sell, sale, making, and/or importation of Macleods' Generic Lopinavir/Ritonavir Tablets, once approved by the FDA, would actively induce infringement under 35 U.S.C. § 271(b) of at least one of the claims of the '613 Patent, either literally or under the doctrine of equivalents.

216. Defendants have knowledge and are aware of AbbVie's '613 Patent, as evidenced by Macleods' Notice Letter.

217. A case or controversy exists between AbbVie and Defendants regarding the infringement and validity of the '613 Patent.

218. Under the totality of the circumstances, there is a substantial controversy between AbbVie and Defendants having sufficient immediacy and reality to establish declaratory judgment jurisdiction relating to Defendants' threatened infringement of the '613 Patent.

219. AbbVie will be substantially and irreparably damaged and harmed by the infring-

ing activities described above unless those activities are enjoined by this Court. AbbVie does not have an adequate remedy at law.

220. In view of the foregoing, there exists a substantial controversy between AbbVie and Defendants, which have adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

FIFTEENTH COUNT
DECLARATORY JUDGMENT AS TO THE '952 PATENT

221. Paragraphs 1–220 are incorporated herein by reference.

222. On information and belief, Defendants are actively seeking FDA approval to sell Macleods' Generic Lopinavir/Ritonavir Tablets for the same indication, the same dosages, and the same method of use as the Kaletra® products sold by AbbVie.

223. On information and belief, upon FDA approval of ANDA No. 204739, Defendants will infringe one or more claims of the '952 Patent under 35 U.S.C. § 271(b), by actively inducing direct infringement by others (for example, by medical practitioners or patients), unless this Court orders that the effective date of any FDA approval of ANDA No. 204739 shall be no earlier than the expiration date of the '952 Patent and any additional periods of exclusivity.

224. On information and belief, Defendants intend to commence sales of Macleods' Generic Lopinavir/Ritonavir Tablets immediately upon receiving final approval from the FDA.

225. On information and belief, in Macleods' ANDA No. 204739, Macleods Pharmaceuticals has represented to the FDA that Macleods' Generic Lopinavir/Ritonavir Tablets are bioequivalent, therapeutically equivalent, and pharmaceutically equivalent to AbbVie's Kaletra® tablets.

226. On information and belief, Defendants' offering to sell, sale, making, and/or importation of Macleods' Generic Lopinavir/Ritonavir Tablets, once approved by the FDA, would

actively induce infringement under 35 U.S.C. § 271(b) of at least one of the claims of the '952 Patent, either literally or under the doctrine of equivalents.

227. Defendants have knowledge and are aware of AbbVie's '952 Patent, as evidenced by Macleods' Notice Letter.

228. A case or controversy exists between AbbVie and Defendants regarding the infringement and validity of the '952 Patent.

229. Under the totality of the circumstances, there is a substantial controversy between AbbVie and Defendants having sufficient immediacy and reality to establish declaratory judgment jurisdiction relating to Defendants' threatened infringement of the '952 Patent.

230. AbbVie will be substantially and irreparably damaged and harmed by the infringing activities described above unless those activities are enjoined by this Court. AbbVie does not have an adequate remedy at law.

231. In view of the foregoing, there exists a substantial controversy between AbbVie and Defendants, which have adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

SIXTEENTH COUNT
DECLARATORY JUDGMENT AS TO THE '015 PATENT

232. Paragraphs 1–231 are incorporated herein by reference.

233. On information and belief, Defendants are actively seeking FDA approval to sell Macleods' Generic Lopinavir/Ritonavir Tablets for the same indication, the same dosages, and the same method of use as the Kaletra® products sold by AbbVie.

234. On information and belief, upon FDA approval of ANDA No. 204739, Defendants will infringe one or more claims of the '015 Patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing

Macleods' Generic Lopinavir/Ritonavir Tablets, unless this Court orders that the effective date of any FDA approval of ANDA No. 204739 shall be no earlier than the expiration date of the '015 Patent and any additional periods of exclusivity.

235. On information and belief, Defendants intend to commence sales of Macleods' Generic Lopinavir/Ritonavir Tablets immediately upon receiving final approval from the FDA.

236. On information and belief, in Macleods' ANDA No. 204739, Macleods Pharmaceuticals has represented to the FDA that Macleods' Generic Lopinavir/Ritonavir Tablets are bioequivalent, therapeutically equivalent, and pharmaceutically equivalent to AbbVie's Kaletra® tablets.

237. On information and belief, therefore, Defendants' manufacture, importation, sale, and/or offer for sale of Macleods' Generic Lopinavir/Ritonavir Tablets, once approved by the FDA, would directly infringe one or more claims of the '015 Patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

238. Defendants have knowledge and are aware of AbbVie's '015 Patent, as evidenced by Macleods' Notice Letter.

239. A case or controversy exists between AbbVie and Defendants regarding the infringement and validity of the '015 Patent.

240. Under the totality of the circumstances, there is a substantial controversy between AbbVie and Defendants having sufficient immediacy and reality to establish declaratory judgment jurisdiction relating to Macleods' threatened infringement of the '015 Patent.

241. AbbVie will be substantially and irreparably damaged and harmed by the infringing activities described above unless those activities are enjoined by this Court. AbbVie does not have an adequate remedy at law.

242. In view of the foregoing, there exists a substantial controversy between AbbVie and Defendants, which have adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

SEVENTEENTH COUNT
DECLARATORY JUDGMENT AS TO THE '347 PATENT

243. Paragraphs 1–242 are incorporated herein by reference.

244. On information and belief, Defendants are actively seeking FDA approval to sell Macleods' Generic Lopinavir/Ritonavir Tablets for the same indication, the same dosages, and the same method of use as the Kaletra® products sold by AbbVie.

245. On information and belief, upon FDA approval of ANDA No. 204739, Defendants will infringe one or more claims of the '347 Patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing Macleods' Generic Lopinavir/Ritonavir Tablets, unless this Court orders that the effective date of any FDA approval of ANDA No. 204739 shall be no earlier than the expiration date of the '347 Patent and any additional periods of exclusivity.

246. On information and belief, Defendants intend to commence sales of Macleods' Generic Lopinavir/Ritonavir Tablets immediately upon receiving final approval from the FDA.

247. On information and belief, in Macleods' ANDA No. 204739, Macleods Pharmaceuticals has represented to the FDA that Macleods' Generic Lopinavir/Ritonavir Tablets are bioequivalent, therapeutically equivalent, and pharmaceutically equivalent to AbbVie's Kaletra® tablets.

248. On information and belief, therefore, Defendants' manufacture, importation, sale, and/or offer for sale of Macleods' Generic Lopinavir/Ritonavir Tablets, once approved by the FDA, would directly infringe one or more claims of the '347 Patent under 35 U.S.C. § 271(a),

either literally or under the doctrine of equivalents.

249. Defendants have knowledge and are aware of AbbVie's '347 Patent, as evidenced by Macleods' Notice Letter.

250. A case or controversy exists between AbbVie and Defendants regarding the infringement and validity of the '347 Patent.

251. Under the totality of the circumstances, there is a substantial controversy between AbbVie and Defendants having sufficient immediacy and reality to establish declaratory judgment jurisdiction relating to Defendants' threatened infringement of the '347 Patent.

252. AbbVie will be substantially and irreparably damaged and harmed by the infringing activities described above unless those activities are enjoined by this Court. AbbVie does not have an adequate remedy at law.

253. In view of the foregoing, there exists a substantial controversy between AbbVie and Defendants, which have adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

EIGHTEENTH COUNT
DECLARATORY JUDGMENT AS TO THE '878 PATENT

254. Paragraphs 1–253 are incorporated herein by reference.

255. On information and belief, Defendants are actively seeking FDA approval to sell Macleods' Generic Lopinavir/Ritonavir Tablets for the same indication, the same dosages, and the same method of use as the Kaletra® products sold by AbbVie.

256. On information and belief, upon FDA approval of ANDA No. 204739, Defendants will infringe one or more claims of the '878 Patent under 35 U.S.C. § 271(b), by actively inducing direct infringement by others (for example, by medical practitioners or patients), unless this Court orders that the effective date of any FDA approval of ANDA No. 204739 shall be no

earlier than the expiration date of the ’878 Patent and any additional periods of exclusivity.

257. On information and belief, Defendants intend to commence sales of Macleods’ Generic Lopinavir/Ritonavir Tablets immediately upon receiving final approval from the FDA.

258. On information and belief, in Macleods’ ANDA No. 204739, Macleods Pharmaceuticals has represented to the FDA that Macleods’ Generic Lopinavir/Ritonavir Tablets are bioequivalent, therapeutically equivalent, and pharmaceutically equivalent to AbbVie’s Kaletra® tablets.

259. On information and belief, Defendants’ offering to sell, sale, making, and/or importation of Macleods’ Generic Lopinavir/Ritonavir Tablets, once approved by the FDA, would actively induce infringement under 35 U.S.C. § 271(b) of at least one of the claims of the ’878 Patent, either literally or under the doctrine of equivalents.

260. Defendants have knowledge and are aware of AbbVie’s ’878 Patent, as evidenced by Macleods’ Notice Letter.

261. A case or controversy exists between AbbVie and Defendants regarding the infringement and validity of the ’878 Patent.

262. Under the totality of the circumstances, there is a substantial controversy between AbbVie and Defendants having sufficient immediacy and reality to establish declaratory judgment jurisdiction relating to Defendants’ threatened infringement of the ’878 Patent.

263. AbbVie will be substantially and irreparably damaged and harmed by the infringing activities described above unless those activities are enjoined by this Court. AbbVie does not have an adequate remedy at law.

264. In view of the foregoing, there exists a substantial controversy between AbbVie and Defendants, which have adverse legal interests, of sufficient immediacy and reality to war-

rant the issuance of a declaratory judgment.

PRAYER FOR RELIEF

WHEREFORE, AbbVie respectfully requests that this Court enter judgment in its favor as follows:

a. declaring that, under 35 U.S.C. § 271(e)(2)(A), Defendants' submission of ANDA No. 204739 to the FDA to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Macleods' Generic Lopinavir/Ritonavir Tablets before the expiration of the '359, '752, '899, '349, '613, '952, '015, '347, and '878 Patents was an act of infringement of each of the '359, '752, '899, '349, '613, '952, '015, '347, and '878 Patents;

b. declaring that Defendants' commercial manufacture, use, offer for sale, or sale in, or importation into the United States, of Macleods' Generic Lopinavir/Ritonavir Tablets would constitute direct infringement under 35 U.S.C. §§ 271(a) and/or 271(e)(2)(A) of one or more claims of each of the '359, '752, '899, '349, '015, and '347 Patents;

c. declaring that Defendants' commercial manufacture, use, offer for sale, or sale in, or importation into the United States, of Macleods' Generic Lopinavir/Ritonavir Tablets would constitute induced infringement of one or more claims of each of the '752, '613, '952, and '878 Patents;

d. declaring that Defendants would induce infringement of one or more claims of each of the '752, '613, '952, and '878 Patents under 35 U.S.C. §§ 271(b) and/or 271(e)(2)(A) by its manufacture, use, offer to sell, and sale in, and importation into the United States, of Macleods' Generic Lopinavir/Ritonavir Tablets prior to expiration of the '752, '613, '952, and '878 Patents, and any additional dates of exclusivity;

e. enjoining Defendants, and all persons acting in concert with Defendants, from

seeking, obtaining, or maintaining approval of ANDA No. 204739 until the expiration of the '359, '752, '899, '349, '613, '952, '015, '347, and '878 Patents and any additional periods of exclusivity;

f. enjoining Defendants and all persons acting in concert with Defendants, from commercially manufacturing, using, offering for sale, or selling Macleods' Generic Lopinavir/Ritonavir Tablets within the United States, or importing into the United States Macleods' Generic Lopinavir/Ritonavir Tablets, until the expiration of the '359, '752, '899, '349, '613, '952, '015, '347, and '878 Patents, and any additional periods of exclusivity;

g. declaring the '359, '752, '899, '349, '613, '952, '015, '347, and '878 Patents valid and enforceable;

h. finding this to be an exceptional case and awarding AbbVie its costs, expenses, and disbursements in this action, including reasonable attorney fees, pursuant to 35 U.S.C. § 285;

i. awarding AbbVie its costs and expenses in this action; and

j. awarding AbbVie any further and additional relief as this Court deems just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Mary B. Graham

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