

**IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF ILLINOIS**

ABBVIE INC. and	)	
ABBVIE DEUTSCHLAND GMBH & CO. KG,	)	
	)	
Plaintiffs,	)	
	)	Civil Action No. 15-cv-1402
v.	)	
	)	
MYLAN PHARMACEUTICALS INC.,	)	
MYLAN LABORATORIES LTD.	)	
(f/k/a MATRIX LABORATORIES LTD.),	)	
MYLAN LABORATORIES INC.	)	
(f/k/a MATRIX LABORATORIES INC.), and	)	
MYLAN INC.	)	
(f/k/a MYLAN LABORATORIES LTD.),	)	
	)	
Defendants.	)	

**COMPLAINT**

Plaintiffs AbbVie Inc. and AbbVie Deutschland GmbH & Co. KG (collectively “AbbVie”), by way of this Complaint against Mylan Pharmaceuticals Inc., Mylan Laboratories Ltd. (formerly known as Matrix Laboratories Ltd.), Mylan Laboratories Inc. (formerly known as Matrix Laboratories Inc.), and Mylan Inc. (formerly known as Mylan Laboratories Ltd.) (collectively “Defendants” or “Mylan”), state as follows:

**THE PARTIES**

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

2. Plaintiff AbbVie Deutschland GmbH & Co. KG is a limited partnership organized and existing under the laws of Germany with its headquarters at Mainzer Straße 81, 65189

Wiesbaden, Germany. AbbVie Deutschland GmbH & Co. KG is governed by its General Partner, AbbVie Komplementar GmbH, and is a wholly-owned foreign subsidiary of AbbVie Inc.

3. On information and belief, Defendant Mylan Pharmaceuticals Inc. is a corporation organized and existing under the laws of West Virginia, having its principal place of business located at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505. On information and belief, Mylan Pharmaceuticals Inc. is a subsidiary of and agent for Defendant Mylan Inc.

4. On information and belief, Defendant Mylan Laboratories Limited (“Mylan Labs Ltd.”) is a limited company with a principal place of business located at Plot No. 564/A/22, Road No. 92, Jubilee Hills, Hyderabad, 500034 India. On information and belief, Defendant Mylan Inc. holds approximately 98% ownership and control in Mylan Labs Ltd. On information and belief, Mylan Labs Ltd. is formerly known as, and is the same entity as, Matrix Laboratories Limited.

5. On information and belief, Defendant Mylan Laboratories Inc. (“Mylan Labs Inc.”) is a corporation organized under the laws of Delaware, with a principal place of business located at 76 South Orange Avenue, Suite 301, South Orange, New Jersey 07079. On information and belief, Mylan Labs Inc. is a subsidiary of and agent for Defendant Mylan Inc. On information and belief, Mylan Labs Inc. is formerly known as, and is the same entity as, Matrix Laboratories Inc.

6. On information and belief, Defendant Mylan Inc. is a corporation organized under the laws of the commonwealth of Pennsylvania, with a principal place of business located at 1000 Mylan Blvd., Canonsburg, Pennsylvania, 15317. On information and belief, Mylan Inc., directly and/or through its subsidiaries, is in the business of manufacturing, marketing, and

selling generic pharmaceutical drugs for U.S. consumers. On information and belief, Mylan Inc. is formerly known as, and is the same entity as, Mylan Laboratories Inc.

7. On information and belief, the acts of Mylan Pharmaceuticals Inc. complained of herein were done at the direction of, with the authorization of, and/or with the cooperation, participation, and assistance of, and at least in part for the benefit of, Mylan Labs Ltd., Mylan Inc., and/or Mylan Labs Inc.

8. On information and belief, the acts of Mylan Labs Ltd. complained of herein were done at the direction of, with the authorization of, and/or with the cooperation, participation, and assistance of, and at least in part for the benefit of, Mylan Pharmaceuticals Inc., Mylan Inc., and/or Mylan Labs Inc.

9. On information and belief, the acts of Mylan Labs Inc. complained of herein were done at the direction of, with the authorization of, and/or with the cooperation, participation, and assistance of, and at least in part for the benefit of, Mylan Labs Ltd., Mylan Inc., and/or Mylan Pharmaceuticals Inc.

10. On information and belief, the acts of Mylan Inc. complained of herein were done at the direction of, with the authorization of, and/or with the cooperation, participation, and assistance of, and at least in part for the benefit of, Mylan Labs Ltd., Mylan Labs Inc., and/or Mylan Pharmaceuticals Inc.

11. On information and belief, Mylan Pharmaceuticals Inc., Mylan Labs Inc., Mylan Inc., and Mylan Labs Ltd. participate in the formulation, manufacture, and sales of various generic drug products, and regularly conduct business throughout the United States, including the State of Illinois, at least through participation in the sales of or selling those products.

**NATURE OF THE ACTION**

12. This is a civil action for patent infringement of United States Patent Number 8,025,899 B2 (“the ’899 Patent”), United States Patent Number 8,268,349 B2 (“the ’349 Patent”), United States Patent Number 8,309,613 B2 (“the ’613 Patent”), United States Patent Number 8,377,952 B2 (“the ’952 Patent”), United States Patent Number 8,399,015 B2 (“the ’015 Patent”), United States Patent Number 8,470,347 B2 (“the ’347 Patent”), and United States Patent Number 8,691,878 B2 (“the ’878 Patent”) arising 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 action relates to Abbreviated New Drug Application (“ANDA”) No. 91-202, which Mylan 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 a generic copy of AbbVie’s successful Kaletra<sup>®</sup> tablet product that is sold in the United States.

**JURISDICTION AND VENUE**

13. This is a civil action for patent infringement and declaratory judgment arising under the patent laws of the United States, 35 U.S.C. §§ 1 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).

14. On information and belief, this Court has personal jurisdiction over each Defendant.

15. On information and belief, Mylan Labs Ltd. formulates, develops, manufactures, markets, and sells or participates in the sales of active pharmaceutical ingredients (“APIs”), solid oral dosage forms, pharmaceutical formulations, and/or pharmaceutical products containing such APIs or pharmaceutical formulations (collectively “Mylan’s Products”). On information and

belief, Mylan Labs Ltd. routinely seeks FDA approval to market Mylan's Products in the United States through ANDA filings, or actively participates in those activities. Most of Mylan Labs Ltd.'s manufacturing facilities are FDA-approved and it focuses its marketing efforts on regulated markets such as the United States.

16. On information and belief, Mylan Labs Ltd., either directly or through one or more of its subsidiaries, affiliates, agents, distributors, or parent corporations (for example, including, but not limited to, Mylan Inc., Mylan Pharmaceuticals Inc., and Mylan Labs Inc.), sells and/or distributes a substantial volume of Mylan's Products in this judicial district, or actively participates in those activities. On information and belief, Mylan Labs Ltd. purposefully has conducted and continues to conduct substantial business in this judicial district, from which it has derived, directly or indirectly, substantial revenue.

17. On information and belief, Mylan Pharmaceuticals Inc., either directly or through one or more of its subsidiaries, affiliates, agents, distributors, or parent corporations (for example, including, but not limited to, Mylan Labs Ltd., Mylan Inc., or Mylan Labs Inc.), seeks FDA approval for, markets, sells, and/or distributes a substantial volume of Mylan's Products in this judicial district, or actively participates in those activities. On information and belief, Mylan Pharmaceuticals Inc. purposefully has conducted and continues to conduct substantial business in this judicial district, from which it has derived, directly or indirectly, substantial revenue.

18. On information and belief, this judicial district is a likely destination of products that will be manufactured and sold as a result of any FDA approval of Mylan's ANDA No. 91-202, which is the subject of this lawsuit. On information and belief, Mylan's actions relating to ANDA No. 91-202 complained of herein were done at the direction of, with the authorization of,

and with the cooperation, participation, and assistance of, and at least in part for the benefit of, companies Mylan Labs Ltd., Mylan Inc., and/or Mylan Labs Inc.

19. On information and belief, Mylan Labs Inc., either directly or through one or more of its subsidiaries, affiliates, agents, distributors, or parent corporations (for example, including, but not limited to, Mylan Pharmaceuticals Inc., Mylan Inc., or Mylan Labs Inc.), seeks FDA approval for, markets, sells, and/or distributes a substantial volume of Mylan's Products in this judicial district, or actively participates in those activities. On information and belief, Mylan Labs Inc. has purposefully conducted and continues to conduct substantial business in this judicial district, from which it has derived substantial revenue.

20. Mylan Inc. is in the business of formulating, developing, manufacturing, and selling generic drugs. Mylan Inc.'s U.S. product portfolio includes more than 1,300 products, 320 pharmaceutical products, and 260 drug products in tablet or capsule form. Mylan Inc., either directly or through one or more of its wholly owned subsidiaries, agents, or distributors, sells and/or distributes a substantial volume of its pharmaceutical products in this judicial district, or actively participates in those activities. Mylan Inc. has purposefully conducted and continues to conduct substantial business in this judicial district, from which it has derived substantial revenue.

21. On information and belief, Mylan Pharmaceuticals Inc. is qualified to do business in the State of Illinois and holds a current and valid wholesale drug distributor license and controlled substance drug distribution license issued by the State of Illinois, for the purpose of, *inter alia*, distributing Mylan's Products in Illinois and in this judicial district.

22. On information and belief, Mylan Pharmaceuticals Inc., Mylan Labs Inc., Mylan Inc., and Mylan Labs Ltd. operate as an integrated business ultimately controlled by Mylan Inc.

23. On information and belief, Defendants have collaborated to develop, seek FDA approval for, manufacture, import, distribute, and sell pharmaceutical products (including generic drug products manufactured and sold pursuant to approved ANDAs) in the United States, and in Illinois, including this judicial district.

24. On information and belief, Defendants acted in concert to seek approval from the FDA to market generic copies of AbbVie's Kaletra<sup>®</sup> tablets that are the subject of ANDA No. 91-202 throughout the United States and in this judicial district.

25. Mylan's ANDA No. 91-202 is already the subject of a pending lawsuit in this District, *AbbVie Inc. v. Matrix Laboratories Inc.*, Case No. 1:09-cv-01586 (N.D. Ill. 2009), currently involving Plaintiffs, Mylan Inc., Matrix Laboratories Ltd. (now known as Mylan Laboratories Ltd.), and Matrix Laboratories Inc. (now known as Mylan Laboratories Inc.).

26. Mylan Pharmaceuticals Inc. and Mylan Inc. have previously availed themselves of this forum by asserting counterclaims arising under the Patent Laws of the United States in other civil actions initiated in this Court.

27. This Court has personal jurisdiction over each of the Defendants by virtue of, *inter alia*, their 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 to residents of this judicial district, and the fact that they have availed themselves of the rights afforded in this judicial district.

28. This Court also has personal jurisdiction over each of the Defendants by virtue of the fact that, *inter alia*, Defendants have 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 Inc., a Delaware corporation whose corporate headquarters is located in Illinois in this District.

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

### **BACKGROUND**

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

31. On information and belief, Mylan Pharmaceuticals Inc., Mylan Labs Ltd., Mylan Inc., and Mylan Labs Inc. acted in concert to file with the FDA ANDA No. 91-202 under 21 U.S.C. § 355(j), seeking FDA approval to market two dosage strengths of generic lopinavir/ritonavir (“Mylan’s generic lopinavir/ritonavir tablets”) as generic copies of AbbVie’s Kaletra<sup>®</sup> tablets in the United States.

32. ANDA No. 91-202 seeks FDA approval of a pharmaceutical composition comprising ritonavir and lopinavir in 100 mg/25 mg and 200 mg/50 mg tablet dosage forms and strengths.

33. On or about December 30, 2014, AbbVie Inc. received a letter sent on behalf of Mylan Pharmaceuticals Inc., dated December 23, 2014, purporting to be a “Notice of Paragraph IV Certification” for ANDA No. 91-202 (“Mylan’s Second Notice Letter”) pursuant to sections 505(j)(2)(B)(ii) and 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act and 21 C.F.R. §§ 314.94 and 314.95. Mylan’s Second Notice Letter notified AbbVie that Mylan Pharmaceuticals Inc. had filed ANDA No. 91-202, seeking approval to market Mylan’s generic



lopinavir/ritonavir tablets prior to the expiration of the '899, '349, '613, '952, '015, '347, and '878 Patents.

34. On information and belief, Defendants intend to capture some of the market for AbbVie's Kaletra<sup>®</sup> products with Mylan's generic lopinavir/ritonavir tablets, so as to induce healthcare providers who currently prescribe Kaletra<sup>®</sup> products and/or patients who currently take Kaletra<sup>®</sup> products to switch to the prescription and/or taking of Mylan's generic lopinavir/ritonavir tablets.

#### **THE PATENTS-IN-SUIT**

35. The '899 Patent was duly and legally issued by the United States Patent and Trademark Office ("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 FDA publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations" (also called the "Orange Book") for NDA No. 21-906. A true and correct copy of the '899 Patent is attached as Exhibit A.

36. 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. A true and correct copy of the '613 Patent is attached as Exhibit B.

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. A true and correct copy of the '349 Patent is attached as Exhibit C.

38. 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. A true and correct copy of the '015 Patent is attached as Exhibit D.

39. 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. A true and correct copy of the '347 Patent is attached as Exhibit E.

40. 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. A true and correct copy of the '878 Patent is attached as Exhibit F.

41. 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. A true and correct copy of the '952 Patent is attached as Exhibit G.

**FIRST COUNT**  
**PATENT INFRINGEMENT OF THE '899 PATENT**

42. Paragraphs 1–41 are incorporated herein by reference.

43. On information and belief, Defendants acted in concert to file and have maintained ANDA No. 91-202 in order to obtain approval to manufacture, use, and market Mylan's generic lopinavir/ritonavir tablets in the United States before the expiration of the '899 Patent.

44. 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, unenforceable, and/or not infringed.

45. On information and belief, Mylan Pharmaceuticals Inc. has represented to the FDA in Mylan's ANDA No. 91-202 that Mylan's generic lopinavir/ritonavir tablets are bioequivalent, therapeutically equivalent, and pharmaceutically equivalent to AbbVie's Kaletra<sup>®</sup> tablets.

46. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 91-202 seeking approval for the commercial manufacture, use, or sale of Mylan's 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.

47. AbbVie will be irreparably harmed if Defendants are permitted to make, use, sell, offer to sell, and/or import their 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. 91-202 for Mylan's generic lopinavir/ritonavir tablets 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.

**SECOND COUNT**  
**PATENT INFRINGEMENT OF THE '613 PATENT**

48. Paragraphs 1–47 are incorporated herein by reference.

49. On information and belief, Defendants acted in concert to file and have maintained ANDA No. 91-202 in order to obtain approval to manufacture, use, and market Mylan's generic lopinavir/ritonavir tablets in the United States before the expiration of the '613 Patent.

50. 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, unenforceable, and/or not infringed.

51. On information and belief, Mylan Pharmaceuticals Inc. has represented to the FDA in Mylan's ANDA No. 91-202 that Mylan's generic lopinavir/ritonavir tablets are bioequivalent, therapeutically equivalent, and pharmaceutically equivalent to AbbVie's Kaletra<sup>®</sup> tablets.

52. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 91-202 seeking approval for the commercial manufacture, use, or sale of Mylan's generic lopinavir/ritonavir tablets before the expiration date of the '613 Patent constitutes infringement of one or more claims of the '613 patent, either literally or under the doctrine of equivalents.

53. Under 35 U.S.C. §§ 271(b) and (e)(2)(A), the submission to the FDA of ANDA No. 91-202 seeking approval for the commercial manufacture, use, or sale of Mylan's 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.

54. On information and belief, Defendants are actively seeking FDA approval to sell Mylan's generic lopinavir/ritonavir tablets for the same indication, the same dosages, and the same method of use as the Kaletra<sup>®</sup> products sold by AbbVie.

55. On information and belief, Defendants' offering to sell, sale, making, and/or importation of Mylan's generic lopinavir/ritonavir tablets, once ANDA No. 91-202 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.

56. Defendants have knowledge and are aware of AbbVie's '613 Patent, as evidenced by Mylan's Second Notice Letter.

57. On information and belief, by the filing of ANDA No. 91-202 with a proposed package insert having directions that encourage patients to administer and/or use Mylan's generic lopinavir/ritonavir tablets to treat an HIV infection, Defendants have an affirmative intent to actively induce infringement by others of one or more claims of the '613 Patent, either literally or under the doctrine of equivalents.

58. On information and belief, by the filing of ANDA No. 91-202 with a proposed package insert having directions that encourage medical practitioners to prescribe and/or administer Mylan's generic lopinavir/ritonavir tablets to treat an HIV infection, Defendants have an affirmative intent to actively induce infringement by others of one or more claims of the '613 Patent, either literally or under the doctrine of equivalents.

59. On information and belief, Defendants are aware and/or have knowledge that patients will administer and/or use Mylan's generic lopinavir/ritonavir tablets and, therefore, will directly infringe at least one claim of the '613 Patent, either literally or under the doctrine of equivalents.

60. On information and belief, Defendants are aware and/or have knowledge that medical practitioners will prescribe and/or administer Mylan's generic lopinavir/ritonavir tablets and, therefore, will directly infringe at least one claim of the '613 Patent, either literally or under the doctrine of equivalents.

61. On information and belief, Defendants are aware and/or have knowledge that patients will administer and/or use Mylan's generic lopinavir/ritonavir tablets in a method of treatment according to the directions and instructions in the proposed package insert and, therefore, will directly infringe at least one claim of the '613 Patent, either literally or under the doctrine of equivalents.

62. On information and belief, Defendants are aware and/or have knowledge that medical practitioners will prescribe and/or administer Mylan's generic lopinavir/ritonavir tablets in a method of treatment according to the directions and instructions in the proposed package insert and, therefore, will directly infringe at least one claim of the '613 Patent, either literally or under the doctrine of equivalents.

63. 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 Mylan's generic lopinavir/ritonavir tablets.

64. On information and belief, therefore, Defendants' offering to sell, sale, making, and/or importation of Mylan's 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.

65. On information and belief, Mylan's generic lopinavir/ritonavir tablets, if approved by the FDA, will be imported by Defendants into the United States, and marketed, offered for sale, and sold in the United States by them or on their behalf, and will be administered and/or used in patients in the United States, and will be administered and/or prescribed 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 Mylan, patients, and/or medical practitioners. On information and belief, use, administration, and prescription of Mylan's 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.

66. Defendants' threatened actions in actively aiding, abetting, encouraging, and inducing sales of Mylan's generic lopinavir/ritonavir tablets would infringe one or more claims of the '613 Patent, either literally or under the doctrine of equivalents.

67. AbbVie will be irreparably harmed if Defendants are permitted to make, use, sell, offer to sell, and/or import Mylan's 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. 91-202 for Mylan's generic lopinavir/ritonavir tablets 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.

**THIRD COUNT**  
**PATENT INFRINGEMENT OF THE '349 PATENT**

68. Paragraphs 1–67 are incorporated herein by reference.

69. On information and belief, Defendants collectively filed and have maintained ANDA No. 91-202 in order to obtain approval to manufacture, use, and market Mylan's generic lopinavir/ritonavir tablets in the United States before the expiration of the '349 Patent.

70. 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, unenforceable, and/or not infringed.

71. On information and belief, Mylan Pharmaceuticals Inc. has represented to the FDA in Mylan's ANDA No. 91-202 that Mylan's generic lopinavir/ritonavir tablets are bioequivalent, therapeutically equivalent, and pharmaceutically equivalent to AbbVie's Kaletra<sup>®</sup> tablets.

72. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 91-202 seeking approval for the commercial manufacture, use, or sale of Mylan's 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.

73. AbbVie will be irreparably harmed if Defendants are permitted to make, use, sell, offer to sell, and/or import Mylan's 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. 91-202 for Mylan's generic lopinavir/ritonavir tablets 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.

**FOURTH COUNT**  
**PATENT INFRINGEMENT OF THE '015 PATENT**

74. Paragraphs 1–73 are incorporated herein by reference.

75. On information and belief, Defendants collectively filed and have maintained ANDA No. 91-202 in order to obtain approval to manufacture, use, and market Mylan's generic lopinavir/ritonavir tablets in the United States before the expiration of the '015 Patent.



76. 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, unenforceable, and/or not infringed.

77. On information and belief, Mylan Pharmaceuticals Inc. has represented to the FDA in Mylan's ANDA No. 91-202 that Mylan's generic lopinavir/ritonavir tablets are bioequivalent, therapeutically equivalent, and pharmaceutically equivalent to AbbVie's Kaletra<sup>®</sup> tablets.

78. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 91-202 seeking approval for the commercial manufacture, use, or sale of Mylan's 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.

79. AbbVie will be irreparably harmed if Defendants are permitted to make, use, sell, offer to sell, and/or import Mylan's 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. 91-202 for Mylan's generic lopinavir/ritonavir tablets 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.

**FIFTH COUNT**  
**PATENT INFRINGEMENT OF THE '347 PATENT**

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

81. On information and belief, Defendants collectively filed and have maintained ANDA No. 91-202 in order to obtain approval to manufacture, use, and market Mylan's generic lopinavir/ritonavir tablets in the United States before the expiration of the '347 Patent.

82. 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, unenforceable, and/or not infringed.

83. On information and belief, Mylan Pharmaceuticals Inc. has represented to the FDA in Mylan's ANDA No. 91-202 that Mylan's generic lopinavir/ritonavir tablets are bioequivalent, therapeutically equivalent, and pharmaceutically equivalent to AbbVie's Kaletra<sup>®</sup> tablets.

84. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 91-202 seeking approval for the commercial manufacture, use, or sale of Mylan's 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.

85. AbbVie will be irreparably harmed if Defendants are permitted to make, use, sell, offer to sell, and/or import Mylan's 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. 91-202 for Mylan's generic lopinavir/ritonavir tablets 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.

**SIXTH COUNT**  
**PATENT INFRINGEMENT OF THE '878 PATENT**

86. Paragraphs 1–85 are incorporated herein by reference.

87. On information and belief, Defendants collectively filed and have maintained ANDA No. 91-202 in order to obtain approval to manufacture, use, and market Mylan's generic lopinavir/ritonavir tablets in the United States before the expiration of the '878 Patent.

88. 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, unenforceable, and/or not infringed.

89. On information and belief, Mylan Pharmaceuticals Inc. has represented to the FDA in Mylan's ANDA No. 91-202 that Mylan's generic lopinavir/ritonavir tablets are bioequivalent, therapeutically equivalent, and pharmaceutically equivalent to AbbVie's Kaletra<sup>®</sup> tablets.

90. Under 35 U.S.C. §§ 271(b) and (e)(2)(A), the submission to the FDA of ANDA No. 91-202 seeking approval for the commercial manufacture, use, or sale of Mylan's 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.

91. On information and belief, Defendants are actively seeking FDA approval to sell Mylan's generic lopinavir/ritonavir tablets for the same indication, the same dosages, and the same method of use as the Kaletra<sup>®</sup> products sold by AbbVie.

92. On information and belief, Defendants' offering to sell, sale, making, and/or importation of Mylan's generic lopinavir/ritonavir tablets, once ANDA No. 91-202 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.

93. Defendants have knowledge and are aware of AbbVie's '878 Patent, as evidenced by Mylan's Second Notice Letter.

94. On information and belief, by the filing of ANDA No. 91-202 with a proposed package insert having directions that encourage patients to administer and/or use Mylan's

generic lopinavir/ritonavir tablets to treat HIV, Defendants have an affirmative intent to actively induce infringement by others of one or more claims of the '878 Patent, either literally or under the doctrine of equivalents.

95. On information and belief, by the filing of ANDA No. 91-202 with a proposed package insert having directions that encourage medical practitioners to prescribe and/or administer Mylan's generic lopinavir/ritonavir tablets to treat HIV, Defendants have an affirmative intent to actively induce infringement by others of one or more claims of the '878 Patent, either literally or under the doctrine of equivalents.

96. On information and belief, Defendants are aware and/or have knowledge that patients will administer and/or use Mylan's generic lopinavir/ritonavir tablets and, therefore, will directly infringe at least one claim of the '878 Patent, either literally or under the doctrine of equivalents.

97. On information and belief, Defendants are aware and/or have knowledge that medical practitioners will prescribe and/or administer Mylan's generic lopinavir/ritonavir tablets and, therefore, will directly infringe at least one claim of the '878 Patent, either literally or under the doctrine of equivalents.

98. On information and belief, Defendants are aware and/or have knowledge that patients will administer and/or use Mylan's generic lopinavir/ritonavir tablets in a method of treatment according to the directions and instructions in the proposed package insert and, therefore, will directly infringe at least one claim of the '878 Patent, either literally or under the doctrine of equivalents.

99. On information and belief, Defendants are aware and/or have knowledge that medical practitioners will prescribe and/or administer Mylan's generic lopinavir/ritonavir tablets

in a method of treatment according to the directions and instructions in the proposed package insert and, therefore, will directly infringe at least one claim of the '878 Patent, either literally or under the doctrine of equivalents.

100. 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 Mylan's generic lopinavir/ritonavir tablets.

101. On information and belief, therefore, Defendants' offering to sell, sale, making, and/or importation of Mylan's 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.

102. On information and belief, Mylan's generic lopinavir/ritonavir tablets, if approved by the FDA, will be imported by Defendants into the United States, and marketed, offered for sale, and sold in the United States by them or on their behalf, and will be administered and/or used by patients in the United States, and will be administered and/or prescribed 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 Mylan, patients, and/or medical practitioners. On information and belief, use, administration, and prescription of Mylan's 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.

103. Defendants' threatened actions in actively aiding, abetting, encouraging, and inducing sales of Mylan's generic lopinavir/ritonavir tablets would infringe one or more claims of the '878 Patent, either literally or under the doctrine of equivalents.

104. AbbVie will be irreparably harmed if Defendants are permitted to make, use, sell, offer to sell, and/or import Mylan's 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. 91-202 for Mylan's generic lopinavir/ritonavir tablets 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.

**SEVENTH COUNT**  
**PATENT INFRINGEMENT OF THE '952 PATENT**

105. Paragraphs 1–104 are incorporated herein by reference.

106. On information and belief, Defendants acted in concert to file and have maintained ANDA No. 91-202 in order to obtain approval to manufacture, use, and market Mylan's generic lopinavir/ritonavir tablets in the United States before the expiration of the '952 Patent.

107. 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, unenforceable, and/or not infringed.

108. On information and belief, Mylan Pharmaceuticals Inc. has represented to the FDA in Mylan's ANDA No. 91-202 that Mylan's generic lopinavir/ritonavir tablets are

bioequivalent, therapeutically equivalent, and pharmaceutically equivalent to AbbVie's Kaletra<sup>®</sup> tablets.

109. Under 35 U.S.C. §§ 271(b) and (e)(2)(A), the submission to the FDA of ANDA No. 91-202 seeking approval for the commercial manufacture, use, or sale of Mylan's 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.

110. On information and belief, Defendants are actively seeking FDA approval to sell Mylan's generic lopinavir/ritonavir tablets for the same indication, the same dosages, and the same method of use as the Kaletra<sup>®</sup> products sold by AbbVie.

111. On information and belief, Defendants' offering to sell, sale, making, and/or importation of Mylan's generic lopinavir/ritonavir tablets, once ANDA No. 91-202 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.

112. Defendants have knowledge and are aware of AbbVie's '952 Patent, as evidenced by Mylan's Second Notice Letter.

113. On information and belief, by the filing of ANDA No. 91-202 with a proposed package insert having directions that encourage patients to administer and/or use Mylan's generic lopinavir/ritonavir tablets to treat HIV, Defendants have an affirmative intent to actively induce infringement by others of one or more claims of the '952 Patent, either literally or under the doctrine of equivalents.

114. On information and belief, by the filing of ANDA No. 91-202 with a proposed package insert having directions that encourage medical practitioners to prescribe and/or

administer Mylan's generic lopinavir/ritonavir tablets to treat HIV, Defendants have an affirmative intent to actively induce infringement by others of one or more claims of the '952 Patent, either literally or under the doctrine of equivalents.

115. On information and belief, Defendants are aware and/or have knowledge that patients will administer and/or use Mylan's generic lopinavir/ritonavir tablets and, therefore, will directly infringe at least one claim of the '952 Patent, either literally or under the doctrine of equivalents.

116. On information and belief, Defendants are aware and/or have knowledge that medical practitioners will prescribe and/or administer Mylan's generic lopinavir/ritonavir tablets and, therefore, will directly infringe at least one claim of the '952 Patent, either literally or under the doctrine of equivalents.

117. On information and belief, Defendants are aware and/or have knowledge that patients will administer and/or use Mylan's generic lopinavir/ritonavir tablets in a method of treatment according to the directions and instructions in the proposed package insert and, therefore, will directly infringe at least one claim of the '952 Patent, either literally or under the doctrine of equivalents.

118. On information and belief, Defendants are aware and/or have knowledge that medical practitioners will prescribe and/or administer Mylan's generic lopinavir/ritonavir tablets in a method of treatment according to the directions and instructions in the proposed package insert and, therefore, will directly infringe at least one claim of the '952 Patent, either literally or under the doctrine of equivalents.

119. 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 Mylan's generic lopinavir/ritonavir tablets.

120. On information and belief, therefore, Defendants' offering to sell, sale, making, and/or importation of Mylan's 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.

121. On information and belief, Mylan's generic lopinavir/ritonavir tablets, if approved by the FDA, will be imported by Defendants into the United States, and marketed, offered for sale, and sold in the United States by them or on their behalf, and will be administered and/or used by patients in the United States, and will be administered and/or prescribed 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 Mylan, patients, and/or medical practitioners. On information and belief, use, administration, and prescription of Mylan's 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.

122. Defendants' threatened actions in actively aiding, abetting, encouraging, and inducing sales of Mylan's generic lopinavir/ritonavir tablets would infringe one or more claims of the '952 Patent, either literally or under the doctrine of equivalents.

123. AbbVie will be irreparably harmed if Defendants are permitted to make, use, sell, offer to sell, and/or import Mylan's 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. 91-202 for Mylan's generic lopinavir/ritonavir tablets 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.

**EIGHTH COUNT**  
**DECLARATORY JUDGMENT AS TO THE '899 PATENT**

124. Paragraphs 1–123 are incorporated herein by reference.

125. On information and belief, Defendants are actively seeking FDA approval to sell Mylan's generic lopinavir/ritonavir tablets for the same indication, the same dosages, and the same method of use as the Kaletra<sup>®</sup> products sold by AbbVie.

126. On information and belief, upon FDA approval of ANDA No. 91-202, 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 Mylan's generic lopinavir/ritonavir tablets, unless this Court orders that the effective date of any FDA approval of ANDA No. 91-202 shall be no earlier than the expiration date of the '899 Patent and any additional periods of exclusivity.

127. On information and belief, Defendants intend to commence sales of Mylan's generic lopinavir/ritonavir tablets immediately upon receiving final approval from the FDA.

128. On information and belief, in Mylan's ANDA No. 91-202, Mylan Pharmaceuticals Inc. has represented to the FDA that Mylan's generic lopinavir/ritonavir tablets are bioequivalent, therapeutically equivalent, and pharmaceutically equivalent to AbbVie's Kaletra<sup>®</sup> tablets.

129. On information and belief, therefore, Defendants' manufacture, importation, sale, and/or offer for sale of Mylan's 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.

130. Defendants have knowledge and are aware of AbbVie's '899 Patent, as evidenced by Mylan's Second Notice Letter.

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

132. 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 '899 Patent.

133. 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.

134. 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.

**NINTH COUNT**  
**DECLARATORY JUDGMENT AS TO THE '613 PATENT**

135. Paragraphs 1–134 are incorporated herein by reference.

136. On information and belief, Defendants are actively seeking FDA approval to sell Mylan's generic lopinavir/ritonavir tablets for the same indication, the same dosages, and the same method of use as the Kaletra<sup>®</sup> products sold by AbbVie.

137. On information and belief, upon FDA approval of ANDA No. 91-202, 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. 91-202 shall be no earlier than the expiration date of the '613 Patent and any additional periods of exclusivity.

138. On information and belief, Defendants intend to commence sales of Mylan's generic lopinavir/ritonavir tablets immediately upon receiving final approval from the FDA.

139. On information and belief, in Mylan's ANDA No. 91-202, Mylan Pharmaceuticals Inc. has represented to the FDA that Mylan's generic lopinavir/ritonavir tablets are bioequivalent, therapeutically equivalent, and pharmaceutically equivalent to AbbVie's Kaletra<sup>®</sup> tablets.

140. On information and belief, Defendants' offering to sell, sale, making, and/or importation of Mylan's generic lopinavir/ritonavir tablets, once approved by the FDA, would actively induce infringement of at least one of the claims of the '613 Patent, either literally or under the doctrine of equivalents.

141. Defendants have knowledge and are aware of AbbVie's '613 Patent, as evidenced by Mylan's Second Notice Letter.

142. On information and belief, by the filing of ANDA No. 91-202 with a proposed package insert having directions that encourage patients to administer and/or use Mylan's generic lopinavir/ritonavir tablets to treat an HIV infection, Defendants have an affirmative intent to actively induce infringement by others of one or more claims of the '613 Patent, either literally or under the doctrine of equivalents.

143. On information and belief, by the filing of ANDA No. 91-202 with a proposed package insert having directions that encourage medical practitioners to prescribe and/or administer Mylan's generic lopinavir/ritonavir tablets to treat an HIV infection, Defendants have an affirmative intent to actively induce infringement by others of one or more claims of the '613 Patent, either literally or under the doctrine of equivalents.

144. On information and belief, Defendants are aware and/or have knowledge that patients will administer and/or use Mylan's generic lopinavir/ritonavir tablets and, therefore, will directly infringe at least one claim of the '613 Patent, either literally or under the doctrine of equivalents.

145. On information and belief, Defendants are aware and/or have knowledge that medical practitioners will prescribe and/or administer Mylan's generic lopinavir/ritonavir tablets and, therefore, will directly infringe at least one claim of the '613 Patent, either literally or under the doctrine of equivalents.

146. On information and belief, Defendants are aware and/or have knowledge that patients will administer and/or use Mylan's generic lopinavir/ritonavir tablets in a method of treatment according to the directions and instructions in the proposed package insert and, therefore, will directly infringe at least one claim of the '613 Patent, either literally or under the doctrine of equivalents.

147. On information and belief, Defendants are aware and/or have knowledge that medical practitioners will prescribe and/or administer Mylan's generic lopinavir/ritonavir tablets in a method of treatment according to the directions and instructions in the proposed package insert and, therefore, will directly infringe at least one claim of the '613 Patent, either literally or under the doctrine of equivalents.

148. 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 Mylan's generic lopinavir/ritonavir tablets.

149. On information and belief, therefore, Defendants' offering to sell, sale, making, and/or importation of Mylan's 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.

150. On information and belief, Mylan's generic lopinavir/ritonavir tablets, if approved by the FDA, will be imported by Defendants into the United States, and marketed, offered for sale, and sold in the United States by Defendants, and will be administered and/or used by patients in the United States, and will be administered and/or prescribed 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 Mylan, patients, and/or medical practitioners. On information and belief, use, administration, and prescription of Mylan's 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 medical practitioners and patients, with knowledge and specific intent that the conduct will be in contravention of AbbVie's rights under the '613 Patent.

151. If the FDA approves ANDA No. 91-202, Defendants will make, sell, offer to sell, or import into the United States Mylan's generic lopinavir/ritonavir tablets before the expiration

of the '613 Patent, and will actively induce infringement by others under 35 U.S.C. § 271(b) of one or more claims of the '613 Patent, either literally or under the doctrine of equivalents.

152. Defendants' threatened actions in actively aiding, abetting, encouraging, and inducing sales of Mylan's generic lopinavir/ritonavir tablets would infringe one or more claims of the '613 Patent, either literally or under the doctrine of equivalents.

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

154. 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.

155. 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.

156. 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.

**TENTH COUNT**  
**DECLARATORY JUDGMENT AS TO THE '349 PATENT**

157. Paragraphs 1–156 are incorporated herein by reference.

158. On information and belief, Defendants are actively seeking FDA approval to sell Mylan's generic lopinavir/ritonavir tablets for the same indication, the same dosages, and the same method of use as the Kaletra<sup>®</sup> products sold by AbbVie.

159. On information and belief, upon FDA approval of ANDA No. 91-202, 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 Mylan's generic lopinavir/ritonavir tablets, unless this Court orders that the effective date of any FDA approval of ANDA No. 91-202 shall be no earlier than the expiration date of the '349 Patent and any additional periods of exclusivity.

160. On information and belief, Defendants intend to commence sales of Mylan's generic lopinavir/ritonavir tablets immediately upon receiving final approval from the FDA.

161. On information and belief, in Mylan's ANDA No. 91-202, Mylan Pharmaceuticals Inc. has represented to the FDA that Mylan's generic lopinavir/ritonavir tablets are bioequivalent, therapeutically equivalent, and pharmaceutically equivalent to AbbVie's Kaletra<sup>®</sup> tablets.

162. On information and belief, therefore, Defendants' manufacture, importation, sale, and/or offer for sale of Mylan's 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.

163. Defendants have knowledge and are aware of AbbVie's '349 Patent, as evidenced by Mylan's Second Notice Letter.

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

165. 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.



166. 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.

167. In view of the foregoing, there exists a substantial controversy between AbbVie and Mylan, 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 '015 PATENT**

168. Paragraphs 1–167 are incorporated herein by reference.

169. On information and belief, Defendants are actively seeking FDA approval to sell Mylan's generic lopinavir/ritonavir tablets for the same indication, the same dosages, and the same method of use as the Kaletra<sup>®</sup> products sold by AbbVie.

170. On information and belief, upon FDA approval of ANDA No. 91-202, 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 Mylan's generic lopinavir/ritonavir tablets, unless this Court orders that the effective date of any FDA approval of ANDA No. 91-202 shall be no earlier than the expiration date of the '015 Patent and any additional periods of exclusivity.

171. On information and belief, Defendants intend to commence sales of Mylan's generic lopinavir/ritonavir tablets immediately upon receiving final approval from the FDA.

172. On information and belief, in Mylan's ANDA No. 91-202, Mylan Pharmaceuticals Inc. has represented to the FDA that Mylan's generic lopinavir/ritonavir tablets are bioequivalent, therapeutically equivalent, and pharmaceutically equivalent to AbbVie's Kaletra<sup>®</sup> tablets.

173. On information and belief, therefore, Defendants' manufacture, importation, sale, and/or offer for sale of Mylan's 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.

174. Defendants have knowledge and are aware of AbbVie's '015 Patent, as evidenced by Mylan's Second Notice Letter.

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

176. 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 Mylan's threatened infringement of the '015 Patent.

177. 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.

178. In view of the foregoing, there exists a substantial controversy between AbbVie and Mylan, 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 '347 PATENT**

179. Paragraphs 1–178 are incorporated herein by reference.

180. On information and belief, Defendants are actively seeking FDA approval to sell Mylan's generic lopinavir/ritonavir tablets for the same indication, the same dosages, and the same method of use as the Kaletra<sup>®</sup> products sold by AbbVie.

181. On information and belief, upon FDA approval of ANDA No. 91-202, 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 Mylan's generic lopinavir/ritonavir tablets, unless this Court orders that the effective date of any FDA approval of ANDA No. 91-202 shall be no earlier than the expiration date of the '347 Patent and any additional periods of exclusivity.

182. On information and belief, Defendants intend to commence sales of Mylan's generic lopinavir/ritonavir tablets immediately upon receiving final approval from the FDA.

183. On information and belief, in Mylan's ANDA No. 91-202, Mylan Pharmaceuticals Inc. has represented to the FDA that Mylan's generic lopinavir/ritonavir tablets are bioequivalent, therapeutically equivalent, and pharmaceutically equivalent to AbbVie's Kaletra<sup>®</sup> tablets.

184. On information and belief, therefore, Defendants' manufacture, importation, sale, and/or offer for sale of Mylan's 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.

185. Defendants have knowledge and are aware of AbbVie's '347 Patent, as evidenced by Mylan's Second Notice Letter.

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

187. 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.

188. 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.

189. In view of the foregoing, there exists a substantial controversy between AbbVie and Mylan, 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 '878 PATENT**

190. Paragraphs 1–189 are incorporated herein by reference.

191. On information and belief, Defendants are actively seeking FDA approval to sell Mylan's generic lopinavir/ritonavir tablets for the same indication, the same dosages, and the same method of use as the Kaletra<sup>®</sup> products sold by AbbVie.

192. On information and belief, upon FDA approval of ANDA No. 91-202, 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. 91-202 shall be no earlier than the expiration date of the '878 Patent and any additional periods of exclusivity.

193. On information and belief, Defendants intend to commence sales of Mylan's generic lopinavir/ritonavir tablets immediately upon receiving final approval from the FDA.

194. On information and belief, in Mylan's ANDA No. 91-202, Mylan Pharmaceuticals Inc. has represented to the FDA that Mylan's generic lopinavir/ritonavir tablets are bioequivalent, therapeutically equivalent, and pharmaceutically equivalent to AbbVie's Kaletra<sup>®</sup> tablets.

195. On information and belief, Defendants' offering to sell, sale, making, and/or importation of Mylan's generic lopinavir/ritonavir tablets, once approved by the FDA, would actively induce infringement of at least one of the claims of the '878 Patent, either literally or under the doctrine of equivalents.

196. Defendants have knowledge and are aware of AbbVie's '878 Patent, as evidenced by Mylan's Second Notice Letter.

197. On information and belief, by the filing of ANDA No. 91-202 with a proposed package insert having directions that encourage patients to administer and/or use Mylan's generic lopinavir/ritonavir tablets to treat HIV, Defendants have an affirmative intent to actively induce infringement by others of one or more claims of the '878 Patent, either literally or under the doctrine of equivalents.

198. On information and belief, by the filing of ANDA No. 91-202 with a proposed package insert having directions that encourage medical practitioners to prescribe and/or administer Mylan's generic lopinavir/ritonavir tablets to treat HIV, Defendants have an affirmative intent to actively induce infringement by others of one or more claims of the '878 Patent, either literally or under the doctrine of equivalents.

199. On information and belief, Defendants are aware and/or have knowledge that patients will administer and/or use Mylan's generic lopinavir/ritonavir tablets and, therefore, will directly infringe at least one claim of the '878 Patent, either literally or under the doctrine of equivalents.

200. On information and belief, Defendants are aware and/or have knowledge that medical practitioners will prescribe and/or administer Mylan's generic lopinavir/ritonavir tablets

and, therefore, will directly infringe at least one claim of the '878 Patent, either literally or under the doctrine of equivalents.

201. On information and belief, Defendants are aware and/or have knowledge that patients will administer and/or use Mylan's generic lopinavir/ritonavir tablets in a method of treatment according to the directions and instructions in the proposed package insert and, therefore, will directly infringe at least one claim of the '878 Patent, either literally or under the doctrine of equivalents.

202. On information and belief, Defendants are aware and/or have knowledge that medical practitioners will prescribe and/or administer Mylan's generic lopinavir/ritonavir tablets in a method of treatment according to the directions and instructions in the proposed package insert and, therefore, will directly infringe at least one claim of the '878 Patent, either literally or under the doctrine of equivalents.

203. 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 Mylan's generic lopinavir/ritonavir tablets.

204. On information and belief, therefore, Defendants' offering to sell, sale, making, and/or importation of Mylan's 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.

205. On information and belief, Mylan's generic lopinavir/ritonavir tablets, if approved by the FDA, will be imported by Defendants into the United States, and marketed, offered for sale, and sold in the United States by Defendants, and will be administered and/or used by

patients in the United States, and will be administered and/or prescribed 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 Mylan, patients, and/or medical practitioners. On information and belief, use, administration, and prescription of Mylan's 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 medical practitioners and patients, with knowledge and specific intent that the conduct will be in contravention of AbbVie's rights under the '878 Patent.

206. If the FDA approves ANDA No. 91-202, Defendants will make, sell, offer to sell, or import into the United States Mylan's generic lopinavir/ritonavir tablets before the expiration of the '878 Patent, and will actively induce infringement by others under 35 U.S.C. § 271(b) of one or more claims of the '878 Patent, either literally or under the doctrine of equivalents.

207. Defendants threatened actions in actively aiding, abetting, encouraging, and inducing sales of Mylan's generic lopinavir/ritonavir tablets would infringe one or more claims of the '878 Patent, either literally or under the doctrine of equivalents.

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

209. 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.

210. 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.

211. 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.

**FOURTEENTH COUNT**  
**DECLARATORY JUDGMENT AS TO THE '952 PATENT**

212. Paragraphs 1–211 are incorporated herein by reference.

213. On information and belief, Defendants are actively seeking FDA approval to sell Mylan's generic lopinavir/ritonavir tablets for the same indication, the same dosages, and the same method of use as the Kaletra<sup>®</sup> products sold by AbbVie.

214. On information and belief, upon FDA approval of ANDA No. 91-202, 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. 91-202 shall be no earlier than the expiration date of the '952 Patent and any additional periods of exclusivity.

215. On information and belief, Defendants intend to commence sales of Mylan's generic lopinavir/ritonavir tablets immediately upon receiving final approval from the FDA.

216. On information and belief, in Mylan's ANDA No. 91-202, Mylan Pharmaceuticals Inc. has represented to the FDA that Mylan's generic lopinavir/ritonavir tablets are bioequivalent, therapeutically equivalent, and pharmaceutically equivalent to AbbVie's Kaletra<sup>®</sup> tablets.



217. On information and belief, Defendants' offering to sell, sale, making, and/or importation of Mylan's generic lopinavir/ritonavir tablets, once approved by the FDA, would actively induce infringement of at least one of the claims of the '952 Patent, either literally or under the doctrine of equivalents.

218. Defendants have knowledge and are aware of AbbVie's '952 Patent, as evidenced by Mylan's Second Notice Letter.

219. On information and belief, by the filing of ANDA No. 91-202 with a proposed package insert having directions that encourage patients to administer and/or use Mylan's generic lopinavir/ritonavir tablets to treat HIV, Defendants have an affirmative intent to actively induce infringement by others of one or more claims of the '952 Patent, either literally or under the doctrine of equivalents.

220. On information and belief, by the filing of ANDA No. 91-202 with a proposed package insert having directions that encourage medical practitioners to prescribe and/or administer Mylan's generic lopinavir/ritonavir tablets to treat HIV, Defendants have an affirmative intent to actively induce infringement by others of one or more claims of the '952 Patent, either literally or under the doctrine of equivalents.

221. On information and belief, Defendants are aware and/or have knowledge that patients will administer and/or use Mylan's generic lopinavir/ritonavir tablets and, therefore, will directly infringe at least one claim of the '952 Patent, either literally or under the doctrine of equivalents.

222. On information and belief, Defendants are aware and/or have knowledge that medical practitioners will prescribe and/or administer Mylan's generic lopinavir/ritonavir tablets

and, therefore, will directly infringe at least one claim of the '952 Patent, either literally or under the doctrine of equivalents.

223. On information and belief, Defendants are aware and/or have knowledge that patients will administer and/or use Mylan's generic lopinavir/ritonavir tablets in a method of treatment according to the directions and instructions in the proposed package insert and, therefore, will directly infringe at least one claim of the '952 Patent, either literally or under the doctrine of equivalents.

224. On information and belief, Defendants are aware and/or have knowledge that medical practitioners will prescribe and/or administer Mylan's generic lopinavir/ritonavir tablets in a method of treatment according to the directions and instructions in the proposed package insert and, therefore, will directly infringe at least one claim of the '952 Patent, either literally or under the doctrine of equivalents.

225. 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 Mylan's generic lopinavir/ritonavir tablets.

226. On information and belief, therefore, Defendants' offering to sell, sale, making, and/or importation of Mylan's 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.

227. On information and belief, Mylan's generic lopinavir/ritonavir tablets, if approved by the FDA, will be imported by Defendants into the United States, and marketed, offered for sale, and sold in the United States by Defendants, and will be administered and/or used by

patients in the United States, and will be administered and/or prescribed 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 Mylan, patients, and/or medical practitioners. On information and belief, use, administration, and prescription of Mylan's 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 medical practitioners and patients, with knowledge and specific intent that the conduct will be in contravention of AbbVie's rights under the '952 Patent.

228. If the FDA approves ANDA No. 91-202, Defendants will make, sell, offer to sell, or import into the United States Mylan's generic lopinavir/ritonavir tablets before the expiration of the '952 Patent, and will actively induce infringement by others under 35 U.S.C. § 271(b) of one or more claims of the '952 Patent, either literally or under the doctrine of equivalents.

229. Defendants' threatened actions in actively aiding, abetting, encouraging, and inducing sales of Mylan's generic lopinavir/ritonavir tablets would infringe one or more claims of the '952 Patent, either literally or under the doctrine of equivalents.

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

231. 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.

232. 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.

233. 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.

**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. 91-202 to the FDA to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Mylan's generic lopinavir/ritonavir tablets before the expiration of the '899, '613, '349, '015, '347, '878, and '952 Patents was an act of infringement of the '899, '613, '349, '015, '347, '878, and '952 Patents;

b. declaring that Defendants' commercial manufacture, use, offer for sale, or sale in, or importation into the United States, of Mylan's generic lopinavir/ritonavir tablets would constitute direct infringement of the '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 Mylan's generic lopinavir/ritonavir tablets would constitute induced infringement of the '613, '878, and '952 Patents;

d. declaring that Defendants would induce infringement of one or more claims of the '613, '878, and '952 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 Mylan's

generic lopinavir/ritonavir capsules prior to expiration of the '613, '878, and '952 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. 91-202 until the expiration of the '899, '613, '349, '015, '347, '878, and '952 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 Mylan's generic lopinavir/ritonavir tablets within the United States, or importing into the United States Mylan's generic lopinavir/ritonavir tablets, until the expiration of the '899, '613, '349, '015, '347, '878, and '952 Patents, and any additional periods of exclusivity;

g. declaring the '899, '613, '349, '015, '347, '878, and '952 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.

Respectfully submitted,

/s/ Lynn H. Murray

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