

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ABBVIE INC. and)	
ABBVIE DEUTSCHLAND GMBH & CO. KG,)	
)	
Plaintiffs,)	
)	C.A. No. 1:14-cv-1288-UNA
v.)	
)	
MYLAN PHARMACEUTICALS INC.,)	
)	
Defendant.)	

FIRST AMENDED COMPLAINT

Plaintiffs AbbVie Inc. and AbbVie Deutschland GmbH & Co. KG (collectively “AbbVie”), by way of this First Amended Complaint against Mylan Pharmaceuticals Inc., 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 partnership organized and existing under the laws of Germany with its headquarters at Mainzer Strauße 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. (“Mylan”) 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.

4. On information and belief, Mylan manufactures and sells various generic drug products and regularly conducts business throughout the United States, including the State of Delaware.

NATURE OF THE ACTION

5. This is a civil action for patent infringement of United States Patent Number 7,148,359 B2 (“the ’359 patent”), United States Patent Number 7,364,752 B1 (“the ’752 patent”), United States Patent Number 8,268,349 B2 (“the ’349 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. 20-2738, 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 Norvir[®] tablet product that is sold in the United States.

JURISDICTION AND VENUE

6. 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).

7. On information and belief, this Court has personal jurisdiction over Mylan.

8. On information and belief, Mylan formulates, develops, manufactures, markets, and sells 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 routinely seeks FDA approval to market Mylan’s products in the United States through ANDA filings.

9. On information and belief, Mylan, either directly or through one or more of its wholly owned subsidiaries, affiliates, agents, distributors, or parent corporation, sells and/or distributes a substantial volume of Mylan’s products in this judicial district. On information and belief, Mylan purposefully has conducted and continues to conduct substantial business in this judicial district, from which it has derived, directly or indirectly, substantial revenue.

10. 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. 20-2738, which is the subject of this lawsuit.

11. On information and belief, Mylan is qualified to do business in the State of Delaware and holds current and valid “Distributor/Manufacturer CSR” and “Pharmacy-Wholesale” licenses in Delaware. Further, on information and belief, Mylan is registered to transact business in Delaware and has appointed a registered agent in Delaware (Corporation Service Company, 2711 Centerville Road, Suite 400, Wilmington, Delaware 19808) for service of process.

12. Mylan previously has availed itself of this forum by bringing suits and asserting claims arising under the Patent Laws of the United States in this Court. Mylan has also previously availed itself of this forum by asserting counterclaims arising under the Patent Laws of the United States in other civil actions initiated in this Court, including but not limited to in *AbbVie Inc. & AbbVie Deutschland GmbH & Co. KG v. Mylan Pharmaceuticals Inc. & Mylan Labs. Ltd.*, C.A. No. 1:13-cv-01072-RGA, which is currently pending in this District.

13. This Court has personal jurisdiction over Mylan by virtue of, inter alia, 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 to residents of this judicial district, and the fact that it has availed itself of the rights afforded in this judicial district.

14. This Court also has personal jurisdiction over Mylan by virtue of the fact that, inter alia, Mylan 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 Inc., a Delaware corporation.

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

BACKGROUND

16. AbbVie Inc. is the holder of approved New Drug Application (“NDA”) No. 022-417 for ritonavir tablets, which AbbVie markets and sells under the trademark Norvir[®]. AbbVie manufactures and sells Norvir[®], ritonavir tablets 100 mg, in the United States under NDA No. 022-417.

17. Mylan filed with the FDA ANDA No. 20-2738 under 21 U.S.C. § 355(j), seeking FDA approval to market generic Ritonavir Tablets 100 mg (“Mylan’s generic ritonavir tablets”), as generic copies of AbbVie’s Norvir[®] tablets, in the United States.

18. On or about April 21, 2011, AbbVie Inc. received a letter sent on behalf of Mylan, dated April 20, 2011, purporting to be a “Notice of Paragraph IV Certification” for ANDA No. 20-2738 (“Mylan’s First 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 First Notice Letter notified AbbVie that Mylan had filed ANDA No. 20-2738,

seeking approval to market Mylan's generic ritonavir tablets prior to the expiration of the '359 and '752 patents.

19. On or about October 8, 2014, AbbVie Inc. received a second letter sent on behalf of Mylan, dated October 7, 2014, purporting to be a "Notification of Paragraph IV Certification" for ANDA No. 20-2738 ("Mylan's Second Notice Letter") pursuant to sections 505(j)(2)(B)(i)-(iv) of the Federal Food, Drug and Cosmetic Act and 21 C.F.R. § 314.95. Mylan's Second Notice Letter notified AbbVie that Mylan is also seeking approval to market the generic ritonavir tablets that are the subject of ANDA No. 20-2738 prior to the expiration of the '349, '015, '347, and '878 patents.

20. On information and belief, Mylan intends to capture some of the market for Norvir[®] products with Mylan's generic ritonavir tablets, so as to induce healthcare providers who currently prescribe Norvir[®] products and/or patients who currently take Norvir[®] products to switch to Mylan's generic ritonavir tablets.

THE PATENTS-IN-SUIT

21. The '359 patent was duly and legally issued by the United States Patent and Trademark Office ("PTO") on December 12, 2006. AbbVie Inc. is the owner by assignment of the '359 patent and has the right to sue for infringement thereof. The '359 patent is currently the subject of reexamination proceedings pending at the PTO. AbbVie lists the '359 patent in the Orange Book for NDA No. 022-417. A true and correct copy of the '359 patent is attached as Exhibit A.

22. The '752 patent was duly and legally issued by the PTO on April 29, 2008. AbbVie Inc. is the owner by assignment of the '752 patent and has the right to sue for infringement thereof. The '752 patent is currently the subject of a reexamination proceeding

pending at the PTO. AbbVie lists the '752 patent in the Orange Book for NDA No. 022-417. A true and correct copy of the '752 patent is attached as Exhibit B.

23. 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. 022-417. A true and correct copy of the '349 patent is attached as Exhibit C.

24. 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. 022-417. A true and correct copy of the '015 patent is attached as Exhibit D.

25. 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. 022-417. A true and correct copy of the '347 patent is attached as Exhibit E.

26. 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 022-417. A true and correct copy of the '878 patent is attached as Exhibit F.

FIRST COUNT
PATENT INFRINGEMENT OF THE '359 PATENT

27. Paragraphs 1–26 are incorporated herein by reference.

28. On information and belief, Mylan filed and has maintained ANDA No. 20-2738 in order to obtain approval to manufacture, use, and market Mylan's generic ritonavir tablets in the United States before the expiration of the '359 patent.

29. On information and belief, Mylan is listed as the applicant on ANDA No. 20-2738.

30. On information and belief, Mylan 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 '359 patent are purportedly invalid and/or not infringed.

31. On information and belief, Mylan has represented to the FDA in its ANDA No. 20-2738 that Mylan's generic ritonavir tablets are bioequivalent, therapeutically equivalent, and pharmaceutically equivalent to AbbVie's Norvir[®] tablets.

32. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 20-2738 seeking approval for the commercial manufacture, use, or sale of Mylan's generic 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.

33. AbbVie will be irreparably harmed if Mylan is permitted to make, use, sell, offer to sell, and/or import its generic 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. 20-2738 for Mylan's generic ritonavir tablets 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
PATENT INFRINGEMENT OF THE '752 PATENT

34. Paragraphs 1–33 are incorporated herein by reference.

35. On information and belief, Mylan filed and has maintained ANDA No. 20-2738 in order to obtain approval to manufacture, use, and market Mylan's generic ritonavir tablets in the United States before the expiration of the '752 patent.

36. On information and belief, Mylan is listed as the applicant on ANDA No. 20-2738.

37. On information and belief, Mylan 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 '752 patent are purportedly invalid and/or not infringed.

38. On information and belief, Mylan has represented to the FDA in its ANDA No. 20-2738 that Mylan's generic ritonavir tablets are bioequivalent, therapeutically equivalent, and pharmaceutically equivalent to AbbVie's Norvir[®] tablets.

39. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 20-2738 seeking approval for the commercial manufacture, use, or sale of Mylan's generic 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.

40. Under 35 U.S.C. §§ 271(b) and (e)(2)(A), the submission to the FDA of ANDA No. 20-2738 seeking approval for the commercial manufacture, use, or sale of Mylan's generic 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.

41. On information and belief, Mylan is actively seeking FDA approval to sell its generic ritonavir tablets for the same indication, the same dosage, and the same method of use as the Norvir[®] product sold by AbbVie.

42. On information and belief, Mylan's offering to sell, sale, making, and/or importation of its generic ritonavir tablets, once ANDA No. 20-2738 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.

43. Mylan has knowledge and is aware of AbbVie's '752 patent, as evidenced by Mylan's First Notice Letter.

44. On information and belief, by the filing of ANDA No. 20-2738 with a proposed package insert having directions that encourage patients to administer and/or use Mylan's generic ritonavir tablets to treat an HIV infection, Mylan has an affirmative intent to actively induce infringement by others of one or more claims of the '359 patent, either literally or under the doctrine of equivalents.

45. On information and belief, by the filing of ANDA No. 20-2738 with a proposed package insert having directions that encourage medical practitioners to prescribe and/or administer Mylan's generic ritonavir tablets to treat an HIV infection, Mylan has an affirmative intent to actively induce infringement by others of one or more claims of the '752 patent, either literally or under the doctrine of equivalents.

46. On information and belief, Mylan is aware and/or has knowledge that patients will administer and/or use its generic ritonavir tablets and, therefore, will directly infringe at least one claim of the '752 patent, either literally or under the doctrine of equivalents.

47. On information and belief, Mylan is aware and/or has knowledge that medical practitioners will prescribe and/or administer its generic ritonavir tablets and, therefore, will directly infringe at least one claim of the '752 patent, either literally or under the doctrine of equivalents.

48. On information and belief, Mylan is aware and/or has knowledge that patients will administer and/or use its generic 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 '752 patent, either literally or under the doctrine of equivalents.

49. On information and belief, Mylan is aware and/or has knowledge that medical practitioners will prescribe and/or administer its generic 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 '752 patent, either literally or under the doctrine of equivalents.

50. On information and belief, Mylan knows or should know that it 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 Mylan's proposed package insert for Mylan's generic ritonavir tablets.

51. On information and belief, therefore, Mylan's offering to sell, sale, making, and/or importation of its generic 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.

52. On information and belief, Mylan's generic ritonavir tablets, if approved by the FDA, will be imported by Mylan into the United States, and marketed, offered for sale, and sold in the United States by Mylan, which will constitute direct infringement of at least one claim under 35 U.S.C. § 271(a) of the '752 patent by Mylan. On information and belief, Mylan's generic ritonavir tablets, if approved by the FDA, will be imported by Mylan into the United States, and marketed, offered for sale, and sold in the United States by Mylan, 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 '752 patent by patients or medical practitioners. On information and belief, that use, administration, and prescription will occur with Mylan's specific intent and encouragement, and will be conduct that Mylan knows or should know will occur. On information and belief, Mylan 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.

53. Mylan's threatened actions in actively aiding, abetting, encouraging, and inducing sales of its ritonavir tablets would infringe one or more claims of the '752 patent, either literally or under the doctrine of equivalents.

54. AbbVie will be irreparably harmed if Mylan is permitted to make, use, sell, offer to sell, and/or import its generic 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. 20-2738 for Mylan's generic ritonavir tablets 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
PATENT INFRINGEMENT OF THE '349 PATENT

55. Paragraphs 1–54 are incorporated herein by reference.

56. On information and belief, Mylan filed and has maintained ANDA No. 20-2738 in order to obtain approval to manufacture, use, and market Mylan's generic ritonavir tablets in the United States before the expiration of the '349 patent.

57. On information and belief, Mylan is listed as the applicant on ANDA No. 20-2738.

58. On information and belief, Mylan 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.

59. On information and belief, Mylan has represented to the FDA in its ANDA No. 20-2738 that Mylan's generic ritonavir tablets are bioequivalent, therapeutically equivalent, and pharmaceutically equivalent to AbbVie's Norvir[®] tablets.

60. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 20-2738 seeking approval for the commercial manufacture, use, or sale of Mylan's generic 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.

61. AbbVie will be irreparably harmed if Mylan is permitted to make, use, sell, offer to sell, and/or import its generic 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. 20-2738 for Mylan's generic 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

62. Paragraphs 1–61 are incorporated herein by reference.

63. On information and belief, Mylan filed and has maintained ANDA No. 20-2738 in order to obtain approval to manufacture, use, and market Mylan's generic ritonavir tablets in the United States before the expiration of the '015 patent.

64. On information and belief, Mylan is listed as the applicant on ANDA No. 20-2738.

65. On information and belief, Mylan 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.

66. On information and belief, Mylan has represented to the FDA in its ANDA No. 20-2738 that Mylan's generic ritonavir tablets are bioequivalent, therapeutically equivalent, and pharmaceutically equivalent to AbbVie's Norvir[®] tablets.

67. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 20-2738 seeking approval for the commercial manufacture, use, or sale of Mylan's generic 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.

68. AbbVie will be irreparably harmed if Mylan is permitted to make, use, sell, offer to sell, and/or import its generic 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. 20-2738 for Mylan's generic 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

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

70. On information and belief, Mylan filed and has maintained ANDA No. 20-2738 in order to obtain approval to manufacture, use, and market Mylan's generic ritonavir tablets in the United States before the expiration of the '347 patent.

71. On information and belief, Mylan is listed as the applicant on ANDA No. 20-2738.

72. On information and belief, Mylan 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.

73. On information and belief, Mylan has represented to the FDA in its ANDA No. 20-2738 that Mylan's generic ritonavir tablets are bioequivalent, therapeutically equivalent, and pharmaceutically equivalent to AbbVie's Norvir[®] tablets.

74. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 20-2738 seeking approval for the commercial manufacture, use, or sale of Mylan's generic 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.

75. AbbVie will be irreparably harmed if Mylan is permitted to make, use, sell, offer to sell, and/or import its generic 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. 20-2738 for Mylan's generic 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

76. Paragraphs 1–75 are incorporated herein by reference.

77. On information and belief, Mylan filed and has maintained ANDA No. 20-2738 in order to obtain approval to manufacture, use, and market Mylan's generic ritonavir tablets in the United States before the expiration of the '878 patent.

78. On information and belief, Mylan is listed as the applicant on ANDA No. 20-2738.

79. On information and belief, Mylan 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.

80. On information and belief, Mylan has represented to the FDA in its ANDA No. 20-2738 that Mylan's generic ritonavir tablets are bioequivalent, therapeutically equivalent, and pharmaceutically equivalent to AbbVie's Norvir[®] tablets.

81. Under 35 U.S.C. §§ 271(b) and (e)(2)(A), the submission to the FDA of ANDA No. 20-2738 seeking approval for the commercial manufacture, use, or sale of Mylan's generic 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.

82. On information and belief, Mylan is actively seeking FDA approval to sell its generic ritonavir tablets for the same indication, the same dosage, and the same method of use as the Norvir[®] product sold by AbbVie.

83. On information and belief, Mylan's offering to sell, sale, making, and/or importation of its generic ritonavir tablets, once ANDA NO. 20-2738 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.

84. Mylan has knowledge and is aware of AbbVie's '878 patent, as evidenced by Mylan's Second Notice Letter.

85. On information and belief, by the filing of ANDA No. 20-2738 with a proposed package insert having directions that encourage patients to administer and/or use Mylan's generic ritonavir tablets to treat HIV, Mylan has 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.

86. On information and belief, by the filing of ANDA No. 20-2738 with a proposed package insert having directions that encourage medical practitioners to prescribe and/or administer Mylan's generic ritonavir tablets to treat HIV, Mylan has 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.

87. On information and belief, Mylan is aware and/or has knowledge that patients will administer and/or use its generic ritonavir tablets and, therefore, will directly infringe at least one claim of the '878 patent, either literally or under the doctrine of equivalents.

88. On information and belief, Mylan is aware and/or has knowledge that medical practitioners will prescribe and/or administer its generic ritonavir tablets and, therefore, will directly infringe at least one claim of the '878 patent, either literally or under the doctrine of equivalents.

89. On information and belief, Mylan is aware and/or has knowledge that patients will administer and/or use its generic 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.

90. On information and belief, Mylan is aware and/or has knowledge that medical practitioners will prescribe and/or administer its generic 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.

91. On information and belief, Mylan knows or should know that it 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 Mylan's proposed package insert for Mylan's generic ritonavir tablets.

92. On information and belief, therefore, Mylan's offering to sell, sale, making, and/or importation of its generic 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.

93. On information and belief, Mylan's generic ritonavir tablets, if approved by the FDA, will be imported by Mylan into the United States, and marketed, offered for sale, and sold in the United States by Mylan, 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 the '878 patent by patients or medical practitioners. On information and belief, that use, administration and prescription will occur with Mylan's

specific intent and encouragement, and will be conduct by patients or medical practitioners that Mylan knows or should know will occur. On information and belief, Mylan will actively induce, encourage, aid, and abet that conduct, with knowledge and specific intent that the conduct will be in contravention of AbbVie's rights under the '878 patent.

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

95. AbbVie will be irreparably harmed if Mylan is permitted to make, use, sell, offer to sell, and/or import its generic 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. 20-2738 for Mylan's generic 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
DECLARATORY JUDGMENT AS TO THE '359 PATENT

96. Paragraphs 1–95 are incorporated herein by reference.

97. On information and belief, Mylan is actively seeking FDA approval to sell its generic ritonavir tablets for the same indication, the same dosage, and the same method of use as the Norvir[®] product sold by AbbVie.

98. On information and belief, upon FDA approval of ANDA No. 20-2738, Mylan will infringe one or more claims of the '359 patent under § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing its generic ritonavir tablets, unless this Court orders that the effective date of any FDA approval of ANDA

No. 20-2738 shall be no earlier than the expiration date of the '359 patent and any additional periods of exclusivity.

99. On information and belief, Mylan intends to commence sales of its generic ritonavir tablets immediately upon receiving approval from the FDA.

100. On information and belief, in its ANDA No. 20-2738, Mylan has represented to the FDA that Mylan's generic ritonavir tablets are bioequivalent, therapeutically equivalent, and pharmaceutically equivalent to AbbVie's Norvir[®] tablets.

101. On information and belief, therefore, Mylan's manufacture, importation, sale, and/or offer for sale of its generic 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.

102. Mylan has knowledge and is aware of AbbVie's '359 patent, as evidenced by Mylan's First Notice Letter.

103. A case or controversy exists between AbbVie and Mylan regarding the infringement and validity of the '359 patent.

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

105. 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.

106. 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.

EIGHTH COUNT
DECLARATORY JUDGMENT AS TO THE '752 PATENT

107. Paragraphs 1–106 are incorporated herein by reference.

108. On information and belief, upon FDA approval of ANDA No. 20-2738, Mylan will infringe one or more claims of the '752 patent under § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing its generic ritonavir tablets, and by actively inducing infringement by others under § 271(b), unless this Court orders that the effective date of any FDA approval of ANDA No. 20-2738 shall be no earlier than the expiration date of the '752 patent and any additional periods of exclusivity.

109. On information and belief, Mylan intends to commence sales of its generic ritonavir tablets immediately upon receiving approval from the FDA.

110. On information and belief, in its ANDA No. 20-2738, Mylan has represented to the FDA that Mylan's generic ritonavir tablets are bioequivalent, therapeutically equivalent, and pharmaceutically equivalent to AbbVie's Norvir[®] tablets.

111. On information and belief, therefore, Mylan's manufacture, importation, sale, and/or offer for sale of its generic 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.

112. On information and belief, Mylan's offering to sell, sale, making, and/or importation of its generic ritonavir tablets, once approved by the FDA, would actively induce

infringement of at least one of the claims of the '752 patent, either literally or under the doctrine of equivalents.

113. Mylan has knowledge and is aware of AbbVie's '752 patent, as evidenced by Mylan's First Notice Letter.

114. On information and belief, by the filing of ANDA No. 20-2738 with a proposed package insert having directions that encourage patients to administer and/or use Mylan's generic ritonavir tablets to treat an HIV infection, Mylan has an affirmative intent to actively induce infringement by others of one or more claims of the '752 patent, either literally or under the doctrine of equivalents.

115. On information and belief, by the filing of ANDA No. 20-2738 with a proposed package insert having directions that encourage medical practitioners to prescribe and/or administer Mylan's generic ritonavir tablets to treat an HIV infection, Mylan has an affirmative intent to actively induce infringement by others of one or more claims of the '752 patent, either literally or under the doctrine of equivalents.

116. On information and belief, Mylan is aware and/or has knowledge that patients will administer and/or use its generic ritonavir tablets and, therefore, will directly infringe at least one claim of the '752 patent, either literally or under the doctrine of equivalents.

117. On information and belief, Mylan is aware and/or has knowledge that medical practitioners will prescribe and/or administer its generic ritonavir tablets and, therefore, will directly infringe at least one claim of the '752 patent, either literally or under the doctrine of equivalents.

118. On information and belief, Mylan is aware and/or has knowledge that patients will administer and/or use its generic 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 '752 patent, either literally or under the doctrine of equivalents.

119. On information and belief, Mylan is aware and/or has knowledge that medical practitioners will prescribe and/or administer its generic 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 '752 patent, either literally or under the doctrine of equivalents.

120. On information and belief, Mylan knows or should know that it 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 Mylan's proposed package insert for Mylan's generic ritonavir tablets.

121. On information and belief, therefore, Mylan's offering to sell, sale, making, and/or importation of its generic 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.

122. On information and belief, Mylan's generic ritonavir tablets, if approved by the FDA, will be imported by Mylan into the United States, and marketed, offered for sale, and sold in the United States by Mylan, which will constitute direct infringement of at least one claim under 35 U.S.C. § 271(a) of the '752 patent by Mylan. On information and belief, Mylan's generic ritonavir tablets, if approved by the FDA, will be imported by Mylan into the United States, and marketed, offered for sale, and sold in the United States by Mylan, 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 '752 patent by patients or medical practitioners. On information and belief, that use, administration, and prescription will occur with Mylan's specific intent and encouragement, and will be conduct that Mylan knows or should know will occur. On information and belief, Mylan 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 '752 patent.

123. If the FDA approves ANDA No. 20-2738, Mylan will make, sell, offer to sell, or import into the United States Mylan's generic ritonavir tablets before the expiration of the '752 patent, and will actively induce infringement by others under 35 U.S.C. § 271(b) of one or more claims of the '752 patent, either literally or under the doctrine of equivalents.

124. Mylan's threatened actions in actively aiding, abetting, encouraging, and inducing sales of such ritonavir tablets would infringe one or more claims of the '752 patent.

125. A case or controversy exists between AbbVie and Mylan regarding the infringement and validity of the '752 patent.

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

127. 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.

128. 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.

NINTH COUNT
DECLARATORY JUDGMENT AS TO THE '349 PATENT

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

130. On information and belief, Mylan is actively seeking FDA approval to sell its generic ritonavir tablets for the same indication, the same dosage, and the same method of use as the Norvir[®] product sold by AbbVie.

131. On information and belief, upon FDA approval of ANDA No. 20-2738, Mylan will infringe one or more claims of the '349 patent under § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing its generic ritonavir tablets, unless this Court orders that the effective date of any FDA approval of ANDA No. 20-2738 shall be no earlier than the expiration date of the '349 patent and any additional periods of exclusivity.

132. On information and belief, Mylan intends to commence sales of its generic ritonavir tablets immediately upon receiving approval from the FDA.

133. On information and belief, in its ANDA No. 20-2738, Mylan has represented to the FDA that Mylan's generic ritonavir tablets are bioequivalent, therapeutically equivalent, and pharmaceutically equivalent to AbbVie's Norvir[®] tablets.

134. On information and belief, therefore, Mylan's manufacture, importation, sale, and/or offer for sale of its generic 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.

135. Mylan has knowledge and is aware of AbbVie's '349 patent, as evidenced by Mylan's Second Notice Letter.

136. A case or controversy exists between AbbVie and Mylan regarding the infringement and validity of the '349 patent.

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

138. 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.

139. 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.

TENTH COUNT
DECLARATORY JUDGMENT AS TO THE '015 PATENT

140. Paragraphs 1–139 are incorporated herein by reference.

141. On information and belief, Mylan is actively seeking FDA approval to sell its generic ritonavir tablets for the same indication, the same dosage, and the same method of use as the Norvir[®] product sold by AbbVie.

142. On information and belief, upon FDA approval of ANDA No. 20-2738, Mylan will infringe one or more claims of the '015 patent under § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing its generic ritonavir tablets, unless this Court orders that the effective date of any FDA approval of ANDA No. 20-2738 shall be no earlier than the expiration date of the '015 patent and any additional periods of exclusivity.

143. On information and belief, Mylan intends to commence sales of its generic ritonavir tablets immediately upon receiving approval from the FDA.

144. On information and belief, in its ANDA No. 20-2738, Mylan has represented to the FDA that Mylan's generic ritonavir tablets are bioequivalent, therapeutically equivalent, and pharmaceutically equivalent to AbbVie's Norvir[®] tablets.

145. On information and belief, therefore, Mylan's manufacture, importation, sale, and/or offer for sale of its generic 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.

146. Mylan has knowledge and is aware of AbbVie's '015 patent, as evidenced by Mylan's Second Notice Letter.

147. A case or controversy exists between AbbVie and Mylan regarding the infringement and validity of the '015 patent.

148. Under the totality of the circumstances, there is a substantial controversy between AbbVie and Mylan having sufficient immediacy and reality to establish declaratory judgment jurisdiction relating to Mylan's threatened infringement of the '015 patent.

149. 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.

150. 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 '347 PATENT

151. Paragraphs 1–150 are incorporated herein by reference.

152. On information and belief, Mylan is actively seeking FDA approval to sell its generic ritonavir tablets for the same indication, the same dosage, and the same method of use as the Norvir[®] product sold by AbbVie.

153. On information and belief, upon FDA approval of ANDA No. 20-2738, Mylan will infringe one or more claims of the '347 patent under § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing its generic ritonavir tablets, unless this Court orders that the effective date of any FDA approval of ANDA No. 20-2738 shall be no earlier than the expiration date of the '347 patent and any additional periods of exclusivity.

154. On information and belief, Mylan intends to commence sales of its generic ritonavir tablets immediately upon receiving approval from the FDA.

155. On information and belief, in its ANDA No. 20-2738, Mylan has represented to the FDA that Mylan's generic ritonavir tablets are bioequivalent, therapeutically equivalent, and pharmaceutically equivalent to AbbVie's Norvir[®] tablets.

156. On information and belief, therefore, Mylan's manufacture, importation, sale, and/or offer for sale of its generic 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.

157. Mylan has knowledge and is aware of AbbVie's '347 patent, as evidenced by Mylan's Second Notice Letter.

158. A case or controversy exists between AbbVie and Mylan regarding the infringement and validity of the '347 patent.

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

160. 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.

161. 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 '878 PATENT

162. Paragraphs 1–161 are incorporated herein by reference.

163. On information and belief, upon FDA approval of ANDA No. 20-2738, Mylan will infringe one or more claims of the '878 patent by actively inducing infringement by others under § 271(b), unless this Court orders that the effective date of any FDA approval of ANDA No. 20-2738 shall be no earlier than the expiration date of the '878 patent and any additional periods of exclusivity.

164. On information and belief, Mylan intends to commence sales of its generic ritonavir tablets immediately upon receiving approval from the FDA.

165. On information and belief, in its ANDA No. 20-2738, Mylan has represented to the FDA that Mylan's generic ritonavir tablets are bioequivalent, therapeutically equivalent, and pharmaceutically equivalent to AbbVie's Norvir® tablets.

166. Mylan has knowledge and is aware of AbbVie's '878 patent, as evidenced by Mylan's Second Notice Letter.

167. On information and belief, by the filing of ANDA No. 20-2738 with a proposed package insert having directions that encourage patients to administer and/or use Mylan's generic ritonavir tablets to treat HIV, Mylan has 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.

168. On information and belief, by the filing of ANDA No. 20-2738 with a proposed package insert having directions that encourage medical practitioners to prescribe and/or administer Mylan's generic ritonavir tablets to treat HIV, Mylan has 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.

169. On information and belief, Mylan is aware and/or has knowledge that patients will administer and/or use its generic ritonavir tablets and, therefore, will directly infringe at least one claim of the '878 patent, either literally or under the doctrine of equivalents.

170. On information and belief, Mylan is aware and/or has knowledge that medical practitioners will prescribe and/or administer its generic ritonavir tablets and, therefore, will directly infringe at least one claim of the '878 patent, either literally or under the doctrine of equivalents.

171. On information and belief, Mylan is aware and/or has knowledge that patients will administer and/or use its generic 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.

172. On information and belief, Mylan is aware and/or has knowledge that medical practitioners will prescribe and/or administer its generic 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.

173. On information and belief, Mylan knows or should know that it 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 Mylan's proposed package insert for Mylan's generic ritonavir tablets.

174. On information and belief, therefore, Mylan's offering to sell, sale, making, and/or importation of its generic 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.

175. On information and belief, Mylan's generic ritonavir tablets, if approved by the FDA, will be imported by Mylan into the United States, and marketed, offered for sale, and sold in the United States by Mylan, 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 patients or medical practitioners. On information and belief, that use, administration, and prescription will occur with Mylan's specific intent and encouragement, and will be conduct that Mylan knows or should know will occur. On information and belief, Mylan 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.

176. If the FDA approves ANDA No. 20-2738, Mylan will make, sell, offer to sell, or import into the United States Mylan's generic 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.

177. Mylan's threatened actions in actively aiding, abetting, encouraging, and inducing sales of such ritonavir tablets would infringe one or more claims of the '878 patent.

178. A case or controversy exists between AbbVie and Mylan regarding the infringement and validity of the '878 patent.

179. Under the totality of the circumstances, there is a substantial controversy between AbbVie and Mylan having sufficient immediacy and reality to establish declaratory judgment jurisdiction relating to Mylan's threatened infringement of the '878 patent.

180. 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.

181. 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.

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), Mylan's submission to the FDA of ANDA No. 20-2738 to obtain approval for the commercial manufacture, use, offer for sale, or

sale in, or importation into, the United States of Mylan's generic ritonavir tablets before the expiration of the '359 patent was an act of infringement of the '359 patent;

b. declaring that, under 35 U.S.C. § 271(e)(2)(A), Mylan's submission to the FDA of ANDA No. 20-2738 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Mylan's generic ritonavir tablets before the expiration of the '752 patent was an act of infringement of the '752 patent;

c. declaring that, under 35 U.S.C. § 271(e)(2)(A), Mylan's submission to the FDA of ANDA No. 20-2738 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Mylan's generic ritonavir tablets before the expiration of the '349 patent was an act of infringement of the '349 patent;

d. declaring that, under 35 U.S.C. § 271(e)(2)(A), Mylan's submission to the FDA of ANDA No. 20-2738 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Mylan's generic ritonavir tablets before the expiration of the '015 patent was an act of infringement of the '015 patent;

e. declaring that, under 35 U.S.C. § 271(e)(2)(A), Mylan's submission to the FDA of ANDA No. 20-2738 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Mylan's generic ritonavir tablets before the expiration of the '347 patent was an act of infringement of the '347 patent;

f. declaring that, under 35 U.S.C. § 271(e)(2)(A), Mylan's submission to the FDA of ANDA No. 20-2738 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Mylan's generic ritonavir tablets before the expiration of the '878 patent was an act of infringement of the '878 patent;

g. declaring that Mylan's commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Mylan's generic ritonavir tablets would constitute infringement of the '359 patent;

h. declaring that Mylan's commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Mylan's generic ritonavir tablets would constitute infringement of the '752 patent;

i. declaring that Mylan's commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Mylan's generic ritonavir tablets would constitute infringement of the '349 patent;

j. declaring that Mylan's commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Mylan's generic ritonavir tablets would constitute infringement of the '015 patent;

k. declaring that Mylan's commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Mylan's generic ritonavir tablets would constitute infringement of the '347 patent;

l. declaring that Mylan would infringe one or more claims of the '359 patent under 35 U.S.C. § 271(a) by its manufacture, use, offering to sell, and sale in, and importation into the United States of Mylan's generic ritonavir tablets prior to expiration of the '359 patent, and any additional dates of exclusivity;

m. declaring that Mylan would infringe one or more claims of the '752 patent under 35 U.S.C. §§ 271(a) and/or (b) by its manufacture, use, offering to sell, and sale in, and importation into the United States of Mylan's generic ritonavir tablets, and its active inducement

of others to use those tablets for treatment of an HIV infection, prior to expiration of the '752 patent, and any additional dates of exclusivity;

n. declaring that Mylan would infringe one or more claims of the '349 patent under 35 U.S.C. § 271(a) by its manufacture, use, offering to sell, and sale in, and importation into the United States of Mylan's generic ritonavir tablets prior to expiration of the '349 patent, and any additional dates of exclusivity;

o. declaring that Mylan would infringe one or more claims of the '015 patent under 35 U.S.C. § 271(a) by its manufacture, use, offering to sell, and sale in, and importation into the United States of Mylan's generic ritonavir tablets prior to expiration of the '015 patent, and any additional dates of exclusivity;

p. declaring that Mylan would infringe one or more claims of the '347 patent under 35 U.S.C. § 271(a) by its manufacture, use, offering to sell, and sale in, and importation into the United States of Mylan's generic ritonavir tablets prior to expiration of the '347 patent, and any additional dates of exclusivity;

q. declaring that Mylan would infringe one or more claims of the '878 patent under 35 U.S.C. § 271(b) by its manufacture, use, offering to sell, and sale in, and importation into the United States of Mylan's generic ritonavir tablets, and its active inducement of others to use those tablets to treat HIV, prior to expiration of the '878 patent, and any additional dates of exclusivity;

r. ordering that the effective date of any FDA approval of Mylan's generic ritonavir tablets shall be no earlier than the expiration date of the '359 patent and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(A);

s. ordering that the effective date of any FDA approval of Mylan's generic ritonavir tablets shall be no earlier than the expiration date of the '752 patent and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(A);

t. ordering that the effective date of any FDA approval of Mylan's generic ritonavir tablets shall be no earlier than the expiration date of the '349 patent and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(A);

u. ordering that the effective date of any FDA approval of Mylan's generic ritonavir tablets shall be no earlier than the expiration date of the '015 patent and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(A);

v. ordering that the effective date of any FDA approval of Mylan's generic ritonavir tablets shall be no earlier than the expiration date of the '347 patent and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(A);

w. ordering that the effective date of any FDA approval of Mylan's generic ritonavir tablets shall be no earlier than the expiration date of the '878 patent and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(A);

x. enjoining Mylan and all persons acting in concert with Mylan, from commercially manufacturing, using, offering for sale, or selling Mylan's generic ritonavir tablets within the United States, or importing into the United States Mylan's generic ritonavir tablets, until the expiration of the '359 patent, and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(B);

y. enjoining Mylan and all persons acting in concert with Mylan, from commercially manufacturing, using, offering for sale, or selling Mylan's generic ritonavir tablets within the United States, or importing into the United States Mylan's generic ritonavir tablets, until the

expiration of the '752 patent, and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(B);

z. enjoining Mylan and all persons acting in concert with Mylan, from commercially manufacturing, using, offering for sale, or selling Mylan's generic ritonavir tablets within the United States, or importing into the United States Mylan's generic ritonavir tablets, until the expiration of the '349 patent, and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(B);

aa. enjoining Mylan and all persons acting in concert with Mylan, from commercially manufacturing, using, offering for sale, or selling Mylan's generic ritonavir tablets within the United States, or importing into the United States Mylan's generic ritonavir tablets, until the expiration of the '015 patent, and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(B);

bb. enjoining Mylan and all persons acting in concert with Mylan, from commercially manufacturing, using, offering for sale, or selling Mylan's generic ritonavir tablets within the United States, or importing into the United States Mylan's generic ritonavir tablets, until the expiration of the '347 patent, and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(B);

cc. enjoining Mylan and all persons acting in concert with Mylan, from commercially manufacturing, using, offering for sale, or selling Mylan's generic ritonavir tablets within the United States, or importing into the United States Mylan's generic ritonavir tablets, until the expiration of the '878 patent, and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(B);

dd. enjoining Mylan and all persons acting in concert with Mylan, from seeking, obtaining, or maintaining approval of ANDA No. 20-2738 until the expiration of the '359 patent, and any additional periods of exclusivity;

ee. enjoining Mylan and all persons acting in concert with Mylan, from seeking, obtaining, or maintaining approval of ANDA No. 20-2738 until the expiration of the '752 patent, and any additional periods of exclusivity;

ff. enjoining Mylan and all persons acting in concert with Mylan, from seeking, obtaining, or maintaining approval of ANDA No. 20-2738 until the expiration of the '349 patent, and any additional periods of exclusivity;

gg. enjoining Mylan and all persons acting in concert with Mylan, from seeking, obtaining, or maintaining approval of ANDA No. 20-2738 until the expiration of the '015 patent, and any additional periods of exclusivity;

hh. enjoining Mylan and all persons acting in concert with Mylan, from seeking, obtaining, or maintaining approval of ANDA No. 20-2738 until the expiration of the '347 patent, and any additional periods of exclusivity;

ii. enjoining Mylan and all persons acting in concert with Mylan, from seeking, obtaining, or maintaining approval of ANDA No. 20-2738 until the expiration of the '878 patent, and any additional periods of exclusivity;

jj. declaring the '359 patent valid and enforceable;

kk. declaring the '752 patent valid and enforceable;

ll. declaring the '349 patent valid and enforceable;

mm. declaring the '015 patent valid and enforceable;

nn. declaring the '347 patent valid and enforceable;

- oo. declaring the '878 patent valid and enforceable;
- pp. finding this to be an exceptional case and awarding AbbVie its costs, expenses, costs, and disbursements in this action, including reasonable attorney fees, pursuant to 35 U.S.C. §§ 285 and 271(e)(4)(C); and
- qq. awarding AbbVie any further and additional relief as this Court deems just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Stephen J. Kraftschik

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