IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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| ABBVIE INC., | ) | |
| | ) | |
| Plaintiff, | ) | |
| | ) | |
| v. | ) | C.A. No. _____ |
| | ) | |
| AMNEAL PHARMACEUTICALS, LLC, and AMNEAL PHARMACEUTICALS OF NEW YORK, LLC | ) | |
| | ) | |
| Defendants. | ) | |

**COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiff AbbVie Inc. ("AbbVie") files this Complaint for patent infringement against Defendants Amneal Pharmaceuticals, LLC ("Amneal Pharmaceuticals") and Amneal Pharmaceuticals of New York, LLC ("Amneal NY," collectively "Amneal") under 35 U.S.C. §§ 271(e)(2)(A), (a), and (b). This patent action concerns the pharmaceutical drug product Norvir®. AbbVie hereby alleges 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. On information and belief, Defendant Amneal Pharmaceuticals is a limited liability company organized and existing under the laws of the State of Delaware, having its principal place of business located at 400 Crossing Boulevard, Third Floor, Bridgewater, New Jersey 08807.

3. On information and belief Defendant Amneal NY is a limited liability company organized and existing under the laws of the States of Delaware, having its principal place of business located at 85 Adams Avenue, Hauppauge, New York 11788.

## NATURE OF THE ACTION

4. This is a civil action for patent infringement of United States Patent Number 7,148,359 B2 ("the '359 patent") and United States Patent Number 7,364,752 C1 ("the '752 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. 20-8890, which Amneal 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

5. 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).

6. On information and belief, Amneal Pharmaceuticals is a generic pharmaceutical company in the business of marketing and distributing generic drug products. On information and belief, Amneal Pharmaceuticals directly and through its affiliates markets and sells drug products in the District of Delaware and throughout the United States. Amneal Pharmaceuticals is also qualified to do business in Delaware and has appointed a registered agent for service of process in Delaware. On information and belief, Amneal Pharmaceuticals routinely seeks FDA

approval to market its products in Delaware and throughout the United States, through ANDA filings.

7. Amneal Pharmaceuticals is subject to personal jurisdiction in this district because, *inter alia*, Amneal Pharmaceuticals has committed, or aided, abetted, actively induced, contributed to, or participated in the commission of an act of patent infringement against Plaintiff AbbVie, which is a Delaware corporation.

8. This Court also has personal jurisdiction over Amneal Pharmaceuticals because Amneal Pharmaceuticals has purposefully availed itself of the rights and benefits of Delaware law by engaging in systematic and continuous contacts with Delaware. Upon information and belief, Amneal Pharmaceuticals regularly and continuously transacts business within the State of Delaware.

9. On information and belief, Amneal Pharmaceuticals derives substantial revenue from the sale of its products in Delaware and throughout the United States.

10. This Court also has personal jurisdiction over Amneal Pharmaceuticals because Amneal Pharmaceuticals has affirmatively availed itself of this Court's jurisdiction by filing counterclaims in this District, and has previously been sued in this District and has not challenged personal jurisdiction. *See, e.g.*, *Forest Laboratories, Inc. v. Amneal Pharmaceuticals*, LLC, 1:13-cv-01737-SLR (D. Del.) (consolidated with 1:13-cv-1602-SLR); *Endo Pharmaceuticals Inc. v. Amneal Pharmaceuticals, LLC*, 1:14-cv-1382-RGA (D. Del.); *UCB, Inc. v. Amneal Pharmaceuticals, LLC*, 1:13-cv-1208-LPS (D. Del.); *Forest Laboratories, Inc. v. Amneal Pharmaceuticals, LLC*, 1:14-cv-508-LPS (D. Del.); *Abbott Laboratories v. Amneal Pharmaceuticals, LLC*, 1:12-cv-235-SLR (D. Del.); *Forest Laboratories, LLC v. Amneal Pharmaceuticals, LLC*, 1:15-cv-00430-SLR (D. Del.).

11. The Court also has personal jurisdiction over Amneal Pharmaceuticals because its filing of ANDA No. 20-8890 in concert with Amneal NY constitutes a formal act that reliably indicates Amneal's plan to engage in the marketing and sale of its proposed generic drug product in Delaware.

12. This Court has personal jurisdiction over Amneal Pharmaceuticals by virtue of, among other things: (1) its existence as a Delaware limited liability company; (2) its registration to do business in Delaware, including appointment of a registered agent; (3) its sale and distribution of generic drugs in Delaware; (4) its course of conduct that is designed to cause the performance of the tortious act of patent infringement that has led to foreseeable harm and injury to Plaintiff AbbVie, a Delaware corporation; (5) its purposeful availment of this forum previously for the purpose of litigating a patent dispute; (6) its consent that it is subject to the Court's jurisdiction in other patent litigations, and (7) its acting in concert with Amneal NY to file ANDA No. 20-8890 reliably indicates Amneal's intent to market and sell its proposed generic drug product in Delaware.

13. On information and belief, Amneal NY is a pharmaceutical company that directly or indirectly through its affiliates and agents, including Amneal Pharmaceuticals, formulates, manufactures, packages and markets generic drug products for distribution in the District of Delaware and throughout the United States. Amneal NY is also qualified to do business in Delaware and has appointed a registered agent for service of process in Delaware.

14. On information and belief, Defendant Amneal NY is a wholly owned subsidiary of Defendant Amneal Pharmaceuticals.

15. This Court also has personal jurisdiction over Amneal NY because Amneal NY has affirmatively availed itself of this Court's jurisdiction by filing counterclaims in this District,

and has previously been sued in this District and has not challenged personal jurisdiction. *See, e.g., Forest Laboratories, Inc. v. Amneal Pharmaceuticals, LLC*, 1:13-cv-01737-SLR (D. Del.) (consolidated with 1:13-cv-1602-SLR); *Endo Pharmaceuticals Inc. v. Amneal Pharmaceuticals, LLC*, 1:14-cv-1382-RGA (D. Del.); *UCB, Inc. v. Amneal Pharmaceuticals*, LLC, 1:13-cv-1208-LPS (D. Del.); *Forest Laboratories, Inc. v. Amneal Pharmaceuticals, LLC*, 1:14-cv-508-LPS (D. Del.); *Forest Laboratories, LLC v. Amneal Pharmaceuticals, LLC*, 1:15-cv-00430-SLR (D. Del.).

16. The Court also has personal jurisdiction over Amneal NY because its filing of ANDA No. 20-8890 in concert with Amneal Pharmaceuticals constitutes a formal act that reliably indicates Amneal's plan to engage in the marketing and sale of its proposed generic drug product in Delaware.

17. This Court has personal jurisdiction over Amneal NY by virtue of, among other things: (1) its existence as Delaware limited liability company; (2) its registration to do business in Delaware, including appointment of a registered agent; (3) its sale and distribution of generic drugs in Delaware; (4) its course of conduct that is designed to cause the performance of the tortious act of patent infringement that has led to foreseeable harm and injury to Plaintiff AbbVie, a Delaware corporation; (5) its purposeful availment of this forum previously for the purpose of litigating a patent dispute; (6) its consent that it is subject to the Court's jurisdiction in other patent litigations, and (7) its filing of ANDA No. 20-8890 reliably indicates Amneal's intent to market and sell its proposed generic drug product in Delaware.

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

## BACKGROUND

19. AbbVie Inc. is the holder of approved New Drug Application ("NDA") No. 022-417 for ritonavir tablets, which AbbVie manufactures, markets and sells in the United States under the trademark Norvir®.

20. On information and belief, Amneal Pharmaceuticals and Amneal NY acted in concert to file with the FDA ANDA No. 20-8890 under 21 U.S.C. § 355(j), seeking FDA approval to market generic Ritonavir Tablets 100 mg ("Amneal's generic ritonavir tablets"), as generic copies of AbbVie's Norvir® tablets, in the United States.

21. On or about April 15, 2016, AbbVie Inc. received a letter sent on behalf of "Amneal Pharmaceuticals," dated April 14, 2016, purporting to be a "Notice of Paragraph IV Certification" for ANDA No. 20-8890 ("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. Amneal's Notice Letter notified AbbVie that "Amneal Pharmaceuticals" had filed ANDA No. 20-8890, seeking approval to market its generic ritonavir tablets prior to the expiration of, *inter alia*, the '359 and '752 patents.

22. On information and belief, Amneal intends to capture some of the market for Norvir® products with its 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 Amneal's generic ritonavir tablets.

## THE PATENTS-IN-SUIT

23. 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, but the PTO has not issued a

Reexamination Certificate as of the date of this Complaint. 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.

24. The '752 patent was duly and legally issued by the PTO on April 29, 2008. The '752 patent was the subject of reexamination proceedings before the PTO. On January 23, 2015, after the conclusion of the reexamination proceedings, the PTO issued an Inter Partes Reexamination Certificate, which amended the '752 Patent as United States Patent Number 7,364,752 C1. AbbVie Inc. is the owner by assignment of the '752 patent and has the right to sue for infringement thereof. AbbVie lists the '752 patent in the Orange Book for NDA No. 022-417. A true and correct copy of the '752 patent is attached as Exhibit B.

## FIRST COUNT
### PATENT INFRINGEMENT OF THE '359 PATENT

25. Paragraphs 1–24 are incorporated herein by reference.

26. On information and belief, Amneal Pharmaceuticals and Amneal NY acted in concert to file and have maintained ANDA No. 20-8890 in order to obtain approval to manufacture, use, and market Amneal's generic ritonavir tablets in the United States before the expiration of the '359 patent.

27. On information and belief, Amneal NY is listed as the applicant on ANDA No. 20-8890.

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

29. On information and belief, Amneal NY has represented to the FDA in its ANDA No. 20-8890 that Amneal's generic ritonavir tablets are bioequivalent, therapeutically equivalent, and pharmaceutically equivalent to AbbVie's Norvir® tablets.

30. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 20-8890 seeking approval for the commercial manufacture, use, or sale of Amneal's generic ritonavir tablets before the expiration date of the '359 patent constitutes infringement of at least claims 1, 2, and 4-7 of the '359 patent, either literally or under the doctrine of equivalents.

31. AbbVie will be irreparably harmed if Amneal 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. 20-8890 for Amneal'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

32. Paragraphs 1–31 are incorporated herein by reference.

33. On information and belief, Amneal Pharmaceuticals and Amneal NY acted in concert to file and have maintained ANDA No. 20-8890 in order to obtain approval to manufacture, use, and market Amneal's generic ritonavir tablets in the United States before the expiration of the '752 patent.

34. On information and belief, Amneal NY is listed as the applicant on ANDA No. 20-8890.

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

36. On information and belief, Amneal NY has represented to the FDA in its ANDA No. 20-8890 that Amneal's generic ritonavir tablets are bioequivalent, therapeutically equivalent, and pharmaceutically equivalent to AbbVie's Norvir® tablets.

37. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 20-8890 seeking approval for the commercial manufacture, use, or sale of Amneal's generic ritonavir tablets before the expiration date of the '752 patent constitutes infringement of at least claims 11, 13, 17, 18, 20, 22, 26, 27, 29, 31, 35, 36, and 37 of the '752 patent, either literally or under the doctrine of equivalents.

38. Under 35 U.S.C. §§ 271(b) and (e)(2)(A), the submission to the FDA of ANDA No. 20-8890 seeking approval for the commercial manufacture, use, or sale of Amneal's generic ritonavir tablets before the expiration date of the '752 patent constitutes induced infringement of at least claims 11, 13, 17, 18, 20, 22, 26, 27, 29, 31, 35, 36, and 37 of the '752 patent, either literally or under the doctrine of equivalents.

39. On information and belief, Amneal 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.

40. On information and belief, Amneal's offering to sell, sale, making, and/or importation of its generic ritonavir tablets, once ANDA No. 20-8890 is approved by the FDA,

would actively induce infringement of at least claim 37 of the ’752 patent under 35 U.S.C. § 271(b), either literally or under the doctrine of equivalents.

41. Amneal has knowledge and is aware of AbbVie’s ’752 patent, as evidenced by Amneal’s Notice Letter.

42. On information and belief, by the filing of ANDA No. 20-8890 with a proposed package insert having directions that encourage patients to administer and/or use Amneal’s generic ritonavir tablets to treat an HIV infection, Amneal has an affirmative intent to actively induce infringement by others of at least claim 37 of the ’752 patent, either literally or under the doctrine of equivalents.

43. On information and belief, by the filing of ANDA No. 20-8890 with a proposed package insert having directions that encourage medical practitioners to prescribe and/or administer Amneal’s generic ritonavir tablets to treat an HIV infection, Amneal has an affirmative intent to actively induce infringement by others of at least claims 11, 13, 17, 18, 20, 22, 26, 27, 29, 31, 35, 36, and 37 of the ’752 patent, either literally or under the doctrine of equivalents.

44. On information and belief, Amneal is aware and/or has knowledge that patients will administer and/or use its generic ritonavir tablets and, therefore, will directly infringe at least claims 11, 13, 17, 18, 20, 22, 26, 27, 29, 31, 35, 36, and 37 of the ’752 patent, either literally or under the doctrine of equivalents.

45. On information and belief, Amneal 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 claims 11, 13, 17, 18, 20, 22, 26, 27, 29, 31, 35, 36, and 37 of the ’752 patent, either literally or under the doctrine of equivalents.

46. On information and belief, Amneal 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 claims 11, 13, 17, 18, 20, 22, 26, 27, 29, 31, 35, 36, and 37 of the '752 patent, either literally or under the doctrine of equivalents.

47. On information and belief, Amneal 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 claims 11, 13, 17, 18, 20, 22, 26, 27, 29, 31, 35, 36, and 37 of the '752 patent, either literally or under the doctrine of equivalents.

48. On information and belief, Amneal knows or should know that it will aid and abet another's direct infringement of at least claims 11, 13, 17, 18, 20, 22, 26, 27, 29, 31, 35, 36, and 37 of the '752 patent, either literally or under the doctrine of equivalents, by Amneal's proposed package insert for Amneal's generic ritonavir tablets.

49. On information and belief, therefore, Amneal'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 at least claims 11, 13, 17, 18, 20, 22, 26, 27, 29, 31, 35, 36, and 37 of the '752 patent, either literally or under the doctrine of equivalents.

50. On information and belief, Amneal's generic ritonavir tablets, if approved by the FDA, will be imported by Amneal into the United States, and marketed, offered for sale, and sold in the United States by Amneal, which will constitute direct infringement under 35 U.S.C. § 271(a) of at least claims 11, 13, 17, 18, 20, 22, 26, 27, 29, 31, 35, 36, and 37 of the '752 patent by Amneal. On information and belief, Amneal's generic ritonavir tablets, if approved by the

FDA, will be imported by Amneal into the United States, and marketed, offered for sale, and sold in the United States by Amneal, 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 under 35 U.S.C. § 271(a) of at least claims 11, 13, 17, 18, 20, 22, 26, 27, 29, 31, 35, 36, and 37 of the '752 patent by patients or medical practitioners. On information and belief, that use, administration, and prescription will occur with Amneal's specific intent and encouragement, and will be conduct that Amneal knows or should know will occur. On information and belief, Amneal 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.

51. Amneal's threatened actions in actively aiding, abetting, encouraging, and inducing sales of its ritonavir tablets would infringe at least claims 11, 13, 17, 18, 20, 22, 26, 27, 29, 31, 35, 36, and 37 of the '752 patent, either literally or under the doctrine of equivalents.

52. AbbVie will be irreparably harmed if Amneal 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. 20-8890 for Amneal'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
### DECLARATORY JUDGMENT AS TO THE '359 PATENT

53. Paragraphs 1–52 are incorporated herein by reference.

54. On information and belief, Amneal 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.

55. On information and belief, upon FDA approval of ANDA No. 20-8890, Amneal will infringe at least claims 1, 2, and 4-7 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. 20-8890 shall be no earlier than the expiration date of the '359 patent and any additional periods of exclusivity.

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

57. On information and belief, in its ANDA No. 20-8890, Amneal NY has represented to the FDA that Amneal's generic ritonavir tablets are bioequivalent, therapeutically equivalent, and pharmaceutically equivalent to AbbVie's Norvir® tablets.

58. On information and belief, therefore, Amneal's manufacture, importation, sale, and/or offer for sale of its generic ritonavir tablets, once approved by the FDA, would directly infringe at least claims 1, 2, and 4-7 of the '359 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

59. Amneal has knowledge and is aware of AbbVie's '359 patent, as evidenced by Amneal's Notice Letter.

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

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

62. 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.

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

## FOURTH COUNT
### DECLARATORY JUDGMENT AS TO THE '752 PATENT

64. Paragraphs 1–63 are incorporated herein by reference.

65. On information and belief, upon FDA approval of ANDA No. 20-8890, Amneal will infringe at least claims 11, 13, 17, 18, 20, 22, 26, 27, 29, 31, 35, 36, and 37 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. 20-8890 shall be no earlier than the expiration date of the '752 patent and any additional periods of exclusivity.

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

67. On information and belief, in its ANDA No. 20-8890, Amneal NY has represented to the FDA that Amneal's generic ritonavir tablets are bioequivalent, therapeutically equivalent, and pharmaceutically equivalent to AbbVie's Norvir® tablets.

68. On information and belief, therefore, Amneal's manufacture, importation, sale, and/or offer for sale of its generic ritonavir tablets, once approved by the FDA, would directly infringe at least claims 11, 13, 17, 18, 20, 22, 26, 27, 29, 31, 35, 36, and 37 of the '752 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

69. On information and belief, Amneal'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 claims 11, 13, 17, 18, 20, 22, 26, 27, 29, 31, 35, 36, and 37 of the '752 patent, either literally or under the doctrine of equivalents.

70. Amneal has knowledge and is aware of AbbVie's '752 patent, as evidenced by Amneal's Notice Letter.

71. On information and belief, by the filing of ANDA No. 20-8890 with a proposed package insert having directions that encourage patients to administer and/or use Amneal's generic ritonavir tablets to treat an HIV infection, Amneal has an affirmative intent to actively induce infringement by others of at least claims 11, 13, 17, 18, 20, 22, 26, 27, 29, 31, 35, 36, and 37 of the '752 patent, either literally or under the doctrine of equivalents.

72. On information and belief, by the filing of ANDA No. 20-8890 with a proposed package insert having directions that encourage medical practitioners to prescribe and/or administer Amneal's generic ritonavir tablets to treat an HIV infection, Amneal has an affirmative intent to actively induce infringement by others of at least claims 11, 13, 17, 18, 20, 22, 26, 27, 29, 31, 35, 36, and 37 of the '752 patent, either literally or under the doctrine of equivalents.

73. On information and belief, Amneal is aware and/or has knowledge that patients will administer and/or use its generic ritonavir tablets and, therefore, will directly infringe at least

claims 11, 13, 17, 18, 20, 22, 26, 27, 29, 31, 35, 36, and 37 of the ’752 patent, either literally or under the doctrine of equivalents.

74. On information and belief, Amneal 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 claims 11, 13, 17, 18, 20, 22, 26, 27, 29, 31, 35, 36, and 37 of the ’752 patent, either literally or under the doctrine of equivalents.

75. On information and belief, Amneal 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 claims 11, 13, 17, 18, 20, 22, 26, 27, 29, 31, 35, 36, and 37 of the ’752 patent, either literally or under the doctrine of equivalents.

76. On information and belief, Amneal 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 claims 11, 13, 17, 18, 20, 22, 26, 27, 29, 31, 35, 36, and 37 of the ’752 patent, either literally or under the doctrine of equivalents.

77. On information and belief, Amneal knows or should know that it will aid and abet another’s direct infringement of at least claims 11, 13, 17, 18, 20, 22, 26, 27, 29, 31, 35, 36, and 37 of the ’752 patent, either literally or under the doctrine of equivalents, by Amneal’s proposed package insert for Amneal’s generic ritonavir tablets.

78. On information and belief, therefore, Amneal’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 at least claims 11, 13, 17, 18, 20, 22, 26, 27, 29, 31, 35, 36, and 37 of the '752 patent, either literally or under the doctrine of equivalents.

79. On information and belief, Amneal's generic ritonavir tablets, if approved by the FDA, will be imported by Amneal into the United States, and marketed, offered for sale, and sold in the United States by Amneal, which will constitute direct infringement under 35 U.S.C. § 271(a) of at least claims 11, 13, 17, 18, 20, 22, 26, 27, 29, 31, 35, 36, and 37 of the '752 patent by Amneal. On information and belief, Amneal's generic ritonavir tablets, if approved by the FDA, will be imported by Amneal into the United States, and marketed, offered for sale, and sold in the United States by Amneal, 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 under 35 U.S.C. § 271(a) of at least claims 11, 13, 17, 18, 20, 22, 26, 27, 29, 31, 35, 36, and 37 of the '752 patent by patients or medical practitioners. On information and belief, that use, administration, and prescription will occur with Amneal's specific intent and encouragement, and will be conduct that Amneal knows or should know will occur. On information and belief, Amneal 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.

80. If the FDA approves ANDA No. 20-8890, Amneal will make, sell, offer to sell, or import into the United States Amneal'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 at least claims 11, 13, 17, 18, 20, 22, 26, 27, 29, 31, 35, 36, and 37 of the '752 patent, either literally or under the doctrine of equivalents.

81. Amneal's threatened actions in actively aiding, abetting, encouraging, and inducing sales of such ritonavir tablets would infringe at least claims 11, 13, 17, 18, 20, 22, 26, 27, 29, 31, 35, 36, and 37 of the '752 patent.

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

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

84. 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.

85. In view of the foregoing, there exists a substantial controversy between AbbVie and Amneal, 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), Amneal's submission to the FDA of ANDA No. 20-8890 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Amneal'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), Amneal's submission to the FDA of ANDA No. 20-8890 to obtain approval for the commercial manufacture, use, offer for sale, or

sale in, or importation into, the United States of Amneal's generic ritonavir tablets before the expiration of the '752 patent was an act of infringement of the '752 patent;

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

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

e. declaring that Amneal 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 Amneal's generic ritonavir tablets prior to expiration of the '359 patent, and any additional dates of exclusivity;

f. declaring that Amneal 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 Amneal'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;

g. ordering that the effective date of any FDA approval of Amneal'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);

h. ordering that the effective date of any FDA approval of Amneal'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);

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

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

k. enjoining Amneal and all persons acting in concert with Amneal, from seeking, obtaining, or maintaining approval of ANDA No. 20-8890 until the expiration of the '359 patent, and any additional periods of exclusivity;

l. enjoining Amneal and all persons acting in concert with Amneal, from seeking, obtaining, or maintaining approval of ANDA No. 20-8890 until the expiration of the '752 patent, and any additional periods of exclusivity;

m. declaring the '359 patent infringed, valid, and enforceable;

n. declaring the '752 patent infringed, valid, and enforceable;

o. 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

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

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

*/s/ Mary B. Graham*

Mary B. Graham (#2256)
Derek J. Fahnestock (#4705)
Stephen J. Kraftschik (#5623)
1201 N. Market Street
P.O. Box 1347
Wilmington, DE 19899-1347
(302) 658-9200
mgraham@mnat.com
dfahnestock@mnat.com
skraftschik@mnat.com

*Attorneys for Abbvie Inc.*

OF COUNSEL:

Barbara R. Rudolph
Jonathan R. Davies
Mindy L. Ehrenfried
FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, LLP
901 New York Avenue, N.W.
Washington, DC 20001-4413
(202) 408-4000

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