IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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| PFIZER INC., PFIZER IRELAND PHARMACEUTICALS, and BRISTOL-MYERS SQUIBB COMPANY, | ) | |
| Plaintiffs, | ) | |
| v. | ) | C.A. No. _____ |
| APOTEX INC. and APOTEX CORP., | ) | |
| Defendants. | ) | |

**COMPLAINT**

Plaintiffs Pfizer Inc. and Pfizer Ireland Pharmaceuticals, (collectively "Pfizer"), and Bristol-Myers Squibb Company ("BMS") (collectively with Pfizer, "Plaintiffs"), by their undersigned attorneys, for their Complaint against defendants Apotex Inc. and Apotex Corp. (collectively, "Apotex" or "Defendants"), allege as follows:

**NATURE OF THE ACTION**

1. This is a civil action for patent infringement under the patent laws of the United States, Title 35 of the United States Code, and the Declaratory Judgment Act, 28 U.S.C. § 2201, *et seq.*, arising from Apotex's submission of Abbreviated New Drug Application ("ANDA") No. 219399 (the "Apotex ANDA") to the United States Food and Drug Administration ("FDA"), seeking approval to market a generic version of Pfizer Inc.'s NURTEC ODT® (rimegepant sulfate) tablet before the expiration of U.S. Patent Nos. 8,314,117 ("the '117 patent"), 8,759,372 ("the '372 patent"), and 11,083,724 ("the '724 patent") (collectively, "the patents-in-suit").

**THE PARTIES**

2. Plaintiff Pfizer Inc. is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 66 Hudson Boulevard East, New York, NY 10001.

3. Plaintiff Pfizer Ireland Pharmaceuticals is a private unlimited liability company organized under the laws of Ireland and has its registered office at Operations Support Group, Ringaskiddy, Co. Cork, Ireland. Pfizer Ireland Pharmaceuticals is a wholly owned, indirect subsidiary of Pfizer Inc.

4. Plaintiff BMS is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at Route 206 and Province Line Road, Princeton, New Jersey 08540.

5. Upon information and belief, Defendant Apotex Inc. is a corporation organized and existing under the laws of Canada, having a principal place of business at 150 Signet Drive, Toronto, Ontario M9L 1T9, Canada.

6. Upon information and belief, Defendant Apotex Corp. is a corporation organized and existing under the laws of Delaware, having a principal place of business at 2400 North Commerce Parkway, Weston, Florida 33326.

7. Upon information and belief, Apotex Corp. is a subsidiary of Apotex Inc. and the U.S. Agent for the Apotex ANDA.

8. Upon information and belief, Apotex Inc. and Apotex Corp. are generic pharmaceutical companies that, in coordination with each other or at the direction of Apotex Inc., develop, manufacture, market, and distribute generic pharmaceutical products for sale in the State of Delaware and throughout the United States.

## THE PATENTS-IN-SUIT

9. On November 20, 2012, the United States Patent and Trademark Office ("USPTO") duly and legally issued the '117 patent, entitled "CGRP Receptor Antagonists." The '117 patent

is assigned to BMS. Pfizer Ireland Pharmaceuticals is the exclusive licensee of the '117 patent. A copy of the '117 patent is attached to this Complaint as Exhibit A.

10. On June 24, 2014, the USPTO duly and legally issued the '372 patent, entitled "*N*-(5S,6S,9R)-5-Amino-6-(2,3-Difluorophenyl)-6,7,8,9-Tetrahydro-5H-Cyclohepta[b]Pyridin-9-yl-4-(2-Oxo-2,3-Dihydro-1H-Imidazo[4,5-b]Pyridin-1-yl)Piperidine-1-Carboxylate Salt." The '372 patent is assigned to BMS. Pfizer Ireland Pharmaceuticals is the exclusive licensee of the '372 patent. A copy of the '372 patent is attached to this Complaint as Exhibit B.

11. On August 10, 2021, the USPTO duly and legally issued the '724 patent, entitled "Rimegepant for CGRP Related Disorders." The '724 patent is assigned to Pfizer Ireland Pharmaceuticals. A copy of the '724 patent is attached to this Complaint as Exhibit C.

**NURTEC ODT®**

12. Pfizer Inc. holds approved New Drug Application No. 212728 for rimegepant sulfate orally disintegrating tablets (trade name NURTEC ODT®) for the acute treatment of migraine with or without aura in adults and the preventive treatment of episodic migraine in adults.

13. Pursuant to 21 U.S.C. § 355(c)(2), and attendant FDA regulations, the patents-in-suit are listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to NURTEC ODT®.

**THE APOTEX ANDA**

14. Upon information and belief, Apotex Inc. prepared and submitted, through Apotex Corp., the Apotex ANDA to the FDA in accordance with 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, or sale of a rimegepant sulfate drug product ("Apotex's ANDA Product") before the expiration of the patents-in-suit.

15. Upon information and belief, Apotex Inc. acted in concert with or directed Apotex Corp. to prepare and submit the Apotex ANDA.

16. Upon information and belief, Apotex's ANDA Product is a generic copy of NURTEC ODT®.

17. Upon information and belief, the Apotex ANDA refers to and relies upon Pfizer Inc.'s New Drug Application No. 212728 and purports to contain data on the bioequivalence of Apotex's ANDA Product to NURTEC ODT®.

18. By a letter to Pfizer Inc., Pfizer Ireland Pharmaceuticals, and BMS dated April 18, 2024 ("Apotex's Paragraph IV Notice Letter"), Apotex stated that the Apotex ANDA contained certifications, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that no valid and enforceable claim of the patents-in-suit will be infringed by the manufacture, use, or sale of Apotex's ANDA Product (the "Paragraph IV Certifications"). Apotex's Paragraph IV Notice Letter included a statement purporting to allege the factual and legal bases for the Paragraph IV Certifications.

19. Upon information and belief, if the FDA approves the Apotex ANDA, Apotex will manufacture, distribute, import, offer for sale and/or sell Apotex's ANDA Product throughout the United States, including within the State of Delaware.

20. This action is being filed within 45 days of Plaintiffs' receipt of Apotex's Paragraph IV Notice Letter.

## JURISDICTION AND VENUE

21. This case arises under the patent laws of the United States, 35 U.S.C. § 100, *et seq.*, and this Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

22. This Court has personal jurisdiction over Apotex Inc. because, inter alia, it has purposefully availed itself of the privileges and benefits of Delaware's laws such that it should

reasonably anticipate being haled into court here. Upon information and belief, Apotex Inc. is in the business of manufacturing, marketing, importing, and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Apotex Inc. directly, or indirectly, develops, manufactures, markets, and sells generic drugs throughout the United States and Delaware. By continuously placing its products into the stream of commerce for distribution and consumption in Delaware, Apotex Inc.'s contacts with Delaware have been systematic and continuous, and this judicial district is a likely destination of Apotex's ANDA Product.

23. Upon information and belief, Apotex Inc. is the holder of the Apotex ANDA.

24. Upon information and belief, Apotex Inc. acted in concert with or directed Apotex Corp. to prepare and submit the Apotex ANDA, with the intention of receiving a significant financial benefit from the FDA's approval of the Apotex ANDA.

25. This Court has personal jurisdiction over Apotex Corp. because its affiliations with the State of Delaware, including by virtue of its incorporation in Delaware, are so continuous and systematic that Apotex Corp. resides in Delaware.

26. This Court also has personal jurisdiction over Apotex Corp. because, inter alia, it has purposefully availed itself of the privileges and benefits of Delaware's laws such that it should reasonably anticipate being haled into court here. Upon information and belief, Apotex Corp. is in the business of manufacturing, marketing, importing, and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Apotex Corp. directly, or indirectly, develops, manufactures, markets, and sells generic drugs throughout the United States and Delaware. By continuously placing its products into the stream of commerce for distribution and consumption in Delaware, Apotex Corp.'s contacts with the State of Delaware have been

systematic and continuous, and this judicial district is a likely destination of Apotex's ANDA Product.

27. Upon information and belief, Apotex Corp. acted in concert with or at the direction of Apotex Inc. to prepare and submit the Apotex ANDA, with the intention of receiving a significant financial benefit from the marketing and distribution of Apotex's ANDA Product throughout the United States, including in Delaware.

28. Upon information and belief, Apotex Inc. and Apotex Corp. have thus been, and continue to be, agents of each other and/or operate in concert with respect to the drafting, submission, approval, and maintenance of the Apotex ANDA.

29. Upon information and belief, Apotex Inc. and Apotex Corp. are agents of each other and/or operate in concert as integrated parts of the same business group, including with respect to Apotex's ANDA Product.

30. This Court also has personal jurisdiction over Apotex Inc. and Apotex Corp. because they have availed themselves of the legal protections of the State of Delaware by previously consenting to personal jurisdiction in this judicial district and by asserting counterclaims against plaintiffs. *See, e.g.*, *Eagle Pharms. Inc. v. Apotex Inc. & Apotex Corp.*, C.A. No. 24-064 (D. Del.); *Gilead Scis., Inc. v. Apotex Inc. & Apotex Corp.*, C.A. No. 23-775 (D. Del.); *Boehringer Ingelheim Pharms. Inc. et al. v. Apotex Inc. & Apotex Corp.*, C.A. No. 23-685 (D. Del.); *Merck KGaA et al. v. Apotex Inc. & Apotex Corp.*, C.A. No. 23-655 (D. Del.); *Bayer Intellectual Prop. GmbH et al. v. Apotex Inc. & Apotex Corp.*, C.A. No. 23-327 (D. Del.).

31. For these and other reasons that will be presented to the Court if jurisdiction is challenged, the Court has personal jurisdiction over Apotex.

32. Venue is proper in this Court for Apotex Inc. under 28 U.S.C. § 1391 because, upon information and belief, Apotex Inc. is not a resident of the United States and may thus be sued in any judicial district.

33. Venue is proper in this Court for Apotex Corp. under 28 U.S.C. §§ 1391 and 1400(b) because Apotex Corp. is a corporation organized and existing under the laws of Delaware.

**COUNT I**
**(Infringement of the '117 Patent)**

34. Plaintiffs reallege, and incorporate fully herein, each preceding paragraph.

35. Defendants have infringed one or more claims of the '117 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting to the FDA and maintaining the Apotex ANDA, by which Defendants seek approval from the FDA to sell, offer to sell, use, and/or engage in the commercial manufacture of Apotex's ANDA Product before the expiration of the '117 patent.

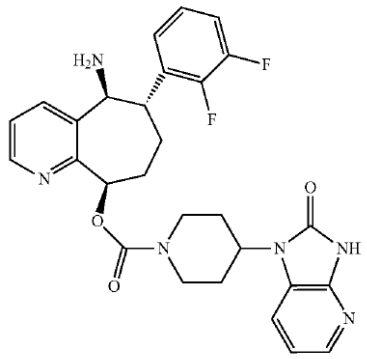
36. Upon information and belief, Defendants' commercial manufacture, sale, offer for sale, or use of Apotex's ANDA Product within the United States, or importation of Apotex's ANDA Product into the United States, during the term of the '117 patent would infringe one or more claims of the '117 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

37. Upon information and belief, Defendants' commercial manufacture, sale, offer for sale, or use of Apotex's ANDA Product within the United States, or importation of Apotex's ANDA Product into the United States, during the term of the '117 patent would induce and/or contribute to the infringement of one or more claims of the '117 patent under 35 U.S.C. §§ 271(b) and/or (c).

38. For example, claim 14 of the '117 patent recites:

The compound of claim **1**

(5S,6S,9R)-5-amino-6-(2,3-difluorophenyl)-6,7,8,9-tetrahydro-5H-cyclohepta[b]pyridin-9-yl 4-(2-oxo-2,3-dihydro-1H-imidazo[4,5-b]pyridin-1-yl)piperidine-1-carboxylate;




or a pharmaceutically acceptable salt thereof.

39. The chemical name and chemical structure recited in claim 14 correspond to the compound rimegepant. Upon information and belief, Apotex's ANDA Product contains rimegepant sulfate. Rimegepant sulfate is a pharmaceutically acceptable salt of rimegepant.

40. Upon information and belief, Defendants have acted with full knowledge of the '117 patent and without a reasonable basis for believing that they would not be liable for infringement of the '117 patent. Notwithstanding this knowledge, Defendants have continued to assert their intent to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Apotex's ANDA Product with its proposed labeling immediately and imminently upon approval of the Apotex ANDA. Upon information and belief, through such activities, Defendants specifically intend infringement of the '117 patent.

41. Upon information and belief, if the FDA approves the Apotex ANDA, Defendants plan and intend to, and will, infringe, actively induce infringement of, and/or contribute to the infringement of the '117 patent, and will do so immediately and imminently upon approval.

42. Upon information and belief, Defendants know that Apotex's ANDA Product is especially made or adapted for use in infringing the '117 patent, and that Apotex's ANDA Product

is not suitable for any substantial non-infringing use. Upon information and belief, Defendants plan and intend to, and will, contribute to infringement of the '117 patent immediately and imminently upon approval of the Apotex ANDA.

43. Plaintiffs will be harmed substantially and irreparably if Defendants are not enjoined from infringing the '117 patent.

44. Plaintiffs have no adequate remedy at law.

45. Plaintiffs are entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

**COUNT II**
**(Declaratory Judgment of Infringement of the '117 Patent)**

46. Plaintiffs reallege, and incorporate fully herein, each preceding paragraph.

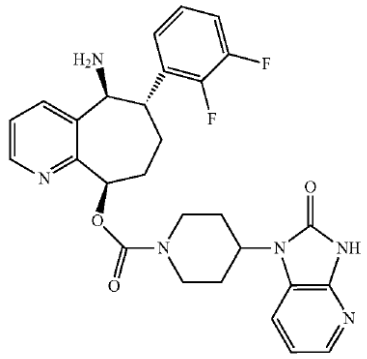
47. There is a substantial and immediate controversy between Plaintiffs and Apotex concerning the '117 patent. Plaintiffs are entitled to a declaratory judgment under 28 U.S.C. §§ 2201 and 2202 that Apotex will infringe, actively induce infringement of, and/or contribute to the infringement of the '117 patent upon approval of the Apotex ANDA.

48. Upon information and belief, Defendants' commercial manufacture, sale, offer for sale, or use of Apotex's ANDA Product within the United States, or importation of Apotex's ANDA Product into the United States, during the term of the '117 patent would infringe one or more claims of the '117 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

49. Upon information and belief, Defendants' commercial manufacture, sale, offer for sale, or use of Apotex's ANDA Product within the United States, or importation of Apotex's ANDA Product into the United States, during the term of the '117 patent would induce and/or

contribute to the infringement of one or more claims of the '117 patent under 35 U.S.C. §§ 271(b) and/or (c).

50. For example, claim 14 of the '117 patent recites:

> The compound of claim **1** (5S,6S,9R)-5-amino-6-(2,3-difluorophenyl)-6,7,8,9-tetrahydro-5H-cyclohepta[b]pyridin-9-yl 4-(2-oxo-2,3-dihydro-1H-imidazo[4,5-b]pyridin-1-yl)piperidine-1-carboxylate;
>
> 
> 
>
> or a pharmaceutically acceptable salt thereof.

51. The chemical name and chemical structure recited in claim 14 correspond to the compound rimegepant. Upon information and belief, Apotex's ANDA Product will contain rimegepant sulfate. Rimegepant sulfate is a pharmaceutically acceptable salt of rimegepant.

52. Upon information and belief, Defendants have acted with full knowledge of the '117 patent and without a reasonable basis for believing that they would not be liable for infringement of the '117 patent. Notwithstanding this knowledge, Defendants have continued to assert their intent to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Apotex's ANDA Product with its proposed labeling immediately and imminently upon approval of the Apotex ANDA. Upon information and belief, through such activities, Defendants specifically intend infringement of the '117 patent.

53. Upon information and belief, if the FDA approves the Apotex ANDA, Defendants plan and intend to, and will, infringe, actively induce infringement of, and/or contribute to the infringement of the '117 patent, and will do so immediately and imminently upon approval.

54. Upon information and belief, Defendants know that Apotex's ANDA Product is especially made or adapted for use in infringing the '117 patent, and that Apotex's ANDA Product is not suitable for any substantial non-infringing use. Upon information and belief, Defendants plan and intend to, and will, contribute to infringement of the '117 patent immediately and imminently upon approval of the Apotex ANDA.

55. Plaintiffs will be harmed substantially and irreparably if Defendants are not enjoined from infringing the '117 patent.

56. Plaintiffs have no adequate remedy at law.

57. Plaintiffs are entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

58. The Court should declare that the commercial manufacture, use, sale, offer for sale, or importation of Apotex's ANDA Product with its proposed labeling will infringe the '117 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

## COUNT III
**(Infringement of the '372 Patent)**

59. Plaintiffs reallege, and incorporate fully herein, each preceding paragraph.

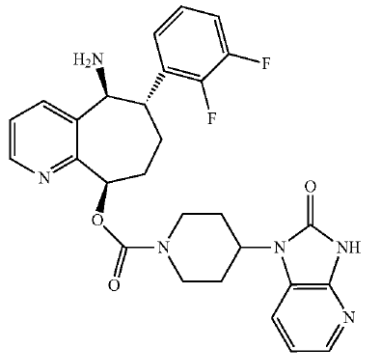
60. Defendants have infringed one or more claims of the '372 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting to the FDA and maintaining the Apotex ANDA, by which Defendants seek approval from the FDA to sell, offer to sell, use, and/or engage in the commercial manufacture of Apotex's ANDA Product before the expiration of the '372 patent.

61. Upon information and belief, Defendants' commercial manufacture, sale, offer for sale, or use of Apotex's ANDA Product within the United States, or importation of Apotex's ANDA Product into the United States, during the term of the '372 patent would infringe one or more claims of the '372 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

62. Upon information and belief, Defendants' commercial manufacture, sale, offer for sale, or use of Apotex's ANDA Product within the United States, or importation of Apotex's ANDA Product into the United States, during the term of the '372 patent would induce and/or contribute to the infringement of one or more claims of the '372 patent under 35 U.S.C. §§ 271(b) and/or (c).

63. For example, claim 1 of the '372 patent recites:

A hemisulfate salt of Compound (I):




64. The chemical structure recited in claim 1 for Compound (I) corresponds to rimegepant. Upon information and belief, Apotex's ANDA Product will contain a hemisulfate salt of rimegepant.

65. Upon information and belief, Defendants have acted with full knowledge of the '372 patent and without a reasonable basis for believing that they would not be liable for infringement of the '372 patent. Notwithstanding this knowledge, Defendants have continued to

assert their intent to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Apotex's ANDA Product with its proposed labeling immediately and imminently upon approval of the Apotex ANDA. Upon information and belief, through such activities, Defendants specifically intend infringement of the '372 patent.

66. Upon information and belief, if the FDA approves the Apotex ANDA, Defendants plan and intend to, and will, infringe, actively induce infringement of, and/or contribute to the infringement of the '372 patent, and will do so immediately and imminently upon approval.

67. Upon information and belief, Defendants know that Apotex's ANDA Product is especially made or adapted for use in infringing the '372 patent, and that Apotex's ANDA Product is not suitable for any substantial non-infringing use. Upon information and belief, Defendants plan and intend to, and will, contribute to infringement of the '372 patent immediately and imminently upon approval of the Apotex ANDA.

68. Plaintiffs will be harmed substantially and irreparably if Defendants are not enjoined from infringing the '372 patent.

69. Plaintiffs have no adequate remedy at law.

70. Plaintiffs are entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

**COUNT IV**
**(Declaratory Judgment of Infringement of the '372 Patent)**

71. Plaintiffs reallege, and incorporate fully herein, each preceding paragraph.

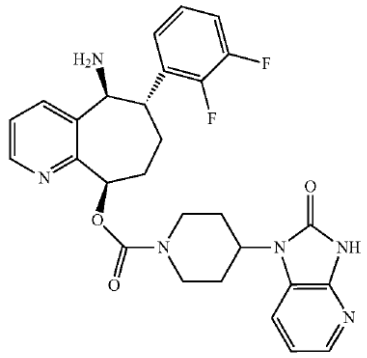
72. There is a substantial and immediate controversy between Plaintiffs and Apotex concerning the '372 patent. Plaintiffs are entitled to a declaratory judgment under 28 U.S.C. §§ 2201 and 2202 that Apotex will infringe, actively induce infringement of, and/or contribute to the infringement of the '372 patent upon approval of the Apotex ANDA.

73. Upon information and belief, Defendants' commercial manufacture, sale, offer for sale, or use of Apotex's ANDA Product within the United States, or importation of Apotex's ANDA Product into the United States, during the term of the '372 patent would infringe one or more claims of the '372 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

74. Upon information and belief, Defendants' commercial manufacture, sale, offer for sale, or use of Apotex's ANDA Product within the United States, or importation of Apotex's ANDA Product into the United States, during the term of the '372 patent would induce and/or contribute to the infringement of one or more claims of the '372 patent under 35 U.S.C. §§ 271(b) and/or (c).

75. For example, claim 1 of the '372 patent recites:

A hemisulfate salt of Compound (I):




76. The chemical structure recited in claim 1 for Compound (I) corresponds to rimegepant. Upon information and belief, Apotex's ANDA Product will contain a hemisulfate salt of rimegepant.

77. Upon information and belief, Defendants have acted with full knowledge of the '372 patent and without a reasonable basis for believing that they would not be liable for infringement of the '372 patent. Notwithstanding this knowledge, Defendants have continued to

assert their intent to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Apotex's ANDA Product with its proposed labeling immediately and imminently upon approval of the Apotex ANDA. Upon information and belief, through such activities, Defendants specifically intend infringement of the '372 patent.

78. Upon information and belief, if the FDA approves the Apotex ANDA, Defendants plan and intend to, and will, infringe, actively induce infringement of, and/or contribute to the infringement of the '372 patent, and will do so immediately and imminently upon approval.

79. Upon information and belief, Defendants know that Apotex's ANDA Product is especially made or adapted for use in infringing the '372 patent, and that Apotex's ANDA Product is not suitable for any substantial non-infringing use. Upon information and belief, Defendants plan and intend to, and will, contribute to infringement of the '372 patent immediately and imminently upon approval of the Apotex ANDA.

80. Plaintiffs will be harmed substantially and irreparably if Defendants are not enjoined from infringing the '372 patent.

81. Plaintiffs have no adequate remedy at law.

82. Plaintiffs are entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

83. The Court should declare that the commercial manufacture, use, sale, offer for sale, or importation of Apotex's ANDA Product with its proposed labeling will infringe the '372 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

## COUNT V
## (Infringement of the '724 Patent)

84. Pfizer realleges, and incorporates fully herein, each preceding paragraph.

85. Defendants have infringed one or more claims of the '724 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting to the FDA and maintaining the Apotex ANDA, by which Defendants seek approval from the FDA to sell, offer to sell, use, and/or engage in the commercial manufacture of Apotex's ANDA Product before the expiration of the '724 patent.

86. Upon information and belief, Defendants' commercial manufacture, sale, offer for sale, or use of Apotex's ANDA Product within the United States, or importation of Apotex's ANDA Product into the United States, during the term of the '724 patent would infringe one or more claims of the '724 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

87. Upon information and belief, Defendants' commercial manufacture, sale, offer for sale, or use of Apotex's ANDA Product within the United States, or importation of Apotex's ANDA Product into the United States, during the term of the '724 patent would induce and/or contribute to the infringement of one or more claims of the '724 patent under 35 U.S.C. §§ 271(b) and/or (c).

88. For example, claim 1 of the '724 patent recites:

> A pharmaceutical composition comprising a pharmaceutically acceptable carrier and a therapeutically effective amount of a CGRP receptor antagonist, or a pharmaceutically acceptable salt thereof, wherein the pharmaceutical composition is in a form of an oral solid molded fast-dispersing dosage form.

89. Upon information and belief, Apotex's ANDA Product will contain a pharmaceutical composition comprising a therapeutically effective amount of rimegepant sulfate, which is a pharmaceutically acceptable salt of the CGRP receptor antagonist rimegepant. Upon information and belief, the pharmaceutical composition of Apotex's ANDA Product will be in a form of an oral solid molded fast-dispersing dosage form.

90. Upon information and belief, Defendants have acted with full knowledge of the '724 patent and without a reasonable basis for believing that they would not be liable for infringement of the '724 patent. Notwithstanding this knowledge, Defendants have continued to assert their intent to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Apotex's ANDA Product with its proposed labeling immediately and imminently upon approval of the Apotex ANDA. Upon information and belief, through such activities, Defendants specifically intend infringement of the '724 patent.

91. Upon information and belief, if the FDA approves the Apotex ANDA, Defendants plan and intend to, and will, infringe, actively induce infringement of, and/or contribute to the infringement of the '724 patent, and will do so immediately and imminently upon approval.

92. Upon information and belief, Defendants know that Apotex's ANDA Product is especially made or adapted for use in infringing the '724 patent, and that Apotex's ANDA Product is not suitable for any substantial non-infringing use. Upon information and belief, Defendants plan and intend to, and will, contribute to infringement of the '724 patent immediately and imminently upon approval of the Apotex ANDA.

93. Pfizer will be harmed substantially and irreparably if Defendants are not enjoined from infringing the '724 patent.

94. Pfizer has no adequate remedy at law.

95. Pfizer is entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

**COUNT VI**
**(Declaratory Judgment of Infringement of the '724 Patent)**

96. Pfizer realleges, and incorporates fully herein, each preceding paragraph.

97. There is a substantial and immediate controversy between Pfizer and Apotex concerning the '724 patent. Pfizer is entitled to a declaratory judgment under 28 U.S.C. §§ 2201 and 2202 that Apotex will infringe, actively induce infringement of, and/or contribute to the infringement of the '724 patent upon approval of the Apotex ANDA.

98. Upon information and belief, Defendants' commercial manufacture, sale, offer for sale, or use of Apotex's ANDA Product within the United States, or importation of Apotex's ANDA Product into the United States, during the term of the '724 patent would infringe one or more claims of the '724 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

99. Upon information and belief, Defendants' commercial manufacture, sale, offer for sale, or use of Apotex's ANDA Product within the United States, or importation of Apotex's ANDA Product into the United States, during the term of the '724 patent would induce and/or contribute to the infringement of one or more claims of the '724 patent under 35 U.S.C. §§ 271(b) and/or (c).

100. For example, claim 1 of the '724 patent recites:

> A pharmaceutical composition comprising a pharmaceutically acceptable carrier and a therapeutically effective amount of a CGRP receptor antagonist, or a pharmaceutically acceptable salt thereof, wherein the pharmaceutical composition is in a form of an oral solid molded fast-dispersing dosage form.

101. Upon information and belief, Apotex's ANDA Product will contain a pharmaceutical composition comprising a therapeutically effective amount of rimegepant sulfate, which is a pharmaceutically acceptable salt of the CGRP receptor antagonist rimegepant. Upon information and belief, the pharmaceutical composition of Apotex's ANDA product will be in a form of an oral solid molded fast-dispersing dosage form.

102. Upon information and belief, Defendants have acted with full knowledge of the '724 patent and without a reasonable basis for believing that they would not be liable for infringement of the '724 patent. Notwithstanding this knowledge, Defendants have continued to assert their intent to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Apotex's ANDA Product with its proposed labeling immediately and imminently upon approval of the Apotex ANDA. Upon information and belief, through such activities, Defendants specifically intend infringement of the '724 patent.

103. Upon information and belief, if the FDA approves the Apotex ANDA, Defendants plan and intend to, and will, infringe, actively induce infringement of, and/or contribute to the infringement of the '724 patent, and will do so immediately and imminently upon approval.

104. Upon information and belief, Defendants know that Apotex's ANDA Product is especially made or adapted for use in infringing the '724 patent, and that Apotex's ANDA Product is not suitable for any substantial non-infringing use. Upon information and belief, Defendants plan and intend to, and will, contribute to infringement of the '724 patent immediately and imminently upon approval of the Apotex ANDA.

105. Pfizer will be harmed substantially and irreparably if Defendants are not enjoined from infringing the '724 patent.

106. Pfizer has no adequate remedy at law.

107. Pfizer is entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

108. The Court should declare that the commercial manufacture, use, sale, offer for sale, or importation of Apotex's ANDA Product with its proposed labeling will infringe the '724 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

## PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for a judgment in their favor and against Defendants and respectfully request the following relief:

A. A judgment that Defendants have infringed the patents-in-suit pursuant to 35 U.S.C. § 271(e)(2)(A) by submitting to the FDA and maintaining ANDA No. 219399;

B. An order pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of approval of ANDA No. 219399 shall be a date not earlier than the expiration of the patents-in-suit, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

C. A judgment declaring that the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Apotex's ANDA Product will directly infringe, induce and/or contribute to infringement of the patents-in-suit;

D. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining Defendants, their officers, agents, servants, and employees, and those persons acting in privity or concert with them, from manufacturing, using, offering to sell, or selling Apotex's ANDA Product within the United States, or importing Apotex's ANDA Product into the United States, before the expiration of the patents-in-suit, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

E. If Defendants commercially manufacture, use, offer to sell, or sell Apotex's ANDA Product within the United States, or import Apotex's ANDA Product into the United States, before the expiration of the patents-in-suit, including any extensions, a judgment awarding damages to Plaintiffs resulting from such infringement, together with interest;

F. A judgment that this is an exceptional case pursuant to 35 U.S.C. § 285 and awarding Plaintiffs their attorneys' fees incurred in this action;

G. A judgment awarding Plaintiffs costs and expenses incurred in this action; and

H. Such further and other relief as this Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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May 23, 2024