

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

PFIZER INC., PFIZER IRELAND )  
PHARMACEUTICALS, and )  
BRISTOL-MYERS SQUIBB )  
COMPANY, )  
                               )  
Plaintiffs,                 ) C.A. No. 1:24-cv-00621-CFC  
                               )  
                               )  
v.                             )  
                               )  
APOTEX INC. and APOTEX CORP., )  
                               )  
                               )  
Defendants.

**APOTEX INC. AND APOTEX CORP.’S ANSWER,  
AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS TO COMPLAINT**

Defendants Apotex Inc. and Apotex Corp. (collectively, “Apotex”), by and through their counsel, hereby answer and respond to each of the allegations of the Complaint of Pfizer Inc., Pfizer Ireland Pharmaceuticals, and Bristol-Myers Squibb Company (collectively, “Plaintiffs”) (D.I. 1), and assert their affirmative defenses as follows:

**GENERAL DENIAL**

Pursuant to Rule 8(b)(3) of the Federal Rules of Civil Procedure, Apotex denies all allegations in Plaintiffs’ Complaint except those specifically admitted below. To the extent that any of the Complaint’s headings constitute factual allegations, Apotex specifically denies each and every such allegation.

## **NATURE OF THE ACTION**

1. This Paragraph states a legal conclusion that does not require an answer. To the extent that an answer is required, Apotex admits that Plaintiffs' Complaint purports to set forth an action for infringement arising from Apotex's submission of Abbreviated New Drug Application ("ANDA") No. 219399 regarding a generic version of Pfizer Inc.'s NURTEC ODT® (rimegepant sulfate) and related United States 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") arising 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.* Otherwise, denied.

## **THE PARTIES**

2. Apotex lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this Paragraph and, therefore, denies those allegations, aside from Pfizer Inc.'s address.

3. Apotex lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this Paragraph and, therefore, denies those allegations, aside from Pfizer Ireland Pharmaceuticals' address.

4. Apotex lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this Paragraph and, therefore, denies those allegations, aside from the address of Bristol-Myers Squibb Company's address.

5. Admitted.

6. Admitted.

7. This Paragraph states a legal conclusion that does not require an answer. To the extent that an answer is required, Apotex admits that Apotex Corp. is the U.S. Agent for Apotex Inc. with respect to the Apotex ANDA. Otherwise, denied.

8. This Paragraph states a legal conclusion that does not require an answer. To the extent that an answer is required, Apotex admits that Apotex Corp. sells pharmaceutical products in the United States. Otherwise, denied.

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

9. Apotex admits only that the '117 patent is entitled "CGRP receptor Antagonists," issued on November 20, 2012, and that a purported copy thereof was attached as Exhibit A to the Complaint. Apotex lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of this Paragraph and, therefore, denies those allegations. To the extent that any allegations of this Paragraph require a legal conclusion, Apotex further denies those allegations.

10. Apotex admits only that the '372 patent is 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," issued on June 24, 2014, and that a purported copy thereof was attached as

Exhibit B to the Complaint. Apotex lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of this Paragraph and, therefore, denies those allegations. To the extent that any allegations of this Paragraph require a legal conclusion, Apotex further denies those allegations.

11. Apotex admits only that the '724 patent is entitled "Rimegepant for CGRP Related Disorders," issued on August 10, 2021, and that a purported copy thereof was attached as Exhibit C to the Complaint. Apotex lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of this Paragraph and, therefore, denies those allegations. To the extent that any allegations of this Paragraph require a legal conclusion, Apotex further denies those allegations.

**NURTEC ODT®**

12. This Paragraph states a legal conclusion that does not require an answer. To the extent that an answer is required, Apotex admits that information published by FDA identifies Pfizer Inc. as the holder of New Drug Application ("NDA") No. 212728. Apotex lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of this Paragraph and, therefore, denies those allegations.

13. This Paragraph states a legal conclusion that does not require an answer. To the extent that an answer is required, Apotex lacks knowledge or

information sufficient to form a belief as to the truth of the allegations of this Paragraph and, therefore, denies those allegations, but admits that the patents-in-suit are listed in the “Orange Book” with respect to NURTEC ODT®.

### **THE APOTEX ANDA**

14. This Paragraph states a legal conclusion that does not require an answer. To the extent that an answer is required, Apotex admits that Apotex Corp. is the U.S. Agent for Apotex Inc. with respect to the Apotex ANDA and that Apotex submitted the Apotex ANDA to the FDA seeking approval for Apotex’s ANDA Product. Otherwise, denied.

15. This Paragraph states a legal conclusion that does not require an answer. To the extent that an answer is required, Apotex admits that Apotex Corp. is the U.S. Agent for Apotex Inc. with respect to the Apotex ANDA. Otherwise, denied.

16. This Paragraph states a legal conclusion that does not require an answer. To the extent that an answer is required, Apotex admits that Apotex’s ANDA Product will use rimegepant sulfate as an active ingredient. Otherwise, denied.

17. This Paragraph states a legal conclusion that does not require an answer. To the extent that an answer is required, Apotex admits that the Apotex

ANDA references New Drug Application 212728 and addresses bioequivalence of Apotex's ANDA Product. Otherwise, denied.

18. Admitted.

19. Apotex lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this Paragraph and, therefore, denies those allegations.

20. Admitted.

### **JURISDICTION AND VENUE**

21. This Paragraph states a legal conclusion that does not require an answer. To the extent that an answer is required, Apotex admits that this Paragraph alleges that this case arises under the "patent laws of the United States" and that this Court has subject matter jurisdiction.

22. This Paragraph states a legal conclusion that does not require an answer. To the extent that an answer is required, solely for the purposes of this action, Apotex Inc. is not contesting personal jurisdiction or Plaintiffs' choice of venue. Otherwise, denied.

23. Admitted.

24. This Paragraph states a legal conclusion that does not require an answer. To the extent that an answer is required, denied.

25. This Paragraph states a legal conclusion that does not require an answer. To the extent that an answer is required, solely for the purposes of this

action, Apotex Corp. is not contesting personal jurisdiction or Plaintiffs' choice of venue. Otherwise, denied.

26. This Paragraph states a legal conclusion that does not require an answer. To the extent that an answer is required, solely for the purposes of this action, Apotex Corp. is not contesting personal jurisdiction or Plaintiffs' choice of venue. Otherwise, denied.

27. This Paragraph states a legal conclusion that does not require an answer. To the extent that an answer is required, denied.

28. This Paragraph states a legal conclusion that does not require an answer. To the extent that an answer is required, denied.

29. This Paragraph states a legal conclusion that does not require an answer. To the extent that an answer is required, denied.

30. Apotex admits that Apotex Inc. and Apotex Corp. has been a party to the actions listed in this Paragraph. To the extent that a further answer is required, solely for the purpose of this action, Apotex is not contesting personal jurisdiction in this district. Apotex denies the remaining allegations, to the extent that legal conclusions are required, of this Paragraph.

31. This Paragraph states a legal conclusion that does not require an answer. To the extent that an answer is required, solely for the purposes of this action, Apotex is not contesting personal jurisdiction. Otherwise, denied.

32. This Paragraph states a legal conclusion that does not require an answer. To the extent that an answer is required, solely for the purposes of this action, Apotex Inc. is not contesting Plaintiffs' choice of venue. Otherwise, denied.

33. This Paragraph states a legal conclusion that does not require an answer. To the extent that an answer is required, solely for the purposes of this action, Apotex Corp. is not contesting Plaintiffs' choice of venue. Otherwise, denied.

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

34. Apotex restates, realleges, and incorporates by reference fully herein each of the responses to each preceding Paragraph.

35. Denied.

36. Denied.

37. Denied.

38. Apotex admits that claim 14 of the '117 patent recites the quotation provided in this Paragraph.

39. This Paragraph states a legal conclusion that does not require an answer. To the extent that an answer is required, Apotex lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this Paragraph and, therefore, denies those allegations.

40. This Paragraph states a legal conclusion that does not require an answer. To the extent that an answer is required, Apotex admits that it was aware of the '117 patent as of the date of the filing of its ANDA. Otherwise, denied.

41. Denied.

42. Denied.

43. Denied.

44. Denied.

45. Denied.

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

46. Apotex restates, realleges, and incorporates by reference fully herein each of the responses to each preceding Paragraph.

47. Denied.

48. Denied.

49. Denied.

50. Apotex admits that claim 14 of the '117 patent recites the quotation provided in this Paragraph.

51. This Paragraph states a legal conclusion that does not require an answer. To the extent that an answer is required, Apotex lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this Paragraph and, therefore, denies those allegations.

52. This Paragraph states a legal conclusion that does not require an answer. To the extent that an answer is required, Apotex admits that it was aware of the '117 patent as of the date of the filing of its ANDA. Otherwise, denied.

53. Denied.

54. Denied.

55. Denied.

56. Denied.

57. Denied.

58. Denied.

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

59. Apotex restates, realleges, and incorporates by reference fully herein each of the responses to each preceding Paragraph.

60. Denied.

61. Denied.

62. Denied.

63. Apotex admits that claim 1 of the '372 patent recites the quotation provided in this Paragraph.

64. This Paragraph states a legal conclusion that does not require an answer. To the extent that an answer is required, Apotex lacks knowledge or

information sufficient to form a belief as to the truth of the allegations of this Paragraph and, therefore, denies those allegations.

65. This Paragraph states a legal conclusion that does not require an answer. To the extent that an answer is required, Apotex admits that it was aware of the '372 patent as of the date of the filing of its ANDA. Otherwise, denied.

66. Denied.

67. Denied.

68. Denied.

69. Denied.

70. Denied.

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

71. Apotex restates, realleges, and incorporates by reference fully herein each of the responses to each preceding Paragraph.

72. Denied.

73. Denied.

74. Denied.

75. Apotex admits that claim 1 of the '372 patent recites the quotation provided in this Paragraph.

76. This Paragraph states a legal conclusion that does not require an answer. To the extent that an answer is required, Apotex lacks knowledge or

information sufficient to form a belief as to the truth of the allegations of this Paragraph and, therefore, denies those allegations.

77. This Paragraph states a legal conclusion that does not require an answer. To the extent that an answer is required, Apotex admits that it was aware of the '372 patent as of the date of the filing of its ANDA. Otherwise, denied.

78. Denied.

79. Denied.

80. Denied.

81. Denied.

82. Denied.

83. Denied.

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

84. Apotex restates, realleges, and incorporates by reference fully herein each of the responses to each preceding Paragraph.

85. Denied.

86. Denied.

87. Denied.

88. Apotex admits that claim 1 of the '724 patent recites the quotation provided in this Paragraph.

89. This Paragraph states a legal conclusion that does not require an answer. To the extent that an answer is required, Apotex lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this Paragraph and, therefore, denies those allegations.

90. This Paragraph states a legal conclusion that does not require an answer. To the extent that an answer is required, Apotex admits that it was aware of the '724 patent as of the date of the filing of its ANDA. Otherwise, denied.

91. Denied.

92. Denied.

93. Denied.

94. Denied.

95. Denied.

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

96. Apotex restates, realleges, and incorporates by reference fully herein each of the responses to each preceding Paragraph.

97. Denied.

98. Denied.

99. Denied.

100. Apotex admits that claim 1 of the '724 patent recites the quotation provided in this Paragraph.

101. This Paragraph states a legal conclusion that does not require an answer. To the extent that an answer is required, Apotex lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this Paragraph and, therefore, denies those allegations.

102. This Paragraph states a legal conclusion that does not require an answer. To the extent that an answer is required, Apotex admits that it was aware of the '724 patent as of the date of the filing of its ANDA. Otherwise, denied.

103. Denied.

104. Denied.

105. Denied.

106. Denied.

107. Denied.

108. Denied.

#### **PRAAYER FOR RELIEF**

All remaining allegations not specifically admitted herein are denied. It is further denied that Plaintiffs are entitled to the relief requested in the Complaint or to any relief whatsoever.

#### **AFFIRMATIVE DEFENSES**

Without prejudice to the denials set forth in its Answer, and without admitting any allegations of the Complaint not expressly admitted, Apotex asserts the

following separate defenses to the Complaint without assuming the burden of proof on any such defense that would otherwise rest with Plaintiffs.

### **FIRST AFFIRMATIVE DEFENSE**

Plaintiffs have failed to state a claim upon which relief can be granted.

### **SECOND AFFIRMATIVE DEFENSE**

The claims of the patents-in-suit are invalid for failure to satisfy one or more of the conditions for patentability contained in 35 U.S.C. §§ 101, 102, 103, 112, and/or obviousness-type double patenting.

### **THIRD AFFIRMATIVE DEFENSE**

Apotex has not and will not directly or indirectly infringe any valid or enforceable claim of the patents-in-suit. The manufacture, use, offer for sale, sale, and/or importation of the products that are the subject of the Apotex ANDA does not and will not infringe any valid or enforceable claim of the patents-in-suit, either literally or under the doctrine of equivalents.

### **FOURTH AFFIRMATIVE DEFENSE**

Plaintiffs are barred from asserting infringement based on the doctrine of equivalents in view of prosecution history estoppel, disclaimer, the disclosure-dedication rule, vitiation, and/or ensnarement.

**FIFTH AFFIRMATIVE DEFENSE**

The Complaint fails to state a claim for exceptional case or willful infringement.

**SIXTH AFFIRMATIVE DEFENSE**

35 U.S.C. § 288 prevents Plaintiffs from recovering any costs associated with this case.

**SEVENTH AFFIRMATIVE DEFENSE**

Apotex reserves all defenses, in law or equity, which may now exist or, in the future, be available during discovery and further factual investigation in this case.

## **COUNTERCLAIMS**

Counterclaim-Plaintiffs Apotex Inc. and Apotex Corp. (collectively, “Apotex”) for their counterclaims against Plaintiffs/Counterclaim-Defendants Pfizer Inc., Pfizer Ireland Pharmaceuticals, and Bristol-Myers Squibb Company (collectively, “Plaintiffs/Counterclaim-Defendants”), allege as follows:

1. This is a counterclaim action for declaratory judgment that United States 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”) are invalid and not infringed pursuant to the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02, and the Patent Laws of the United States, 35 U.S.C. §§ 100 *et seq.*, and for such other relief as the Court deems just and proper.

## **THE PARTIES**

2. Apotex Inc. is a Canadian corporation, with its principal place of business at 150 Signet Drive, Toronto, Ontario M9L 1T9, Canada.

3. Apotex Corp. is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326.

4. On information and belief, and based on the allegations in the Complaint, Plaintiff/Counterclaim-Defendant 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, New York 10001.

5. On information and belief, and based on the allegations in the Complaint, Plaintiff/Counterclaim-Defendant 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, and is a wholly owned, indirect subsidiary of Plaintiff/Counterclaim-Defendant Pfizer Inc.

6. On information and belief, and based on the allegations in the Complaint, Plaintiff/Counterclaim-Defendant Bristol-Myers Squibb Company is a corporation organized and existing under the laws of the State of Delaware, having a place of business at Route 206 and Province Line Road, Princeton, New Jersey 08540.

#### **JURISDICTION AND VENUE**

7. The Court has jurisdiction over these counterclaims pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, 2202, and the Patent Laws of the United States, 35 U.S.C. §§ 1 *et seq.*

8. This is an action based on an actual controversy between Apotex and Plaintiffs/Counterclaim-Defendants concerning the noninfringement and invalidity of the patents-in-suit arising under the patent laws of the United States, 35 U.S.C.

§§ 100 *et seq.*, and Apotex’s right to continue to seek approval by the Food and Drug Administration (“FDA”) of Abbreviated New Drug Application (“ANDA”) No. 219399 (the “Apotex ANDA”) and, upon FDA approval, to manufacture, use, sell, and offer to sell within, and/or import into, the United States the products that are the subject of the Apotex ANDA (“Apotex’s ANDA Product(s)”) should Apotex decide to do so.

9. The Court has personal jurisdiction over Plaintiffs/Counterclaim-Defendants because they have availed themselves of the rights and privileges, and subjected themselves to the jurisdiction, of this forum by suing Apotex in this District and, on information and belief, because Plaintiffs/Counterclaim-Defendants transact business within the State of Delaware and/or have engaged in systematic and continuous business contacts—directly or indirectly through a subsidiary—within the State of Delaware.

10. Venue is proper in this District under 28 U.S.C. § 1391, § 1400(b), 21 U.S.C. § 355(j)(5)(C)(i)(II), and/or by Plaintiffs/Counterclaim-Defendants’ choice of forum.

## **BACKGROUND**

11. Apotex incorporates each of its responses to each Paragraph of the Complaint, as well as the foregoing paragraphs 1 through 10 of the Counterclaims, as if fully set forth herein.

12. On or about November 20, 2012, according to the electronic records of the U.S. Patent and Trademark Office (the “USPTO”), the ’117 patent, entitled “CGRP RECEPTOR ANTAGONISTS,” issued, on its face, with named inventors Guanglin Luo, Gene M. Dubowchik, and John E. Macor. Plaintiffs/Counterclaim-Defendants represented that a copy of the ’117 patent was attached as Exhibit A to the Complaint.

13. On or about June 24, 2014, according to the electronic records of the USPTO, 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,” issued, on its face, with named inventors Daniel Richard Roberts, Richard Raymond Schartman, and Chenkou Wei. Plaintiffs/Counterclaim-Defendants represented that a copy of the ’372 patent was attached as Exhibit B to the Complaint.

14. On or about August 10, 2021, according to the electronic records of the USPTO, the ’724 patent, entitled “RIMEGEPANT FOR CGRP RELATED DISORDERS,” issued, on its face, with named inventors Vladimir Coric and Robert Croop. Plaintiffs/Counterclaim-Defendants represented that a copy of the ’724 patent was attached as Exhibit C to the Complaint. The ’724 patent is subject to a terminal disclaimer.

15. On information and belief, one or more of Plaintiffs/Counterclaim-Defendants purport(s) to own, and/or to have the rights to enforce, the patents-in-suit.

16. On information and belief, Plaintiffs/Counterclaim-Defendants caused the FDA to list the patents-in-suit in the FDA's Orange Book publication in connection with New Drug Application ("NDA") No. 212728 for NURTEC ODT®.

17. On information and belief, Plaintiffs/Counterclaim-Defendants have not caused the FDA to remove the patents-in-suit from the Orange Book in connection with NURTEC ODT®.

18. By maintaining that listing of the patents-in-suit in the Orange Book, Plaintiffs/Counterclaim-Defendants represent that the claims of infringement of the patents-in-suit "could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." *See* 21 U.S.C. § 355(b)(1)(A)(viii).

19. By letter dated April 18, 2024, Apotex timely notified Plaintiffs/Counterclaim-Defendants that Apotex had submitted ANDA No. 219399 to the FDA with a Paragraph IV certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the patents-in-suit ("Notice Letter"). Apotex's Notice Letter met the statutory and regulatory requirements for such notice letters and included a detailed statement of the factual and legal bases for Apotex's opinion

that the claims of the patents-in-suit are invalid, unenforceable, and/or will not be infringed by the manufacture, use, sale, offer for sale, and/or importation of Apotex's ANDA Products. Apotex incorporates by reference the positions set forth in its Notice Letter but reserves the right to amend them.

20. Apotex's Notice Letter included an Offer of Confidential Access ("OCA"), provided pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III). Despite providing this OCA, on information and belief, counsel for Apotex is unaware of any attempt by Plaintiffs/Counterclaim-Defendants to negotiate the terms of the OCA or otherwise seek access to Apotex's ANDA in order to make a determination as to whether an infringement action should be brought.

21. On May 23, 2024, without reviewing any portions of Apotex's ANDA, Plaintiffs/Counterclaim-Defendants sued Apotex in this District for purported infringement of the patents-in-suit.

22. In view of the foregoing, there has been, and is now, a definite and concrete, real and substantial, justiciable, and continuing case or controversy existing between Apotex and Plaintiffs/Counterclaim-Defendants having sufficient immediacy and reality to warrant the issuance of a declaration of rights by the Court with respect to noninfringement and invalidity of the patents-in-suit, and as to Apotex's right to obtain FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of Apotex's ANDA Products.

**COUNT I**  
**Declaratory Judgment of Noninfringement of the '117 Patent**

23. Apotex incorporates each of its responses to each Paragraph of the Complaint, as well as the foregoing paragraphs 1 through 22 of the Counterclaims, as if fully set forth herein.

24. There is an actual, substantial, and continuing justiciable case or controversy between Apotex and Plaintiffs/Counterclaim-Defendants regarding whether the manufacture, use, offer for sale, sale, or importation of Apotex's ANDA Products will infringe any claim of the '117 patent.

25. Apotex denies infringement of any valid, enforceable, and properly construed claim of the '117 patent and alleges that Apotex has not, does not, and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid, enforceable, and properly construed claim of the '117 patent.

26. The manufacture, use, sale, or offer for sale within, and/or importation into the United States of Apotex's ANDA Products does not and will not constitute infringement (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), of any valid, enforceable, and properly construed claim of the '117 patent.

27. Apotex is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of Apotex's ANDA Products does not and will not infringe any valid and/or enforceable claim of the '117 patent.

**COUNT II**  
**Declaratory Judgment of Invalidity of the '117 Patent**

28. Apotex incorporates each of its responses to each Paragraph of the Complaint, as well as the foregoing paragraphs 1 through 27 of the Counterclaims, as if fully set forth herein.

29. Plaintiffs/Counterclaim-Defendants have accused Apotex of infringing claims of the '117 patent in connection with ANDA No. 219399.

30. Apotex denies infringement of any claim of the '117 patent because all claims of the '117 patent are invalid for failure to meet one or more of the conditions of patentability specified in Title 35 of the United States Code. Given their invalidity, Apotex cannot infringe any claims of the '117 patent, including for at least the reasons set forth in the detailed statements included with Apotex's Notice Letter.

31. The alleged inventions of the '117 patent do no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the '117 patent is no more than the predictable use of prior art elements. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged inventions

of the '117 patent and would have had a reasonable expectation of success in doing so.

32. The claims of the '117 patent are invalid at least under 35 U.S.C. §§ 102 and/or 103 in view of the prior art. The differences between the subject matter claimed in the '117 patent and the prior art are such that the subject matter as a whole was either fully anticipated by the prior art or would have been obvious, at the time that the alleged inventions were made, to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

33. The claims of the '117 patent are further invalid for failure to satisfy the requirements of 35 U.S.C. § 112.

34. Unless Plaintiffs/Counterclaim-Defendants are enjoined, Apotex believes that Plaintiffs/Counterclaim-Defendants will continue to assert that Apotex infringes the claims of the '117 patent and will continue to interfere with Apotex's business.

35. Apotex will be irreparably harmed if Plaintiffs/Counterclaim-Defendants are not enjoined from continuing to assert the claims of the '117 patent and from interfering with Apotex's business.

36. Apotex is entitled to a declaratory judgment that the asserted claims of the '117 patent are invalid.

**COUNT III**  
**Declaratory Judgment of Noninfringement of the '372 Patent**

37. Apotex incorporates each of its responses to each Paragraph of the Complaint, as well as the foregoing paragraphs 1 through 36 of the Counterclaims, as if fully set forth herein.

38. There is an actual, substantial, and continuing justiciable case or controversy between Apotex and Plaintiffs/Counterclaim-Defendants regarding whether the manufacture, use, offer for sale, sale, or importation of Apotex's ANDA Products will infringe any claim of the '372 patent.

39. Apotex denies infringement of any valid, enforceable, and properly construed claim of the '372 patent and alleges that Apotex has not, does not, and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid, enforceable, and properly construed claim of the '372 patent.

40. The manufacture, use, sale, or offer for sale within, and/or importation into the United States of Apotex's ANDA Products does not and will not constitute infringement (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), of any valid, enforceable, and properly construed claim of the '372 patent.

41. Apotex is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of Apotex's ANDA Products does not and will not infringe any valid and/or enforceable claim of the '372 patent.

**COUNT IV**  
**Declaratory Judgment of Invalidity of the '372 Patent**

42. Apotex incorporates each of its responses to each Paragraph of the Complaint, as well as the foregoing paragraphs 1 through 41 of the Counterclaims, as if fully set forth herein.

43. Plaintiffs/Counterclaim-Defendants have accused Apotex of infringing claims of the '372 patent in connection with ANDA No. 219399.

44. Apotex denies infringement of any claim of the '372 patent because all claims of the '372 patent are invalid for failure to meet one or more of the conditions of patentability specified in Title 35 of the United States Code. Given their invalidity, Apotex cannot infringe any claims of the '372 patent, including for at least the reasons set forth in the detailed statements included with Apotex's Notice Letter.

45. The alleged inventions of the '372 patent do no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the '372 patent is no more than the predictable use of prior art elements. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged inventions

of the '372 patent and would have had a reasonable expectation of success in doing so.

46. The claims of the '372 patent are invalid at least under 35 U.S.C. §§ 102 and/or 103 in view of the prior art. The differences between the subject matter claimed in the '372 patent and the prior art are such that the subject matter as a whole was either fully anticipated by the prior art or would have been obvious, at the time that the alleged inventions were made, to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

47. The claims of the '372 patent are further invalid for failure to satisfy the requirements of 35 U.S.C. § 112.

48. Unless Plaintiffs/Counterclaim-Defendants are enjoined, Apotex believes that Plaintiffs/Counterclaim-Defendants will continue to assert that Apotex infringes the claims of the '372 patent and will continue to interfere with Apotex's business.

49. Apotex will be irreparably harmed if Plaintiffs/Counterclaim-Defendants are not enjoined from continuing to assert the claims of the '372 patent and from interfering with Apotex's business.

50. Apotex is entitled to a declaratory judgment that the asserted claims of the '372 patent are invalid.

**COUNT V**  
**Declaratory Judgment of Noninfringement of the '724 Patent**

51. Apotex incorporates each of its responses to each Paragraph of the Complaint, as well as the foregoing paragraphs 1 through 50 of the Counterclaims, as if fully set forth herein.

52. There is an actual, substantial, and continuing justiciable case or controversy between Apotex and Plaintiffs/Counterclaim-Defendants regarding whether the manufacture, use, offer for sale, sale, or importation of Apotex's ANDA Product will infringe any claim of the '724 patent.

53. Apotex denies infringement of any valid, enforceable, and properly construed claim of the '724 patent and alleges that Apotex has not, does not, and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid, enforceable, and properly construed claim of the '724 patent.

54. The manufacture, use, sale, or offer for sale within, and/or importation into the United States of Apotex's ANDA Products does not and will not constitute infringement (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), of any valid, enforceable, and properly construed claim of the '724 patent.

55. Apotex is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of Apotex's ANDA Products does not and will not infringe any valid and/or enforceable claim of the '724 patent.

**COUNT VI**  
**Declaratory Judgment of Invalidity of the '724 Patent**

56. Apotex incorporates each of its responses to each Paragraph of the Complaint, as well as the foregoing paragraphs 1 through 55 of the Counterclaims, as if fully set forth herein.

57. Plaintiffs/Counterclaim-Defendants have accused Apotex of infringing claims of the '724 patent in connection with ANDA No. 219399.

58. Apotex denies infringement of any claim of the '724 patent because all claims of the '724 patent are invalid for failure to meet one or more of the conditions of patentability specified in Title 35 of the United States Code. Given their invalidity, Apotex cannot infringe any claims of the '724 patent, including for at least the reasons set forth in the detailed statements included with Apotex's Notice Letter.

59. The alleged inventions of the '724 patent do no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the '724 patent is no more than the predictable use of prior art elements. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged inventions

of the '724 patent and would have had a reasonable expectation of success in doing so.

60. The claims of the '724 patent are invalid at least under 35 U.S.C. §§ 102 and/or 103 in view of the prior art. The differences between the subject matter claimed in the '724 patent and the prior art are such that the subject matter as a whole was either fully anticipated by the prior art or would have been obvious, at the time that the alleged inventions were made, to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

61. The claims of the '724 patent are further invalid for failure to satisfy the requirements of 35 U.S.C. § 112.

62. Unless Plaintiffs/Counterclaim-Defendants are enjoined, Apotex believes that Plaintiffs/Counterclaim-Defendants will continue to assert that Apotex infringes the claims of the '724 patent and will continue to interfere with Apotex's business.

63. Apotex will be irreparably harmed if Plaintiffs/Counterclaim-Defendants are not enjoined from continuing to assert the claims of the '724 patent and from interfering with Apotex's business.

64. Apotex is entitled to a declaratory judgment that the asserted claims of the '724 patent are invalid.

**EXCEPTIONAL CASE**

This case is an exceptional one and Apotex is entitled to an award of its reasonable attorneys' fees and costs under 35 U.S.C. § 285.

**PRAAYER FOR RELIEF**

WHEREFORE, Apotex prays that the Court enter judgment in its favor and against Plaintiffs/Counterclaim-Defendants as follows:

- a) Dismissing the Complaint with prejudice and denying each request for relief made by Plaintiffs/Counterclaim-Defendants therein;
- b) Declaring that the claims of the patents-in-suit are not and will not be infringed;
- c) Declaring that the claims of the patents-in-suit are invalid or unenforceable;
- d) Entering judgment in Apotex's favor;
- e) Finding that this case is exceptional pursuant to 35 U.S.C. § 285 and granting an award of Apotex's attorneys' fees and costs to the extent permitted by law; and
- f) Granting Apotex any and all other relief to which Apotex may be justly entitled.

Dated: July 2, 2024

OF COUNSEL:

Deepro R. Mukerjee  
Lance A. Soderstrom  
Christopher B. Prescott  
KATTEN MUCHIN ROSENMAN  
LLP  
50 Rockefeller Plaza  
New York, NY 10020-1605  
Telephone: (212) 940-8800  
[deepro.mukerjee@katten.com](mailto:deepro.mukerjee@katten.com)  
[lance.soderstrom@katten.com](mailto:lance.soderstrom@katten.com)  
[christopher.prescott@katten.com](mailto:christopher.prescott@katten.com)

*/s/ Kenneth L. Dorsney*

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Kenneth L. Dorsney (#3726)  
Cortlan S. Hitch (#6720)  
MORRIS JAMES LLP  
500 Delaware Avenue, Suite 1500  
Wilmington, DE 19801  
(302) 888-6800  
[kdorsney@morrisjames.com](mailto:kdorsney@morrisjames.com)  
[chitch@morrisjames.com](mailto:chitch@morrisjames.com)

*Attorneys for Defendants  
Apotex Inc. and Apotex Corp.*

Joseph M. Janusz  
KATTEN MUCHIN ROSENMAN  
LLP  
550 S. Tryon Street, Suite 2900  
Charlotte, NC 28202-4213  
Telephone: (704) 444-2000  
[joseph.janusz@katten.com](mailto:joseph.janusz@katten.com)