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Attorneys for Defendants, MSN Pharmaceuticals Inc. and MSN Laboratories Private Limited

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

BeiGene USA, Inc. and BeiGene Switzerland GmbH Plaintiffs, v. MSN Pharmaceuticals Inc. and MSN Laboratories Private Limited Defendants.	Civ. No. 24-1971 (ZNQ)(RLS)

MSN'S ANSWER, SEPARATE DEFENSES, AND COUNTERCLAIMS TO BEIGENE'S COMPLAINT

Defendants MSN Pharmaceuticals Inc. ("MSN Pharmaceuticals") and MSN Laboratories Private Limited ("MSN Labs") (collectively, "Defendants"), by and through their attorneys answer the Complaint of Plaintiffs BeiGene USA, Inc. and BeiGene Switzerland GmbH ("BeiGene" or "Plaintiffs"), responding in each numbered paragraph below to correspond to the same numbered paragraph in the Complaint, and assert their separate defenses and counterclaims as follows. Except as otherwise specifically stated in this Answer, Defendants deny each and every allegation of Plaintiffs in the Complaint.

NATURE OF THE ACTION

1. Defendants admit that this purports to be an action for patent infringement relating to the referenced ANDA and the referenced patents. Otherwise, denied.

2. Defendants admit that they sent a Notice Letter on about January 26, 2024, in which they notified Plaintiffs that they had submitted ANDA No. 219095 to FDA under 21 U.S.C. § 355(j)(2)(B)(iv)(I) seeking approval to sell zanubrutinib capsules before the expiration of the '117, '340, and '531 patents listed in the FDA Orange Book for that product. Otherwise, denied.

3. Defendants admit that they sent a Notice Letter on about February 28, 2024, in which they notified Plaintiffs that they had submitted ANDA No. 219095 to FDA under 21 U.S.C. § 355(j)(2)(B)(iv)(I) seeking approval to sell zanubrutinib capsules before the expiration of the '437 patent listed in the FDA Orange Book for that product. Otherwise, denied.

THE PARTIES

4. Admitted that the FDA Orange Book identifies BeiGene USA, Inc., as the holder of NDA No. 213217, which references zanubrutinib capsules, 80 mg. Otherwise, Defendants are without information sufficient to form a belief as to the truth or falsity of the allegations in paragraph 4 of the Complaint; therefore, denied.

5. Defendants are without information sufficient to form a belief as to the truth or falsity of the allegations in paragraph 5 of the Complaint; therefore, denied.

6. Admitted that MSN Pharmaceuticals is a corporation organized and existing under the laws of Delaware and having a principal place of business at 20 Duke Road, Piscataway, New Jersey 08854. Otherwise, denied.

7. Defendants admit that MSN Labs is a private limited company organized and existing under the laws of India and having a principal place of business at the listed address. Further admitted that MSN Labs is in the business of, among other activities, developing and manufacturing pharmaceutical products. Otherwise, denied.

8. Admitted that MSN Pharmaceuticals is a wholly owned subsidiary of MSN Labs. Otherwise, denied.

9. Admitted that MSN Pharmaceuticals and MSN Labs cooperated in preparing MSN's ANDA. Otherwise, denied.

10. Admitted that MSN Pharmaceuticals prepared and filed ANDA No. 219095 with FDA seeking approval to market the MSN ANDA Product in the United States, and that MSN Pharmaceuticals is a wholly owned subsidiary of MSN Labs. Otherwise, denied.

11. Paragraph 11 is wholly speculative; denied.

JURISDICTION

12. Defendants incorporate their responses to each of the paragraphs 1-11 as if fully set forth herein.

13. This paragraph contains allegations and legal conclusions to which no response is required. To the extent a response is required, Defendants do not contest that this Court has subject matter jurisdiction over this action.

14. This paragraph contains allegations and legal conclusions to which no response is required. To the extent a response is required, Defendants do not contest personal jurisdiction for this action only.

15. Admitted that MSN Pharmaceuticals and MSN Labs prepared and submitted MSN's ANDA. Otherwise, denied.

16. Admitted.

17. Admitted that MSN Pharmaceuticals and MSN Labs prepared and submitted MSN's ANDA. Otherwise, denied.

18. Admitted that MSN Pharmaceuticals and MSN Labs prepared and submitted MSN's ANDA with certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV). Otherwise, denied.

19. Paragraph 19 is wholly speculative; denied.

20. Defendants admit that MSN Pharmaceuticals is the named applicant on approved ANDAs for certain products manufactured by MSN Pharmaceuticals that are available at certain retail pharmacies in New Jersey. Otherwise, denied.

21. This paragraph contains allegations and legal conclusions to which no response is required. To the extent a response is required, MSN Pharmaceuticals does not contest personal jurisdiction for this action only.

22. This paragraph contains allegations and legal conclusions to which no response is required. To the extent a response is required, MSN Labs does not contest personal jurisdiction for purposes of this action only.

23. This paragraph contains allegations and legal conclusions to which no response is required. To the extent a response is required, Defendants do not contest personal jurisdiction for this action only.

24. This paragraph contains allegations and legal conclusions to which no response is required. To the extent a response is required, Defendants do not contest personal jurisdiction for this action only.

25. This paragraph contains allegations and legal conclusions to which no response is required. To the extent a response is required, Defendants do not contest personal jurisdiction for this action only.

26. This paragraph contains allegations and legal conclusions to which no response is required. To the extent a response is required, Defendants do not contest personal jurisdiction for this action only.

VENUE

27. Defendants incorporate each of the responses to paragraphs 1-26 as if fully set forth herein.

28. This paragraph contains a legal conclusion to which no response is required. To the extent a response is required, Defendants do not contest venue for this action only.

29. This paragraph contains a legal conclusion to which no response is required. To the extent a response is required, Defendants do not contest venue for this action only.

30. This paragraph contains allegations and legal conclusions to which no response is required. To the extent a response is required, Defendants do not contest venue for this action only.

31. This paragraph contains allegations and legal conclusions to which no response is required. To the extent a response is required, Defendants do not contest venue for this action only.

FACTUAL BACKGROUND

32. Defendants incorporate their responses to paragraphs 1-31 as if fully set forth herein.

33. Defendants admit that the current prescribing information for BRUKINSA® lists zanubrutinib as a component, and states indications for lymphocytic leukemia, small lymphocytic lymphoma, Waldenström's macroglobulinemia, mantle cell lymphoma where the patient has received at least one prior therapy, and relapsed or refractory marginal zone lymphoma where the patient has received at least one anti-CD20-based regimen. Otherwise, denied.

34. Admitted that MSN Pharmaceuticals provided Notice Letters to Plaintiffs indicating it submitted its ANDA under § 355(j)(2)(A) and that Defendants believe the product described in ANDA No. 219095 ("ANDA Product") is bioequivalent to the reference listed drug, BRUKINSA®. Otherwise, denied.

35. Admitted that Defendants submitted ANDA No. 219095 with Paragraph IV certifications to seek FDA approval for their ANDA product prior to expiration of the Patents-in-Suit. Otherwise, denied.

36. Admitted that Defendants submitted ANDA No. 219095 to seek FDA approval for their ANDA product prior to expiration of the Patents-in-Suit. Otherwise, denied.

37. Admitted.

38. Admitted that Defendants extended to Plaintiffs an Offer of Confidential Access to review relevant portions of ANDA No. 219095 with their Notice Letters; otherwise, denied.

39. Admitted that counsel for Plaintiffs and counsel for Defendants corresponded regarding the Offer of Confidential Access to ANDA No. 219095, but Plaintiffs refused to agree to Defendants' Offer of Confidential Access. Otherwise, denied.

40. Admitted.

COUNT I – INFRINGEMENT OF THE '117 PATENT

41. Defendants incorporate their responses to paragraphs 1-40 as if fully set forth herein.

42. Admitted that what purports to be the '117 patent is attached to the Complaint as Exhibit A, and lists the title as "Crystalline Form of (S)-7-(1-acryloylpiperidin-4-yl)-2-(4-phenoxyphenyl)-4,5,6,7-tetrahydropyrazolo[1,5-a]pyrimidine-3-carboxamide, Preparation, and Uses Thereof" and an issue date of February 23, 2021. Otherwise, denied.

43. Admitted that the names Zhiwei Wang, Yunhang Guo, and Gongyin Shi are listed as inventors on the face of Exhibit A. Otherwise, denied.

44. Admitted that BeiGene Switzerland GmbH is listed as the assignee on the face of Exhibit A. Otherwise, denied.

45. Admitted that the '117 patent is listed in the FDA Orange Book in connection with the BRUKINSA® product. Otherwise, denied.

46. Admitted that Defendants submitted ANDA No. 219095 to seek FDA approval for their ANDA product prior to expiration of the Patents-in-Suit.

47. Admitted that Defendants submitted ANDA No. 219095 with Paragraph IV certifications to seek FDA approval for their ANDA product prior to expiration of the Patents-in-Suit.

48. Admitted that Defendants' Notice Letters speak for themselves; otherwise, denied.

49. Admitted that Defendants' Notice Letters speak for themselves.

50. Denied.

51. Admitted that Plaintiffs appear to have correctly reproduced claim 1 of Exhibit A.

52. Denied.

53. Admitted that Plaintiffs appear to have correctly reproduced parts of claim 6 of Exhibit A.

54. Denied.

55. Paragraph 55 sets forth a legal conclusion to which no response is required; therefore, denied.

56. Paragraph 56 sets forth a legal conclusion to which no response is required; therefore, denied.

57. Paragraph 57 sets forth a legal conclusion to which no response is required; therefore, denied.

58. Paragraph 58 is wholly speculative; denied.

59. Paragraph 59 sets forth a legal conclusion to which no response is required; therefore, denied.

60. Paragraph 60 sets forth a legal conclusion to which no response is required; therefore, denied.

61. Paragraph 61 is wholly speculative; denied.

62. Paragraph 62 sets forth a legal conclusion to which no response is required; therefore, denied.

63. Admitted that Defendants submitted ANDA No. 219095 to seek FDA approval for their ANDA product prior to expiration of the Patents-in-Suit; otherwise, denied.

64. Paragraph 64 sets forth a legal conclusion to which no response is required; therefore, denied.

65. Paragraph 65 sets forth a legal conclusion to which no response is required; therefore, denied.

66. Denied.

67. Denied.

COUNT II – DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '117 PATENT

68. Defendants incorporate their responses to paragraphs 1-68 as if fully set forth herein.

69. Paragraph 69 contains legal conclusions to which no response is required. To the extent a response is required, Defendants admit that there is a case of actual controversy between Plaintiffs and Defendants concerning the '117 patent.

70. Denied.

COUNT III – INFRINGEMENT OF THE '340 PATENT

71. Defendants incorporate their responses to paragraphs 1-70 as if fully set forth herein.

72. Admitted that what purports to be the '340 patent is attached to the Complaint as Exhibit B, and lists the title as "Crystalline Form of (S)-7-(1-acryloylpiperidin-4-yl)-2-(4-phenoxyphenyl)-4,5,6,7-tetrahydropyrazolo[1,5-a]pyrimidine-3-carboxamide, Preparation, and Uses Thereof" and an issue date of February 28, 2023. Otherwise, denied.

73. Admitted that the names Zhiwei Wang, Yunhang Guo, Gongyin Shi, and Lai Wang are listed as inventors on the face of Exhibit B. Otherwise, denied.

74. Admitted that BeiGene Switzerland GmbH is listed as the assignee on the face of Exhibit B. Otherwise, denied.

75. Admitted that the '340 patent is listed in the FDA Orange Book in connection with the BRUKINSA® product. Otherwise, denied.

76. Admitted that Defendants submitted ANDA No. 219095 to seek FDA approval for their ANDA product prior to expiration of the Patents-in-Suit.

77. Admitted that Defendants submitted ANDA No. 219095 with Paragraph IV certifications to seek FDA approval for their ANDA product prior to expiration of the Patents-in-Suit.

78. Admitted that Defendants' Notice Letters speak for themselves; otherwise, denied.

79. Admitted that Defendants' Notice Letters speak for themselves.

80. Paragraph 80 sets forth a legal conclusion to which no response is required; therefore, denied.

81. Admitted that Plaintiffs appear to have correctly reproduced claim 1 of Exhibit B.

82. Denied.

83. Admitted that Plaintiffs appear to have correctly reproduced claim 8 of Exhibit B.

84. Denied.

85. Admitted that Plaintiffs appear to have correctly reproduced claim 14 of Exhibit B.

86. Denied.

87. Admitted that Plaintiffs appear to have correctly reproduced claim 21 of Exhibit B.

88. Denied.

89. Paragraph 89 sets forth a legal conclusion to which no response is required; therefore, denied.

90. Paragraph 90 sets forth a legal conclusion to which no response is required; therefore, denied.

91. Paragraph 91 is wholly speculative; denied.

92. Paragraph 92 sets forth a legal conclusion to which no response is required; therefore, denied.

93. Paragraph 93 sets forth a legal conclusion to which no response is required; therefore, denied.

94. Paragraph 94 is wholly speculative; denied.

95. Paragraph 95 sets forth a legal conclusion to which no response is required; therefore, denied.

96. Admitted that Defendants are seeking FDA approval of their ANDA Product; otherwise, denied.

97. Paragraph 97 sets forth a legal conclusion to which no response is required; therefore, denied.

98. Paragraph 98 sets forth a legal conclusion to which no response is required; therefore, denied.

99. Denied.

100. Denied.

COUNT IV – DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '340 PATENT

101. Defendants incorporate their response to paragraphs 1-100 as if fully set forth herein.

102. Paragraph 102 contains legal conclusions to which no response is required. To the extent a response is required, Defendants admit that there is a case of actual controversy between Plaintiffs and Defendants concerning the '340 patent.

103. Denied.

COUNT V – INFRINGEMENT OF THE '531 PATENT

104. Defendants incorporate their responses to paragraphs 1-103 as if fully set forth herein.

105. Admitted that what purports to be the '531 patent is attached to the Complaint as Exhibit C, and lists the title as "Methods of Treating B-Cell Proliferative Disorder" and an issue date of October 17, 2023. Otherwise, denied.

106. Admitted that the names Jason Paik, Tommi Salmi, and Ying Ou are listed as inventors on the face of Exhibit C. Otherwise, denied.

107. Admitted that BeiGene Switzerland GmbH is listed as the assignee on the face of Exhibit C. Otherwise, denied.

108. Admitted that the '531 patent is listed in the FDA Orange Book in connection with the BRUKINSA® product. Otherwise, denied.

109. Admitted that Defendants submitted ANDA No. 219095 to seek FDA approval for their ANDA product prior to expiration of the Patents-in-Suit.

110. Admitted that Defendants submitted ANDA No. 219095 with Paragraph IV certifications to seek FDA approval for their ANDA product prior to expiration of the Patents-in-Suit.

111. Admitted that Defendants' Notice Letters speak for themselves; otherwise, denied.

112. Admitted that Defendants' Notice Letters speak for themselves.

113. Paragraph 113 sets forth a legal conclusion to which no response is required; therefore, denied.

114. Admitted that Plaintiffs appear to have correctly reproduced claim 1 of Exhibit C.

115. Denied.

116. Admitted that Plaintiffs appear to have correctly reproduced claim 11 of Exhibit C.

117. Denied.

118. Admitted that Plaintiffs appear to have correctly reproduced claim 21 of Exhibit C.

119. Denied.

120. Paragraph 120 sets forth a legal conclusion to which no response is required; therefore, denied.

121. Paragraph 121 sets forth a legal conclusion to which no response is required; therefore, denied.

122. Paragraph 122 is wholly speculative; denied.

123. Paragraph 123 sets forth a legal conclusion to which no response is required; therefore, denied.

124. Paragraph 124 sets forth a legal conclusion to which no response is required; therefore, denied.

125. Paragraph 125 is wholly speculative; denied.

126. Paragraph 126 sets forth a legal conclusion to which no response is required; therefore, denied.

127. Admitted that Defendants are seeking FDA approval of their ANDA Product; otherwise, denied.

128. Paragraph 128 sets forth a legal conclusion to which no response is required; therefore, denied.

129. Paragraph 129 sets forth a legal conclusion to which no response is required; therefore, denied.

130. Denied.

131. Denied.

COUNT VI – DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '531 PATENT

132. Defendants incorporate their responses to paragraphs 1-131 as if fully set forth herein.

133. Paragraph 133 contains legal conclusions to which no response is required. To the extent a response is required, Defendants admit that there is a case of actual controversy between Plaintiffs and Defendants concerning the '531 patent.

134. Denied.

COUNT VII – INFRINGEMENT OF THE '437 PATENT

135. Defendants incorporate their responses to paragraphs 1-134 as if fully set forth herein.

136. Admitted that what purports to be the '437 patent is attached to the Complaint as Exhibit D, and lists the title as "Crystalline Form of (S)-7-(1-acryloylpiperidin-4-yl)-2-(4-phenoxyphenyl)-4,5,6,7-tetrahydropyrazolo[1,5-a]pyrimidine-3-carboxamide, Preparation, and Uses Thereof" and an issue date of December 26, 2023. Otherwise, denied.

137. Admitted that the names Zhiwei Wang, Yunhang Guo, and Gongyin Shi are listed as inventors on the face of Exhibit D. Otherwise, denied.

138. Admitted that BeiGene Switzerland GmbH is listed as the assignee on the face of Exhibit D. Otherwise, denied.

139. Admitted that the '437 patent is listed in the FDA Orange Book in connection with the BRUKINSA® product. Otherwise, denied.

140. Admitted that Defendants submitted ANDA No. 219095 to seek FDA approval for their ANDA product prior to expiration of the Patents-in-Suit.

141. Admitted that Defendants submitted ANDA No. 219095 with Paragraph IV certifications to seek FDA approval for their ANDA product prior to expiration of the Patents-in-Suit.

142. Admitted that Defendants' Notice Letters speak for themselves; otherwise, denied.

143. Admitted that Defendants' Notice Letters speak for themselves.

144. Paragraph 144 sets forth a legal conclusion to which no response is required; therefore, denied.

145. Admitted that Plaintiffs appear to have correctly reproduced claim 1 of Exhibit D.

146. Denied.

147. Admitted that Plaintiffs appear to have correctly reproduced claim 11 of Exhibit D.

148. Denied.

149. Admitted that Plaintiffs appear to have correctly reproduced claim 20 of Exhibit D.

150. Denied.

151. Paragraph 151 sets forth a legal conclusion to which no response is required; therefore, denied.

152. Paragraph 152 sets forth a legal conclusion to which no response is required; therefore, denied.

153. Paragraph 153 is wholly speculative; denied.

154. Paragraph 154 sets forth a legal conclusion to which no response is required; therefore, denied.

155. Paragraph 155 sets forth a legal conclusion to which no response is required; therefore, denied.

156. Paragraph 156 is wholly speculative; denied.

157. Paragraph 157 sets forth a legal conclusion to which no response is required; therefore, denied.

158. Admitted that Defendants are seeking FDA approval of their ANDA Product; otherwise, denied.

159. Paragraph 159 sets forth a legal conclusion to which no response is required; therefore, denied.

160. Paragraph 160 sets forth a legal conclusion to which no response is required; therefore, denied.

161. Denied.

162. Denied.

COUNT VIII – DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '437 PATENT

163. Defendants incorporate their responses to paragraphs 1-162 as if fully set forth herein.

164. Paragraph 164 contains legal conclusions to which no response is required. To the extent a response is required, Defendants admit that there is a case of actual controversy between Plaintiffs and Defendants concerning the '437 patent.

165. Denied.

RESPONSE TO PLAINTIFFS' REQUEST FOR RELIEF

166. Defendants deny that Plaintiffs are entitled to the relief as requested in ¶¶ a-g of the Complaint's Prayer for Relief or to any relief whatsoever.

SEPARATE DEFENSES

Without prejudice to the denials set forth in the Answer, without admitting any allegation in the Complaint not otherwise admitted, and without undertaking any of the burdens imposed by law on Plaintiffs, Defendants assert the following separate defenses:

FIRST SEPARATE DEFENSE
(Non-infringement of U.S. Patent No. 10,927,117)

The manufacture, use, sale, offer for sale, or importation of zanubrutinib capsules, 80 mg that are the subject of ANDA No. 219095 has not infringed, does not infringe, and would not—if made, used, sold, offered for sale, imported, or marketed—infringe, directly or indirectly, any valid and enforceable claim of the '117 patent, either literally or under the doctrine of equivalents.

SECOND SEPARATE DEFENSE
(Invalidity of U.S. Patent No. 10,927,117)

The claims of the '117 patent are invalid and/or unenforceable for failure to comply with the requirements for patentability, including but not limited to the requirements set forth in 35 U.S.C. §§ 101 et seq. including but not limited to §§ 102, 103, and/or 112.

THIRD SEPARATE DEFENSE
(Non-infringement of U.S. Patent No. 11,591,340)

The manufacture, use, sale, offer for sale, or importation of zanubrutinib capsules, 80 mg that are the subject of ANDA No. 219095 has not infringed, does not infringe, and would not—if made, used, sold, offered for sale, imported, or marketed—infringe, directly or indirectly, any valid and enforceable claim of the '340 patent, either literally or under the doctrine of equivalents.

FOURTH SEPARATE DEFENSE
(Invalidity of U.S. Patent No. 11,591,340)

The claims of the '340 patent are invalid and/or unenforceable for failure to comply with the requirements for patentability, including but not limited to the requirements set forth in 35 U.S.C. §§ 101 et seq. including but not limited to §§ 102, 103, and/or 112.

FIFTH SEPARATE DEFENSE
(Non-infringement of U.S. Patent No. 11,786,531)

The manufacture, use, sale, offer for sale, or importation of zanubrutinib capsules, 80 mg that are the subject of ANDA No. 219095 has not infringed, does not infringe, and would not—if made, used, sold, offered for sale, imported, or marketed—infringe, directly or indirectly, any valid and enforceable claim of the '531 patent, either literally or under the doctrine of equivalents.

SIXTH SEPARATE DEFENSE
(Invalidity of U.S. Patent No. 11,786,531)

The claims of the '531 patent are invalid and/or unenforceable for failure to comply with the requirements for patentability, including but not limited to the requirements set forth in 35 U.S.C. §§ 101 et seq. including but not limited to §§ 102, 103, and/or 112.

SEVENTH SEPARATE DEFENSE
(Non-infringement of U.S. Patent No. 11,851,437)

The manufacture, use, sale, offer for sale, or importation of zanubrutinib capsules, 80 mg that are the subject of ANDA No. 219095 has not infringed, does not infringe, and would not—if made, used, sold, offered for sale, imported, or marketed—infringe, directly or indirectly, any valid and enforceable claim of the '437 patent, either literally or under the doctrine of equivalents.

EIGHTH SEPARATE DEFENSE
(Invalidity of U.S. Patent No. 11,851,437)

The claims of the '437 patent are invalid and/or unenforceable for failure to comply with the requirements for patentability, including but not limited to the requirements set forth in 35 U.S.C. §§ 101 et seq. including but not limited to §§ 102, 103, and/or 112.

NINTH SEPARATE DEFENSE
(No Exceptional Case)

Defendants' actions in defending this case do not give rise to an exceptional case under 35 U.S.C. § 285.

RESERVATION OF ADDITIONAL SEPARATE DEFENSES

Defendants reserve the right to plead additional separate defenses in the event that discovery or other analysis indicates that additional separate and/or affirmative defenses are appropriate, including, but not limited to, defenses of unenforceability.

DEFENDANTS' COUNTERCLAIMS FOR DECLARATORY JUDGMENT

MSN Pharmaceuticals, Inc. ("MSN Pharmaceuticals") and MSN Laboratories Private Limited ("MSN Labs"; collectively, "Counterclaim-Plaintiffs" or "MSN"), by way of counterclaim against BeiGene USA, Inc. and BeiGene Switzerland GmbH ("Counterclaim-Defendants" or "BeiGene"), allege as follows:

1. Defendant MSN Labs is a private limited company organized and existing under the laws of the Republic of India, having a principal place of business at MSN House, Plot No. C-24, Industrial Estate, Sanath Nagar, Hyperabad, Teleangana, 500018 India.

2. Defendant MSN Pharmaceuticals is a corporation organized and existing under the laws of Delaware and having a principal place of business at 20 Duke Road, Piscataway, New Jersey 08854.

3. On information and belief, Counterclaim-Defendant BeiGene USA, Inc. is a corporation organized and existing under the laws of the state of Delaware, with a principal place of business at 55 Cambridge Parkway, Suite 700W, Cambridge, Massachusetts 02142.

4. On information and belief, Counterclaim-Defendant BeiGene Switzerland GmbH is a limited liability company organized and existing under the laws of Switzerland, with a principal place of business at Aeschengraben 27, 4051 Basel, Switzerland.

5. As alleged in the Complaint, BeiGene USA, Inc. purports to be the owner of U.S. Patent Nos. 10,927,117 ("the '117 patent"), 11,591,340 ("the '340 patent"), 11,786,531 ("the '531 patent"), and 11,851,437 ("the '437 patent").

6. As alleged in the Complaint, BeiGene USA, Inc. purports to be the holder of the New Drug Application ("NDA") No. 213217.

7. On information and belief, BeiGene caused the patents-in-suit to be listed in the publication *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") as patents that claim the drug and/or claim a method of using such a drug for which BeiGene submitted NDA No. 213217.

8. MSN submitted Abbreviated New Drug Application ("ANDA") No. 219095 regarding zanubrutinib capsules, 80 mg ("MSN's Proposed Product") to the Food and Drug Administration ("FDA").

9. MSN's ANDA No. 219095 contains a "Paragraph IV" certification under 21 U.S.C. § 505(j)(2)(A)(vii)(IV) that the patents-in-suit are invalid, unenforceable and/or will not be infringed by the commercial manufacture, use, or sale of MSN's Proposed Product.

10. Pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) and C.F.R. § 314.95(c), on January 26, 2024, MSN sent BeiGene notice of MSN's Paragraph IV certification with ANDA No. 219095

regarding the '117, '340, and '531 patents. On February 28, 2024, MSN sent BeiGene notice of MSN's paragraph IV certification with ANDA No. 219095 regarding the '437 patent (collectively, "MSN's Notice Letters").

11. MSN's Notice Letters contained an Offer of Confidential Access to relevant portions of ANDA No. 219095 to BeiGene so that BeiGene could determine whether MSN's Proposed Product would infringe any valid claim of the Orange Book listed patents, pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III). BeiGene refused to accept the Offer for Confidential Access and so filed this suit without reviewing any materials concerning MSN's Proposed Product.

12. Receipt of MSN's Notice Letters initiated 45-day statutory periods during which BeiGene had the opportunity to file an action for patent infringement.

13. On March 8, 2024, BeiGene filed this instant suit alleging that MSN infringed the patents-in-suit by filing ANDA No. 219095 with the FDA and/or commercially selling, offering for sale, using, and/or manufacturing MSN's Proposed Product.

14. There has been and now is an actual and justiciable controversy between MSN and BeiGene as to whether MSN's Proposed Product infringes, induces infringement, or contributes to the infringement of any valid and enforceable claim of the patents-in-suit.

15. As a consequence of the foregoing, there is an actual and justiciable controversy between MSN and BeiGene as to whether the claims of the patents-in-suit have been, are being, or will be infringed by filing ANDA No. 219095 and/or the use, sale, offer for sale, or manufacture of MSN's Proposed Product.

16. As a consequence of the foregoing, there is an actual and justiciable controversy between MSN and BeiGene as to whether the claims of the patents-in-suit are valid and enforceable.

17. The filing of this Complaint against MSN alleging infringement of the patents-in-suit shows that BeiGene is willing to assert its patents against companies for the filing of ANDAs referencing NDA No. 213217.

JURISDICTION

18. These counterclaims arise under the Patent Laws of the United States, 35 U.S.C. §§ 1 *et seq.*, and under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

19. This Court has jurisdiction over the subject matter of MSN's counterclaims pursuant to 28 U.S.C. §§ 1331, 1338, 1367, 2201, and 2202.

20. BeiGene, by bringing this action in this district, has consented to and is subject to personal jurisdiction in this district.

FIRST COUNTERCLAIM
(Declaration of Non-Infringement of U.S. Patent No. 10,927,117)

21. MSN repeats and realleges its responses to the Complaint and the allegations in Paragraphs 1-20 above as if fully set forth herein.

22. BeiGene has asserted the '117 patent against MSN based on the filing of ANDA No. 219095. BeiGene alleges—and MSN denies—that the claims of the '117 patent cover MSN's Proposed Product.

23. The claims of the '117 patent do not, either literally or under the doctrine of equivalents, cover MSN's Proposed Product. Thus, MSN has not infringed and will not infringe the claims of the '117 patent by making, using, selling, offering or sale, marketing, or importing MSN's Proposed Product.

24. MSN and BeiGene have adverse legal interests, and there is a substantial controversy between BeiGene and MSN of sufficient immediacy and reality to warrant the

issuance of a declaratory judgment that MSN, by virtue of filing ANDA No. 219095, neither has nor will in the future infringe any valid and enforceable claim of the '117 patent.

25. MSN is entitled to a judicial declaration that MSN has not infringed and will not infringe any valid and enforceable claim of the '117 patent by virtue of filing ANDA No. 219095 or by making, using, selling, offering for sale, marketing, or importing MSN's Proposed Product.

SECOND COUNTERCLAIM
(Declaration of Invalidity of U.S. Patent No. 10,927,117)

26. MSN repeats and realleges its responses to the Complaint and the allegations in Paragraphs 1-25 above as if fully set forth herein.

27. BeiGene alleges—and MSN denies—that the '117 patent is valid.

28. Claims 1-6 of the '117 patent are invalid for failure to comply with one or more of the conditions of patentability set forth in Title 35 of the United States Code.

29. MSN and BeiGene have adverse legal interests, and there is a substantial controversy between BeiGene and MSN of sufficient immediacy and reality to warrant the issuance of a declaratory judgement of invalidity of claims 1-6 of the '117 patent.

30. MSN is entitled to a judicial declaration of the invalidity of claims 1-6 of the '117 patent.

THIRD COUNTERCLAIM
(Declaration of Non-Infringement of U.S. Patent No. 11,591,340)

31. MSN repeats and realleges its responses to the Complaint and the allegations in Paragraphs 1-30 above as if fully set forth herein.

32. BeiGene has asserted the '340 patent against MSN based on the filing of ANDA No. 219095. BeiGene alleges—and MSN denies—that the claims of the '340 patent cover MSN's Proposed Product.

33. The claims of the ’340 patent do not, either literally or under the doctrine of equivalents, cover MSN’s Proposed Product. Thus, MSN has not infringed and will not infringe the claims of the ’340 patent by making, using, selling, offering or sale, marketing, or importing MSN’s Proposed Product.

34. MSN and BeiGene have adverse legal interests, and there is a substantial controversy between BeiGene and MSN of sufficient immediacy and reality to warrant the issuance of a declaratory judgment that MSN, by virtue of filing ANDA No. 219095, neither has nor will in the future infringe any valid and enforceable claim of the ’340 patent.

35. MSN is entitled to a judicial declaration that MSN has not infringed and will not infringe any valid and enforceable claim of the ’340 patent by virtue of filing ANDA No. 219095 or by making, using, selling, offering for sale, marketing, or importing MSN’s Proposed Product.

FOURTH COUNTERCLAIM
(Declaration of Invalidity of U.S. Patent No. 11,591,340)

36. MSN repeats and realleges its responses to the Complaint and the allegations in Paragraphs 1-35 above as if fully set forth herein.

37. BeiGene alleges—and MSN denies—that the ’340 patent is valid.

38. Claims 1-27 of the ’340 patent are invalid for failure to comply with one or more of the conditions of patentability set forth in Title 35 of the United States Code.

39. MSN and BeiGene have adverse legal interests, and there is a substantial controversy between BeiGene and MSN of sufficient immediacy and reality to warrant the issuance of a declaratory judgement of invalidity of claims 1-27 of the ’340 patent.

40. MSN is entitled to a judicial declaration of the invalidity of claims 1-27 of the ’340 patent.

FIFTH COUNTERCLAIM
(Declaration of Non-Infringement of U.S. Patent No. 11,786,531)

41. MSN repeats and realleges its responses to the Complaint and the allegations in Paragraphs 1-40 above as if fully set forth herein.

42. BeiGene has asserted the '531 patent against MSN based on the filing of ANDA No. 219095. BeiGene alleges—and MSN denies—that the claims of the '531 patent cover MSN's Proposed Product.

43. The claims of the '531 patent do not, either literally or under the doctrine of equivalents, cover MSN's Proposed Product or MSN's proposed product labeling for the MSN Proposed Product. Thus, MSN has not infringed and will not infringe the claims of the '531 patent by making, using, selling, offering or sale, marketing, or importing MSN's Proposed Product.

44. MSN and BeiGene have adverse legal interests, and there is a substantial controversy between BeiGene and MSN of sufficient immediacy and reality to warrant the issuance of a declaratory judgment that MSN, by virtue of filing ANDA No. 219095, neither has nor will in the future infringe any valid and enforceable claim of the '531 patent.

45. MSN is entitled to a judicial declaration that MSN has not infringed and will not infringe any valid and enforceable claim of the '531 patent by virtue of filing ANDA No. 219095 or by making, using, selling, offering for sale, marketing, or importing MSN's Proposed Product.

SIXTH COUNTERCLAIM
(Declaration of Invalidity of U.S. Patent No. 11,786,531)

46. MSN repeats and realleges its responses to the Complaint and the allegations in Paragraphs 1-45 above as if fully set forth herein.

47. BeiGene alleges—and MSN denies—that the '531 patent is valid.

48. Claims 1-30 of the '531 patent are invalid for failure to comply with one or more of the conditions of patentability set forth in Title 35 of the United States Code.

49. MSN and BeiGene have adverse legal interests, and there is a substantial controversy between BeiGene and MSN of sufficient immediacy and reality to warrant the issuance of a declaratory judgement of invalidity of claims 1-30 of the ’531 patent.

50. MSN is entitled to a judicial declaration of the invalidity of claims 1-30 of the ’531 patent.

SEVENTH COUNTERCLAIM
(Declaration of Non-Infringement of U.S. Patent No. 11,851,437)

51. MSN repeats and realleges its responses to the Complaint and the allegations in Paragraphs 1-50 above as if fully set forth herein.

52. BeiGene has asserted the ’437 patent against MSN based on the filing of ANDA No. 219095. BeiGene alleges—and MSN denies—that the claims of the ’437 patent cover MSN’s Proposed Product.

53. The claims of the ’437 patent do not, either literally or under the doctrine of equivalents, cover MSN’s Proposed Product. Thus, MSN has not infringed and will not infringe the claims of the ’437 patent by making, using, selling, offering or sale, marketing, or importing MSN’s Proposed Product.

54. MSN and BeiGene have adverse legal interests, and there is a substantial controversy between BeiGene and MSN of sufficient immediacy and reality to warrant the issuance of a declaratory judgment that MSN, by virtue of filing ANDA No. 219095, neither has nor will in the future infringe any valid and enforceable claim of the ’437 patent.

55. MSN is entitled to a judicial declaration that MSN has not infringed and will not infringe any valid and enforceable claim of the ’437 patent by virtue of filing ANDA No. 219095 or by making, using, selling, offering for sale, marketing, or importing MSN’s Proposed Product.

EIGHTH COUNTERCLAIM
(Declaration of Invalidity of U.S. Patent No. 11,851,437)

56. MSN repeats and realleges its responses to the Complaint and the allegations in Paragraphs 1-55 above as if fully set forth herein.

57. BeiGene alleges—and MSN denies—that the '437 patent is valid.

58. Claims 1-29 of the '437 patent are invalid for failure to comply with one or more of the conditions of patentability set forth in Title 35 of the United States Code.

59. MSN and BeiGene have adverse legal interests, and there is a substantial controversy between BeiGene and MSN of sufficient immediacy and reality to warrant the issuance of a declaratory judgement of invalidity of claims 1-29 of the '437 patent.

60. MSN is entitled to a judicial declaration of the invalidity of claims 1-29 of the '437 patent.

PRAYER FOR RELIEF

WHEREFORE MSN respectfully prays for judgment in its favor and against BeiGene, including the following specific relief:

A. Dismissing BeiGene's Complaint with prejudice and denying each and every request for relief made therein by BeiGene;

B. Declaring that ANDA No. 219095 has not infringed any valid and enforceable claim of the '117 patent;

C. Declaring that the manufacture, use, sale, offer for sale, or importation of the Proposed Product that is the subject of ANDA No. 219095 has not infringed, does not infringe, and would not, if marketed, infringe any valid and enforceable claim of the '117 patent;

D. Declaring that claims 1-6 of the '117 patent are invalid;

E. Declaring that ANDA No. 219095 has not infringed any valid and enforceable claim of the ’340 patent;

F. Declaring that the manufacture, use, sale, offer for sale, or importation of the Proposed Product that is the subject of ANDA No. 219095 has not infringed, does not infringe, and would not, if marketed, infringe any valid and enforceable claim of the ’340 patent;

G. Declaring that claims 1-27 of the ’340 patent are invalid;

H. Declaring that ANDA No. 219095 has not infringed any valid and enforceable claim of the ’531 patent;

I. Declaring that the manufacture, use, sale, offer for sale, or importation of the Proposed Product that is the subject of ANDA No. 219095 has not infringed, does not infringe, and would not, if marketed, infringe any valid and enforceable claim of the ’531 patent;

J. Declaring that claims 1-30 of the ’531 patent are invalid;

K. Declaring that ANDA No. 219095 has not infringed any valid and enforceable claim of the ’437 patent;

L. Declaring that the manufacture, use, sale, offer for sale, or importation of the Proposed Product that is the subject of ANDA No. 219095 has not infringed, does not infringe, and would not, if marketed, infringe any valid and enforceable claim of the ’437 patent;

M. Declaring that claims 1-29 of the ’437 patent are invalid;

N. Declaring this case exceptional and awarding MSN reasonable attorneys’ fees and costs under 35 U.S.C. § 285; and

O. Awarding MSN such other and further relief as the Court may deem just and proper.

Dated: June 10, 2024

Respectfully submitted,

RIVKIN RADLER LLP

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LOCAL CIVIL RULE 11.2 and 40.1 CERTIFICATION

Pursuant to Local Civil Rule 11.2 and 40.1, I hereby certify that, to the best of my knowledge, the matter in controversy is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding.

Dated: June 10, 2024

s/ Gregory D. Miller
Gregory D. Miller

LOCAL CIVIL RULE 201.1 CERTIFICATION

I hereby certify that the above-captioned matter is not subject to compulsory arbitration in that the parties seek, *inter alia*, injunctive and declaratory relief in their respective pleadings.

I hereby certify under penalty of perjury that the foregoing is true and correct.

Dated: June 10, 2024

s/ Gregory D. Miller
Gregory D. Miller

CERTIFICATE OF SERVICE

I hereby certify that on June 10, 2024, I caused to be filed a true and correct copy of MSN Pharmaceuticals Inc. and MSN Laboratories Private Limited's Answer, Separate Defenses and Counterclaims to BeiGene USA, Inc. and BeiGene Switzerland GmbH's Complaint upon all counsel of record.

s/ Gregory D. Miller
Gregory D. Miller