

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

NOVARTIS PHARMACEUTICALS  
CORPORATION,

*Plaintiff,*

v.

MICRO LABS LIMITED and  
MICRO LABS USA INC.,

*Defendants.*

Civil Action No. 1:21-cv-00969-LPS

**ANSWER TO COMPLAINT, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS  
OF DEFENDANTS MICRO LABS LIMITED AND MICRO LABS USA INC.**

Defendants Micro Labs Limited and Micro Labs USA Inc. (collectively, “Micro Labs”) hereby ANSWER the Complaint of Plaintiff Novartis Pharmaceuticals Corporation (“Plaintiff” or “Novartis”) as follows. Pursuant to Fed. R. Civ. P. 8(b)(3), Micro Labs denies all allegations in Plaintiffs’ Complaint except those specifically admitted below:

1. Paragraph 1 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Micro Labs admits that Plaintiff purports to bring a civil action for patent infringement on the ’938 patent, the ’460 patent, the ’743 patent, the ’122 patent, the ’174 patent, the ’000 patent, the ’047 patent, the ’450 patent, the ’655 patent, the ’701 patent, the ’077 patent, the ’574 patent, the ’088 patent, the ’141 patent, and the ’553 patent (collectively, the “Asserted Patents”). Micro Labs also admits to filing an ANDA seeking approval to commercially manufacture, use, offer for sale, sell, and/or import a generic version of XIIDRA® (lifitegrast ophthalmic solution) 5% (50 mg/ml) prior to the expiration of the Asserted Patents. All remaining allegations are denied.

2. Admitted.

**PARTIES**

3. Micro Labs lacks the knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 3, and on that basis denies these allegations.

4. Micro Labs Ltd. admits that it is a company organized and existing under the laws of India, having a place of business at 31, Race Course Road, Bangalore, India 560 001. Micro Labs Limited further admits that it sells drug products and that such drug products are distributed to the United States. Micro Labs also admits that Micro Labs USA Inc. is a subsidiary of Micro Labs Limited. All remaining allegations are denied.

5. Micro Labs admits Micro Labs USA Inc. is a company organized and existing under the laws of New Jersey, having its principal place of business at 106 Allen Road., Suite 102, Basking Ridge, New Jersey 07920. Micro Labs USA Inc. admits that it distributes and sells drug products throughout the United States. All remaining allegations are denied.

6. Micro Labs admits that Micro Labs USA Inc. is a wholly-owned subsidiary of Micro Labs, Ltd. The remaining allegations of Paragraph 6 of the Complaint contain conclusions of law to which no response is required, and thus are denied.

7. Paragraph 7 of the Complaint contains conclusions of law to which no response is required, and are therefore denied.

**JURISDICTION AND VENUE**

8. Paragraph 8 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Micro Labs does not contest jurisdiction solely for Plaintiff's purported claims against Micro Labs. Micro Labs denies all remaining allegations of paragraph 8.

9. Paragraph 9 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Micro Labs admits that it has represented through counsel that, for the purposes of this litigation only, Micro Labs does not object to personal jurisdiction. Micro Labs denies all remaining allegations of paragraph 9.

10. Paragraph 10 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Micro Labs does not object to personal jurisdiction for the purposes of this litigation only. Micro Labs denies all remaining allegations of paragraph 10.

11. Paragraph 11 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Micro Labs admits that Micro Labs does not object to personal jurisdiction for the purposes of this litigation only. Micro Labs denies all remaining allegations of paragraph 11.

12. Micro Labs intends to sell its ANDA Product at some point in time after approval. All remaining allegations of paragraph 12 are denied.

13. Micro Labs admits that Micro Labs USA Inc. is the authorized U.S. agent for Micro Labs Ltd. The remaining allegations of Paragraph 13 of the Complaint contain conclusions of law to which no response is required, and thus are denied.

14. Paragraph 14 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, solely to conserve the resources of the parties and the Court, Micro Labs does not object to personal jurisdiction for the limited purposes of this action only. Micro Labs denies all remaining allegations of Paragraph 14.

15. Paragraph 15 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Micro Labs admits that it directed its Notice

Letters to Novartis Pharmaceutical Corporation and that it alleged in the Notice Letters that the Asserted Patents are invalid and/or not infringed. Micro Labs further answers that, solely to conserve the resources of the parties and the Court, Micro Labs does not object to personal jurisdiction for the limited purposes of this action only. All remaining allegations of Paragraph 15 are denied.

16. Paragraph 16 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, solely to conserve the resources of the parties and the Court, Micro Labs does not object to personal jurisdiction for the limited purposes of this action only. Micro Labs denies all remaining allegations of Paragraph 16.

17. Paragraph 17 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, solely to conserve the resources of the parties and the Court, Micro Labs does not object to personal jurisdiction for the limited purposes of this action only and further states that any pleadings referenced in this paragraph speak for themselves. Micro Labs denies all remaining allegations of Paragraph 17.

18. Paragraph 18 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, solely to conserve the resources of the parties and the Court, Micro Labs does not object to personal jurisdiction for the limited purposes of this action only. Micro Labs denies all remaining allegations of Paragraph 18.

19. Paragraph 19 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, solely to conserve the resources of the parties and the Court, Micro Labs does not object to personal jurisdiction for the limited purposes of this action only. Micro Labs denies all remaining allegations of Paragraph 19.

20. Paragraph 20 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, solely to conserve the resources of the parties and the Court, Micro Labs does not contest venue in this Judicial District for the limited purposes of this action only. Micro Labs denies all remaining allegations of paragraph 20.

#### **FACTUAL BACKGROUND**

21. Micro Labs admits that, according to the final printed labeling approved by the U.S. Food & Drug Administration, XIIDRA® contains lifitegrast and is indicated for the treatment of the signs and symptoms of dry eye disease (DED). All remaining allegations of Paragraph 21 are denied.

22. Admitted.

23. Admitted.

24. Paragraph 24 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Micro Labs admits that it included an Offer of Confidential Access in its Notice Letters. Micro Labs denies all remaining allegations of Paragraph 24.

25. Micro Labs admits that counsel for Plaintiff exchanged correspondence with counsel for Micro Labs to negotiate access to Micro Labs's ANDA and other materials, and that the parties have not reached agreement. Micro Labs denies all remaining allegations of Paragraph 25.

26. Defendants lack sufficient knowledge to admit or deny the factual allegations of Paragraph 26 of the Complaint and, therefore, deny the same.

**COUNT I – INFRINGEMENT OF THE '938 PATENT**

27. Micro Labs incorporates its Answers to paragraphs 1 through 26 as if fully set forth herein.

28. Paragraph 28 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Micro Labs admits that what purports to be a copy of the '938 patent is attached as Exhibit A to the Complaint, that the patent is titled "Modulators of Cellular Adhesion," and that the patent bears an issue date of January 1, 2008. All remaining allegations of Paragraph 28 are denied.

29. Micro Labs lacks the knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 29, and on that basis denies these allegations.

30. Micro Labs lacks the knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 30, and on that basis denies these allegations.

31. Micro Labs admits that the FDA's Orange Book lists the '938 patent in connection with XIIDRA®. Micro Labs lacks the knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 31, and on that basis denies these allegations.

32. Micro Labs admits that in the Second Notice Letter, Micro Labs notified Novartis of the submission of Micro Labs's ANDA to the FDA. Micro Labs further admits that Micro Labs's ANDA contained a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '938 patent. All remaining allegations of Paragraph 32 are denied.

33. Admitted.

34. Denied.

35. Admitted.

36. Paragraph 36 contains legal conclusions and allegations to which no answer is required. To the extent Micro Labs is required to answer, Micro Labs admits that its Detailed Statement speaks for itself, is legally and duly sufficient, and contains the factual and legal bases for Micro Labs' contention that the '938 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, and/or sale of Micro Labs ANDA Product. Further answering, Micro Labs states that an invalid patent cannot be infringed as a matter of law. All remaining allegations of Paragraph 36 are denied.

37. Denied.

38. Micro Labs intends to sell its ANDA Product at some point in time after approval. All remaining allegations of Paragraph 38 are denied.

39. Denied.

40. Denied.

41. Denied.

42. Micro Labs admits that Micro Labs's ANDA contained a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '938 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Micro Labs's ANDA Product. Micro Labs further admits that the Detailed Statements in its Notice Letters contained the factual and legal bases for Micro Labs's contention that the '938 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Micro Labs's ANDA Product. All remaining allegations of Paragraph 42 are denied.

43. Denied.

44. Denied.

45. Denied.

**COUNT II – DECLARATORY JUDGMENT OF INFRINGEMENT  
OF THE '938 PATENT**

46. Micro Labs incorporates its Answers to paragraphs 1 through 45 as if fully set forth herein.

47. This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Micro Labs admits only that there is an actual controversy concerning Micro Labs's noninfringement and invalidity of the '938 patent, but denies any remaining allegations in paragraph 47.

48. Denied.

**COUNT III – INFRINGEMENT OF THE '460 PATENT**

49. Micro Labs incorporates its Answers to paragraphs 1 through 48 as if fully set forth herein.

50. Paragraph 50 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Micro Labs admits that what purports to be a copy of the '460 patent is attached as Exhibit B to the Complaint, that the patent is titled "Modulators of Cellular Adhesion," and that the patent bears an issue date of June 29, 2010. All remaining allegations of Paragraph 50 are denied.

51. Micro Labs lacks the knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 51, and on that basis denies these allegations.

52. Micro Labs lacks the knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 52, and on that basis denies these allegations.

53. Micro Labs admits that the FDA's Orange Book lists the '460 patent in connection with XIIDRA®. Micro Labs lacks the knowledge or information sufficient to form a belief as to

the truth of the remaining allegations contained in paragraph 53, and on that basis denies these allegations.

54. Micro Labs admits that in the Second Notice Letter, Micro Labs notified Novartis of the submission of Micro Labs's ANDA to the FDA. Micro Labs further admits that Micro Labs's ANDA contained a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '460 patent. All remaining allegations of Paragraph 54 are denied.

55. Admitted.

56. Denied.

57. Admitted.

58. Paragraph 58 contains legal conclusions and allegations to which no answer is required. To the extent Micro Labs is required to answer, Micro Labs admits that its Detailed Statement speaks for itself, is legally and duly sufficient, and contains the factual and legal bases for Micro Labs' contention that the '460 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, and/or sale of Micro Labs ANDA Product. Further answering, Micro Labs states that an invalid patent cannot be infringed as a matter of law. All remaining allegations of Paragraph 58 are denied.

59. Denied.

60. Micro Labs intends to sell its ANDA Product at some point in time after approval.

All remaining allegations of Paragraph 60 are denied.

61. Denied.

62. Denied.

63. Denied.

64. Denied.

65. Micro Labs admits that Micro Labs's ANDA contained a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '460 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Micro Labs's ANDA Product. Micro Labs further admits that the Detailed Statements in its Notice Letters contained the factual and legal bases for Micro Labs's contention that the '460 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Micro Labs's ANDA Product. All remaining allegations of Paragraph 65 are denied.

66. Denied.

67. Denied.

68. Denied.

**COUNT IV – DECLARATORY JUDGMENT OF INFRINGEMENT  
OF THE '460 PATENT**

69. Micro Labs incorporates its Answers to paragraphs 1 through 68 as if fully set forth herein.

70. This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Micro Labs admits only that there is an actual controversy concerning Micro Labs's noninfringement and invalidity of the '460 patent, but denies any remaining allegations in paragraph 70.

71. Denied.

**COUNT V – INFRINGEMENT OF THE '743 PATENT**

72. Micro Labs incorporates its Answers to paragraphs 1 through 71 as if fully set forth herein.

73. Paragraph 73 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Micro Labs admits that what purports to be a

copy of the '743 patent is attached as Exhibit C to the Complaint, that the patent is titled "Modulators of Cellular Adhesion," and that the patent bears an issue date of September 7, 2010. All remaining allegations of Paragraph 73 are denied.

74. Micro Labs lacks the knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 74, and on that basis denies these allegations.

75. Micro Labs lacks the knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 75, and on that basis denies these allegations.

76. Micro Labs admits that the FDA's Orange Book lists the '743 patent in connection with XIIDRA®. Micro Labs lacks the knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 76, and on that basis denies these allegations.

77. Micro Labs admits that in the Second Notice Letter, Micro Labs notified Novartis of the submission of Micro Labs's ANDA to the FDA. Micro Labs further admits that Micro Labs's ANDA contained a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '743 patent. All remaining allegations of Paragraph 77 are denied.

78. Admitted.

79. Denied.

80. Admitted.

81. Admitted.

82. Paragraph 82 contains legal conclusions and allegations to which no answer is required. To the extent Micro Labs is required to answer, Micro Labs admits that its ANDA speaks for itself and that it complies with all legal, statutory, and regulatory requirements. All remaining allegations of Paragraph 82 are denied.

83. Admitted.

84. Paragraph 84 contains legal conclusions and allegations to which no answer is required. To the extent Micro Labs is required to answer, Micro Labs admits that its ANDA speaks for itself and that it complies with all legal, statutory, and regulatory requirements. All remaining allegations of Paragraph 84 are denied.

85. Paragraph 85 contains legal conclusions and allegations to which no answer is required. To the extent Micro Labs is required to answer, Micro Labs admits that its ANDA speaks for itself and that it complies with all legal, statutory, and regulatory requirements. All remaining allegations of Paragraph 85 are denied.

86. Paragraph 86 contains legal conclusions and allegations to which no answer is required. To the extent Micro Labs is required to answer, Micro Labs admits that its Detailed Statement speaks for itself, is legally and duly sufficient, and contains the factual and legal bases for Micro Labs' contention that the '743 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, and/or sale of Micro Labs ANDA Product. Further answering, Micro Labs states that an invalid patent cannot be infringed as a matter of law. All remaining allegations of Paragraph 86 are denied.

87. Denied.

88. Micro Labs intends to sell its ANDA Product at some point in time after approval. All remaining allegations of Paragraph 88 are denied.

89. Denied.

90. Denied.

91. Denied.

92. Denied.

93. Micro Labs admits that Micro Labs's ANDA contained a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '743 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Micro Labs's ANDA Product. Micro Labs further admits that the Detailed Statements in its Notice Letters contained the factual and legal bases for Micro Labs's contention that the '743 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Micro Labs's ANDA Product. All remaining allegations of Paragraph 93 are denied.

94. Denied.

95. Denied.

96. Denied.

**COUNT VI – DECLARATORY JUDGMENT OF INFRINGEMENT  
OF THE '743 PATENT**

97. Micro Labs incorporates its Answers to paragraphs 1 through 96 as if fully set forth herein.

98. This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Micro Labs admits only that there is an actual controversy concerning Micro Labs's noninfringement and invalidity of the '743 patent, but denies any remaining allegations in paragraph 98.

99. Denied.

**COUNT VII – INFRINGEMENT OF THE '122 PATENT**

100. Micro Labs incorporates its Answers to paragraphs 1 through 99 as if fully set forth herein.

101. Paragraph 101 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Micro Labs admits that what purports to be a

copy of the '122 patent is attached as Exhibit D to the Complaint, that the patent is titled "Modulators of Cellular Adhesion," and that the patent bears an issue date of April 19, 2011. All remaining allegations of Paragraph 101 are denied.

102. Micro Labs lacks the knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 102, and on that basis denies these allegations.

103. Micro Labs lacks the knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 103, and on that basis denies these allegations.

104. Micro Labs admits that the FDA's Orange Book lists the '122 patent in connection with XIIDRA®. Micro Labs lacks the knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 104, and on that basis denies these allegations.

105. Micro Labs admits that in the Second Notice Letter, Micro Labs notified Novartis of the submission of Micro Labs's ANDA to the FDA. Micro Labs further admits that Micro Labs's ANDA contained a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '122 patent. All remaining allegations of Paragraph 105 are denied.

106. Admitted.

107. Denied.

108. Micro Labs admits that its ANDA Product contains lifitegrast. Micro Labs lacks the knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 108, and on that basis denies these allegations.

109. Paragraph 109 contains legal conclusions and allegations to which no answer is required. To the extent Micro Labs is required to answer, Micro Labs admits that its Detailed Statement speaks for itself, is legally and duly sufficient, and contains the factual and legal bases

for Micro Labs' contention that the '122 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, and/or sale of Micro Labs ANDA Product. Further answering, Micro Labs states that an invalid patent cannot be infringed as a matter of law. All remaining allegations of Paragraph 109 are denied.

110. Denied.

111. Micro Labs intends to sell its ANDA Product at some point in time after approval.

All remaining allegations of Paragraph 111 are denied.

112. Denied.

113. Denied.

114. Denied.

115. Denied.

116. Micro Labs admits that Micro Labs's ANDA contained a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '122 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Micro Labs's ANDA Product. Micro Labs further admits that the Detailed Statements in its Notice Letters contained the factual and legal bases for Micro Labs's contention that the '122 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Micro Labs's ANDA Product. All remaining allegations of Paragraph 116 are denied.

117. Denied.

118. Denied.

119. Denied.

**COUNT VIII – DECLARATORY JUDGMENT OF INFRINGEMENT  
OF THE '122 PATENT**

120. Micro Labs incorporates its Answers to paragraphs 1 through 119 as if fully set forth herein.

121. This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Micro Labs admits only that there is an actual controversy concerning Micro Labs's noninfringement and invalidity of the '122 patent, but denies any remaining allegations in paragraph 121.

122. Denied.

**COUNT IX – INFRINGEMENT OF THE '174 PATENT**

123. Micro Labs incorporates its Answers to paragraphs 1 through 122 as if fully set forth herein.

124. Paragraph 124 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Micro Labs admits that what purports to be a copy of the '174 patent is attached as Exhibit E to the Complaint, that the patent is titled "Modulators of Cellular Adhesion," and that the patent bears an issue date of December 22, 2015. All remaining allegations of Paragraph 124 are denied.

125. Micro Labs lacks the knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 125, and on that basis denies these allegations.

126. Micro Labs lacks the knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 126, and on that basis denies these allegations.

127. Micro Labs admits that the FDA's Orange Book lists the '174 patent in connection with XIIDRA®. Micro Labs lacks the knowledge or information sufficient to form a belief as to

the truth of the remaining allegations contained in paragraph 127, and on that basis denies these allegations.

128. Micro Labs admits that in the Second Notice Letter, Micro Labs notified Novartis of the submission of Micro Labs's ANDA to the FDA. Micro Labs further admits that Micro Labs's ANDA contained a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '174 patent. All remaining allegations are denied.

129. Admitted.

130. Denied.

131. Admitted.

132. Admitted.

133. Paragraph 133 contains legal conclusions and allegations to which no answer is required. To the extent Micro Labs is required to answer, Micro Labs admits that its ANDA speaks for itself and that it complies with all legal, statutory, and regulatory requirements. All remaining allegations of Paragraph 133 are denied.

134. Micro Labs admits that Micro Labs's ANDA speaks for itself. All remaining allegations of Paragraph 134 are denied.

135. Paragraph 135 contains legal conclusions and allegations to which no answer is required. To the extent Micro Labs is required to answer, Micro Labs admits that its Detailed Statement speaks for itself, is legally and duly sufficient, and contains the factual and legal bases for Micro Labs' contention that the '174 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, and/or sale of Micro Labs ANDA Product. Further answering, Micro Labs states that an invalid patent cannot be infringed as a matter of law. All remaining allegations of Paragraph 135 are denied.

136. Denied.

137. Micro Labs intends to sell its ANDA Product at some point in time after approval.

All remaining allegations of Paragraph 137 are denied.

138. Denied.

139. Denied.

140. Denied.

141. Denied.

142. Micro Labs admits that Micro Labs's ANDA contained a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '174 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Micro Labs's ANDA Product. Micro Labs further admits that the Detailed Statements in its Notice Letters contained the factual and legal bases for Micro Labs's contention that the '174 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Micro Labs's ANDA Product. All remaining allegations of Paragraph 142 are denied.

143. Denied.

144. Denied.

145. Denied.

**COUNT X – DECLARATORY JUDGMENT OF INFRINGEMENT  
OF THE '174 PATENT**

146. Micro Labs incorporates its Answers to paragraphs 1 through 145 as if fully set forth herein.

147. This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Micro Labs admits only that there is an actual controversy concerning

Micro Labs's noninfringement and invalidity of the '174 patent, but denies any remaining allegations in paragraph 147.

148. Denied.

**COUNT XI – INFRINGEMENT OF THE '000 PATENT**

149. Micro Labs incorporates its Answers to paragraphs 1 through 148 as if fully set forth herein.

150. Paragraph 150 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Micro Labs admits that what purports to be a copy of the '000 patent is attached as Exhibit F to the Complaint, that the patent is titled "Modulators of Cellular Adhesion," and that the patent bears an issue date of November 13, 2018. All remaining allegations of Paragraph 150 are denied.

151. Micro Labs lacks the knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 151, and on that basis denies these allegations.

152. Micro Labs lacks the knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 152, and on that basis denies these allegations.

153. Micro Labs admits that the FDA's Orange Book lists the '000 patent in connection with XIIDRA®. Micro Labs lacks the knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 153, and on that basis denies these allegations.

154. Micro Labs admits that in the Second Notice Letter, Micro Labs notified Novartis of the submission of Micro Labs's ANDA to the FDA. Micro Labs further admits that Micro Labs's ANDA contained a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '000 patent. All remaining allegations of Paragraph 154 are denied.

155. Admitted.

156. Denied.

157. Admitted.

158. Admitted.

159. Paragraph 159 contains legal conclusions and allegations to which no answer is required. To the extent Micro Labs is required to answer, Micro Labs admits that its ANDA speaks for itself and that it complies with all legal, statutory, and regulatory requirements. All remaining allegations of Paragraph 159 are denied.

160. Paragraph 160 contains legal conclusions and allegations to which no answer is required. To the extent Micro Labs is required to answer, Micro Labs admits that its ANDA speaks for itself and that it complies with all legal, statutory, and regulatory requirements. All remaining allegations of Paragraph 160 are denied.

161. Paragraph 161 contains legal conclusions and allegations to which no answer is required. To the extent Micro Labs is required to answer, Micro Labs admits that its ANDA speaks for itself and that it complies with all legal, statutory, and regulatory requirements. All remaining allegations of Paragraph 161 are denied.

162. Paragraph 162 contains legal conclusions and allegations to which no answer is required. To the extent Micro Labs is required to answer, Micro Labs admits that its ANDA speaks for itself and that it complies with all legal, statutory, and regulatory requirements. All remaining allegations of Paragraph 162 are denied.

163. Paragraph 163 contains legal conclusions and allegations to which no answer is required. To the extent Micro Labs is required to answer, Micro Labs admits that its Detailed Statement speaks for itself, is legally and duly sufficient, and contains the factual and legal bases

for Micro Labs' contention that the '000 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, and/or sale of Micro Labs ANDA Product. Further answering, Micro Labs states that an invalid patent cannot be infringed as a matter of law. All remaining allegations of Paragraph 163 are denied.

164. Denied.

165. Denied.

166. Denied.

167. Denied.

168. Denied.

169. Denied.

170. Micro Labs admits that Micro Labs's ANDA contained a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '000 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Micro Labs's ANDA Product. Micro Labs further admits that the Detailed Statements in its Notice Letters contained the factual and legal bases for Micro Labs's contention that the '000 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Micro Labs's ANDA Product. All remaining allegations of Paragraph 170 are denied.

171. Denied.

172. Denied.

173. Denied.

**COUNT XII – DECLARATORY JUDGMENT OF INFRINGEMENT  
OF THE '000 PATENT**

174. Micro Labs incorporates its Answers to paragraphs 1 through 173 as if fully set forth herein.

175. This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Micro Labs admits only that there is an actual controversy concerning Micro Labs's noninfringement and invalidity of the '000 patent, but denies any remaining allegations in paragraph 175.

176. Denied.

**COUNT XIII – INFRINGEMENT OF THE '047 PATENT**

177. Micro Labs incorporates its Answers to paragraphs 1 through 176 as if fully set forth herein.

178. Paragraph 178 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Micro Labs admits that what purports to be a copy of the '047 patent is attached as Exhibit G to the Complaint, that the patent is titled "Compositions and Methods for Treatment of Eye Disorders," and that the patent bears an issue date of December 27, 2011. All remaining allegations of Paragraph 178 are denied.

179. Micro Labs lacks the knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 179, and on that basis denies these allegations.

180. Micro Labs lacks the knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 180, and on that basis denies these allegations.

181. Micro Labs admits that the FDA's Orange Book lists the '047 patent in connection with XIIDRA®. Micro Labs lacks the knowledge or information sufficient to form a belief as to

the truth of the remaining allegations contained in paragraph 181, and on that basis denies these allegations.

182. Micro Labs admits that in the Second Notice Letter, Micro Labs notified Novartis of the submission of Micro Labs's ANDA to the FDA. Micro Labs further admits that Micro Labs's ANDA contained a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '047 patent. All remaining allegations of Paragraph 182 are denied.

183. Admitted.

184. Denied.

185. Admitted.

186. Paragraph 186 contains legal conclusions and allegations to which no answer is required. To the extent Micro Labs is required to answer, Micro Labs admits that its Detailed Statement speaks for itself, is legally and duly sufficient, and contains the factual and legal bases for Micro Labs' contention that the '047 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, and/or sale of Micro Labs ANDA Product. Further answering, Micro Labs states that an invalid patent cannot be infringed as a matter of law. All remaining allegations of paragraph 186 are denied.

187. Denied.

188. Micro Labs intends to sell its ANDA Product at some point in time after approval.

All remaining allegations of Paragraph 188 are denied.

189. Denied.

190. Denied.

191. Denied.

192. Denied.

193. Micro Labs admits that Micro Labs's ANDA contained a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '047 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Micro Labs's ANDA Product. Micro Labs further admits that the Detailed Statements in its Notice Letters contained the factual and legal bases for Micro Labs's contention that the '047 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Micro Labs's ANDA Product. All remaining allegations of Paragraph 193 are denied.

194. Denied.

195. Denied.

196. Denied.

**COUNT XIV – DECLARATORY JUDGMENT OF INFRINGEMENT  
OF THE '047 PATENT**

197. Micro Labs incorporates its Answers to paragraphs 1 through 196 as if fully set forth herein.

198. This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Micro Labs admits only that there is an actual controversy concerning Micro Labs's noninfringement and invalidity of the '047 patent, but denies any remaining allegations in paragraph 198.

199. Denied.

**COUNT XV – INFRINGEMENT OF THE '655 PATENT**

200. Micro Labs incorporates its Answers to paragraphs 1 through 199 as if fully set forth herein.

201. Paragraph 201 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Micro Labs admits that what purports to be a copy of the '655 patent is attached as Exhibit H to the Complaint, that the patent is titled "Compositions and Methods for Treatment of Eye Disorders," and that the patent bears an issue date of May 1, 2012. All remaining allegations of Paragraph 201 are denied.

202. Micro Labs lacks the knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 202, and on that basis denies these allegations.

203. Micro Labs lacks the knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 203, and on that basis denies these allegations.

204. Micro Labs lacks the knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 204, and on that basis denies these allegations.

205. Micro Labs admits that the FDA's Orange Book lists the '655 patent in connection with XIIDRA®. Micro Labs lacks the knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 205, and on that basis denies these allegations.

206. Micro Labs admits that in the Second Notice Letter, Micro Labs notified Novartis of the submission of Micro Labs's ANDA to the FDA. Micro Labs further admits that Micro Labs's ANDA contained a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '655 patent. All remaining allegations of Paragraph 206 are denied.

207. Admitted.

208. Denied.

209. Admitted.

210. Admitted.

211. Paragraph 211 contains legal conclusions and allegations to which no answer is required. To the extent Micro Labs is required to answer, Micro Labs admits that its ANDA speaks for itself and that it complies with all legal, statutory, and regulatory requirements. All remaining allegations of Paragraph 211 are denied.

212. Paragraph 212 contains legal conclusions and allegations to which no answer is required. To the extent Micro Labs is required to answer, Micro Labs admits that its ANDA speaks for itself and that it complies with all legal, statutory, and regulatory requirements. All remaining allegations of Paragraph 212 are denied.

213. Admitted.

214. Paragraph 214 contains legal conclusions and allegations to which no answer is required. To the extent Micro Labs is required to answer, Micro Labs admits that its ANDA speaks for itself and that it complies with all legal, statutory, and regulatory requirements. All remaining allegations of Paragraph 214 are denied.

215. Paragraph 215 contains legal conclusions and allegations to which no answer is required. To the extent Micro Labs is required to answer, Micro Labs admits that its Detailed Statement speaks for itself, is legally and duly sufficient, and contains the factual and legal bases for Micro Labs' contention that the '655 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, and/or sale of Micro Labs ANDA Product. Further answering, Micro Labs states that an invalid patent cannot be infringed as a matter of law. All remaining allegations of Paragraph 215 are denied.

216. Denied.

217. Micro Labs intends to sell its ANDA Product at some point in time after approval. All remaining allegations of Paragraph 217 are denied.

218. Denied.

219. Denied.

220. Denied.

221. Denied.

222. Micro Labs admits that Micro Labs's ANDA contained a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '655 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Micro Labs's ANDA Product. Micro Labs further admits that the Detailed Statements in its Notice Letters contained the factual and legal bases for Micro Labs's contention that the '655 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Micro Labs's ANDA Product. All remaining allegations of Paragraph 222 are denied.

223. Denied.

224. Denied.

225. Denied.

**COUNT XVI – DECLARATORY JUDGMENT OF INFRINGEMENT**  
**OF THE '655 PATENT**

226. Micro Labs incorporates its Answers to paragraphs 1 through 225 as if fully set forth herein.

227. This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Micro Labs admits only that there is an actual controversy concerning Micro Labs's noninfringement and invalidity of the '655 patent, but denies any remaining allegations in paragraph 227.

228. Denied.

**COUNT XVII – INFRINGEMENT OF THE '450 PATENT**

229. Micro Labs incorporates its Answers to paragraphs 1 through 228 as if fully set forth herein.

230. Paragraph 230 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Micro Labs admits that what purports to be a copy of the '450 patent is attached as Exhibit I to the Complaint, that the patent is titled "Compositions and Methods for Treatment of Eye Disorders," and that the patent bears an issue date of November 26, 2013. All remaining allegations of Paragraph 230 are denied.

231. Micro Labs lacks the knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 231, and on that basis denies these allegations.

232. Micro Labs lacks the knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 232, and on that basis denies these allegations.

233. Micro Labs lacks the knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 233, and on that basis denies these allegations.

234. Micro Labs lacks the knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 234, and on that basis denies these allegations.

235. Micro Labs admits that the FDA's Orange Book lists the '450 patent in connection with XIIDRA®. Micro Labs lacks the knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 235, and on that basis denies these allegations.

236. Micro Labs admits that in the Second Notice Letter, Micro Labs notified Novartis of the submission of Micro Labs's ANDA to the FDA. Micro Labs further admits that Micro

Labs's ANDA contained a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '450 patent. All remaining allegations of Paragraph 236 are denied.

237. Admitted.

238. Denied.

239. Admitted.

240. Admitted.

241. Paragraph 241 contains legal conclusions and allegations to which no answer is required. To the extent Micro Labs is required to answer, Micro Labs admits that its ANDA speaks for itself and that it complies with all legal, statutory, and regulatory requirements. All remaining allegations of Paragraph 241 are denied.

242. Paragraph 242 contains legal conclusions and allegations to which no answer is required. To the extent Micro Labs is required to answer, Micro Labs admits that its ANDA speaks for itself and that it complies with all legal, statutory, and regulatory requirements. All remaining allegations of Paragraph 242 are denied.

243. Paragraph 243 contains legal conclusions and allegations to which no answer is required. To the extent Micro Labs is required to answer, Micro Labs admits that its ANDA speaks for itself and that it complies with all legal, statutory, and regulatory requirements. All remaining allegations of Paragraph 243 are denied.

244. Admitted.

245. Paragraph 245 contains legal conclusions and allegations to which no answer is required. To the extent Micro Labs is required to answer, Micro Labs admits that its ANDA speaks for itself and that it complies with all legal, statutory, and regulatory requirements. All remaining allegations of Paragraph 245 are denied.

246. Paragraph 246 contains legal conclusions and allegations to which no answer is required. To the extent Micro Labs is required to answer, Micro Labs admits that its Detailed Statement speaks for itself, is legally and duly sufficient, and contains the factual and legal bases for Micro Labs' contention that the '450 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, and/or sale of Micro Labs ANDA Product. Further answering, Micro Labs states that an invalid patent cannot be infringed as a matter of law. All remaining allegations of Paragraph 246 are denied.

247. Denied.

248. Micro Labs intends to sell its ANDA Product at some point in time after approval. All remaining allegations of Paragraph 248 are denied.

249. Denied.

250. Denied.

251. Denied.

252. Denied.

253. Micro Labs admits that Micro Labs's ANDA contained a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '450 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Micro Labs's ANDA Product. Micro Labs further admits that the Detailed Statements in its Notice Letters contained the factual and legal bases for Micro Labs's contention that the '450 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Micro Labs's ANDA Product. All remaining allegations of Paragraph 253 are denied.

254. Denied.

255. Denied.

256. Denied.

**COUNT XVIII – DECLARATORY JUDGMENT OF INFRINGEMENT  
OF THE '450 PATENT**

257. Micro Labs incorporates its Answers to paragraphs 1 through 256 as if fully set forth herein.

258. This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Micro Labs admits only that there is an actual controversy concerning Micro Labs's noninfringement and invalidity of the '450 patent, but denies any remaining allegations in paragraph 258.

259. Denied.

**COUNT XIX – INFRINGEMENT OF THE '701 PATENT**

260. Micro Labs incorporates its Answers to paragraphs 1 through 259 as if fully set forth herein.

261. Paragraph 261 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Micro Labs admits that what purports to be a copy of the '701 patent is attached as Exhibit J to the Complaint, that the patent is titled "Crystalline Pharmaceutical and Methods of Preparation and Use Thereof," and that the patent bears an issue date of February 5, 2013. All remaining allegations of Paragraph 261 are denied

262. Micro Labs lacks the knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 262, and on that basis denies these allegations.

263. Micro Labs lacks the knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 263, and on that basis denies these allegations.

264. Micro Labs admits that the FDA's Orange Book lists the '701 patent in connection with XIIDRA®. Micro Labs lacks the knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 264, and on that basis denies these allegations.

265. Micro Labs admits that in the Second Notice Letter, Micro Labs notified Novartis of the submission of Micro Labs's ANDA to the FDA. Micro Labs further admits that Micro Labs's ANDA contained a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '701 patent. All remaining allegations of Paragraph 265 are denied.

266. Admitted.

267. Denied.

268. Admitted.

269. Admitted.

270. Paragraph 270 contains legal conclusions and allegations to which no answer is required. To the extent Micro Labs is required to answer, Micro Labs admits that its ANDA speaks for itself and that it complies with all legal, statutory, and regulatory requirements. All remaining allegations of Paragraph 270 are denied.

271. Paragraph 271 contains legal conclusions and allegations to which no answer is required. To the extent Micro Labs is required to answer, Micro Labs admits that its Detailed Statement speaks for itself, is legally and duly sufficient, and contains the factual and legal bases for Micro Labs' contention that the '701 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, and/or sale of Micro Labs ANDA Product. Further answering, Micro Labs states that an invalid patent cannot be infringed as a matter of law. All remaining allegations of Paragraph 271 are denied.

272. Denied.

273. Micro Labs intends to sell its ANDA Product at some point in time after approval.

All remaining allegations of Paragraph 273 are denied.

274. Denied.

275. Denied.

276. Denied.

277. Denied.

278. Micro Labs admits that Micro Labs's ANDA contained a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '701 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Micro Labs's ANDA Product. Micro Labs further admits that the Detailed Statements in its Notice Letters contained the factual and legal bases for Micro Labs's contention that the '701 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Micro Labs's ANDA Product. All remaining allegations of Paragraph 278 are denied.

279. Denied.

280. Denied.

281. Denied.

**COUNT XX – DECLARATORY JUDGMENT OF INFRINGEMENT**  
**OF THE '701 PATENT**

282. Micro Labs incorporates its Answers to paragraphs 1 through 281 as if fully set forth herein.

283. This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Micro Labs admits only that there is an actual controversy concerning

Micro Labs's noninfringement and invalidity of the '701 patent, but denies any remaining allegations in paragraph 283.

284. Denied.

**COUNT XXI – INFRINGEMENT OF THE '077 PATENT**

285. Micro Labs incorporates its Answers to paragraphs 1 through 284 as if fully set forth herein.

286. Paragraph 286 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Micro Labs admits that what purports to be a copy of the '077 patent is attached as Exhibit K to the Complaint, that the patent is titled "Crystalline Pharmaceutical and Methods of Preparation and Use Thereof," and that the patent bears an issue date of September 20, 2016. All remaining allegations of Paragraph 286 are denied.

287. Micro Labs lacks the knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 287, and on that basis denies these allegations.

288. Micro Labs lacks the knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 288, and on that basis denies these allegations.

289. Micro Labs admits that the FDA's Orange Book lists the '077 patent in connection with XIIDRA®. Micro Labs lacks the knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 289, and on that basis denies these allegations.

290. Micro Labs admits that in the Second Notice Letter, Micro Labs notified Novartis of the submission of Micro Labs's ANDA to the FDA. Micro Labs further admits that Micro Labs's ANDA contained a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '077 patent. All remaining allegations of Paragraph 290 are denied.

291. Admitted.

292. Denied.

293. Admitted.

294. Admitted.

295. Paragraph 295 contains legal conclusions and allegations to which no answer is required. To the extent Micro Labs is required to answer, Micro Labs admits that its ANDA speaks for itself and that it complies with all legal, statutory, and regulatory requirements. All remaining allegations of Paragraph 295 are denied.

296. Admitted.

297. Denied.

298. Paragraph 298 contains legal conclusions and allegations to which no answer is required. To the extent Micro Labs is required to answer, Micro Labs admits that its ANDA speaks for itself and that it complies with all legal, statutory, and regulatory requirements. All remaining allegations of Paragraph 298 are denied.

299. Paragraph 299 contains legal conclusions and allegations to which no answer is required. To the extent Micro Labs is required to answer, Micro Labs admits that its Detailed Statement speaks for itself, is legally and duly sufficient, and contains the factual and legal bases for Micro Labs' contention that the '077 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, and/or sale of Micro Labs ANDA Product. Further answering, Micro Labs states that an invalid patent cannot be infringed as a matter of law. All remaining allegations of Paragraph 299 are denied.

300. Denied.

301. Micro Labs intends to sell its ANDA Product at some point in time after approval.

All remaining allegations of Paragraph 301 are denied.

302. Denied.

303. Denied.

304. Denied.

305. Denied.

306. Micro Labs admits that Micro Labs's ANDA contained a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '077 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Micro Labs's ANDA Product. Micro Labs further admits that the Detailed Statements in its Notice Letters contained the factual and legal bases for Micro Labs's contention that the '077 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Micro Labs's ANDA Product. All remaining allegations of Paragraph 306 are denied.

307. Denied.

308. Denied.

309. Denied.

**COUNT XXII – DECLARATORY JUDGMENT OF INFRINGEMENT  
OF THE '077 PATENT**

310. Micro Labs incorporates its Answers to paragraphs 1 through 309 as if fully set forth herein.

311. This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Micro Labs admits only that there is an actual controversy concerning

Micro Labs's noninfringement and invalidity of the '077 patent, but denies any remaining allegations in paragraph 311.

312. Denied.

**COUNT XXIII – INFRINGEMENT OF THE '574 PATENT**

313. Micro Labs incorporates its Answers to paragraphs 1 through 312 as if fully set forth herein.

314. Paragraph 314 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Micro Labs admits that what purports to be a copy of the '574 patent is attached as Exhibit L to the Complaint, that the patent is titled "Crystalline Pharmaceutical and Methods of Preparation and Use Thereof," and that the patent bears an issue date of January 6, 2015. All remaining allegations of Paragraph 314 are denied.

315. Micro Labs lacks the knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 315, and on that basis denies these allegations.

316. Micro Labs lacks the knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 316, and on that basis denies these allegations.

317. Micro Labs admits that the FDA's Orange Book lists the '574 patent in connection with XIIDRA®. Micro Labs lacks the knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 317, and on that basis denies these allegations.

318. Micro Labs admits that in the First Notice Letter, Micro Labs notified Novartis of the submission of Micro Labs's ANDA to the FDA. Micro Labs further admits that Micro Labs's ANDA contained a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '574 patent. All remaining allegations of Paragraph 318 are denied.

319. Admitted.

320. Denied.

321. Admitted.

322. Admitted.

323. Denied.

324. Denied.

325. Micro Labs intends to sell its ANDA Product at some point in time after approval.

All remaining allegations of Paragraph 325 are denied.

326. Denied.

327. Denied.

328. Denied.

329. Denied.

330. Micro Labs admits that Micro Labs's ANDA contained a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '574 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Micro Labs's ANDA Product. Micro Labs further admits that the Detailed Statements in its Notice Letters contained the factual and legal bases for Micro Labs's contention that the '574 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Micro Labs's ANDA Product. All remaining allegations of Paragraph 330 are denied.

331. Denied.

332. Denied.

333. Denied.

**COUNT XXIV– DECLARATORY JUDGMENT OF INFRINGEMENT  
OF THE '574 PATENT**

334. Micro Labs incorporates its Answers to paragraphs 1 through 333 as if fully set forth herein.

335. This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Micro Labs admits only that there is an actual controversy concerning Micro Labs's noninfringement and invalidity of the '574 patent, but denies any remaining allegations in paragraph 335.

336. Denied.

**COUNT XXV– INFRINGEMENT OF THE '088 PATENT**

337. Micro Labs incorporates its Answers to paragraphs 1 through 336 as if fully set forth herein.

338. Paragraph 338 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Micro Labs admits that what purports to be a copy of the '088 patent is attached as Exhibit M to the Complaint, that the patent is titled "Crystalline Pharmaceutical and Methods of Preparation and Use Thereof," and that the patent bears an issue date of May 31, 2016. All remaining allegations of Paragraph 338 are denied.

339. Micro Labs lacks the knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 339, and on that basis denies these allegations.

340. Micro Labs lacks the knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 340, and on that basis denies these allegations.

341. Micro Labs admits that the FDA's Orange Book lists the '088 patent in connection with XIIDRA®. Micro Labs lacks the knowledge or information sufficient to form a belief as to

the truth of the remaining allegations contained in paragraph 341, and on that basis denies these allegations.

342. Micro Labs admits that in the First Notice Letter, Micro Labs notified Novartis of the submission of Micro Labs's ANDA to the FDA. Micro Labs further admits that Micro Labs's ANDA contained a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '088 patent. All remaining allegations of Paragraph 342 are denied.

343. Admitted.

344. Denied.

345. Admitted.

346. Admitted.

347. Denied.

348. Denied.

349. Micro Labs intends to sell its ANDA Product at some point in time after approval.

All remaining allegations of Paragraph 349 are denied.

350. Denied.

351. Denied.

352. Denied.

353. Denied.

354. Micro Labs admits that Micro Labs's ANDA contained a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '088 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Micro Labs's ANDA Product. Micro Labs further admits that the Detailed Statements in its Notice Letters contained the factual and legal bases for Micro Labs's contention that the '088 patent is invalid,

unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Micro Labs's ANDA Product. All remaining allegations are denied.

355. Denied.

356. Denied.

357. Denied.

**COUNT XXVI – DECLARATORY JUDGMENT OF INFRINGEMENT  
OF THE '088 PATENT**

358. Micro Labs incorporates its Answers to paragraphs 1 through 357 as if fully set forth herein.

359. This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Micro Labs admits only that there is an actual controversy concerning Micro Labs's noninfringement and invalidity of the '088 patent, but denies any remaining allegations in paragraph 359.

360. Denied.

**COUNT XXVII– INFRINGEMENT OF THE '141 PATENT**

361. Micro Labs incorporates its Answers to paragraphs 1 through 360 as if fully set forth herein.

362. Paragraph 362 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Micro Labs admits that what purports to be a copy of the '141 patent is attached as Exhibit N to the Complaint, that the patent is titled "Crystalline Pharmaceutical and Methods of Preparation and Use Thereof," and that the patent bears an issue date of February 13, 2018. All remaining allegations of Paragraph 362 are denied.

363. Micro Labs lacks the knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 363, and on that basis denies these allegations.

364. Micro Labs lacks the knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 364, and on that basis denies these allegations.

365. Micro Labs admits that the FDA's Orange Book lists the '141 patent in connection with XIIDRA®. Micro Labs lacks the knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 365, and on that basis denies these allegations.

366. Micro Labs admits that in the First Notice Letter, Micro Labs notified Novartis of the submission of Micro Labs's ANDA to the FDA. Micro Labs further admits that Micro Labs's ANDA contained a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '141 patent. All remaining allegations of Paragraph 366 are denied.

367. Admitted.

368. Denied.

369. Admitted.

370. Admitted.

371. Denied.

372. Denied.

373. Micro Labs intends to sell its ANDA Product at some point in time after approval.

All remaining allegations of Paragraph 373 are denied.

374. Denied.

375. Denied.

376. Denied.

377. Denied.

378. Micro Labs admits that Micro Labs's ANDA contained a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '141 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Micro Labs's ANDA Product. Micro Labs further admits that the Detailed Statements in its Notice Letters contained the factual and legal bases for Micro Labs's contention that the '141 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Micro Labs's ANDA Product. All remaining allegations of Paragraph 378 are denied.

379. Denied.

380. Denied.

381. Denied.

**COUNT XXVIII – DECLARATORY JUDGMENT OF INFRINGEMENT  
OF THE '141 PATENT**

382. Micro Labs incorporates its Answers to paragraphs 1 through 381 as if fully set forth herein.

383. This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Micro Labs admits only that there is an actual controversy concerning Micro Labs's noninfringement and invalidity of the '141 patent, but denies any remaining allegations in paragraph 383.

384. Denied.

**COUNT XXIX – INFRINGEMENT OF THE '553 PATENT**

385. Micro Labs incorporates its Answers to paragraphs 1 through 384 as if fully set forth herein.

386. Paragraph 386 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Micro Labs admits that what purports to be a copy of the '553 patent is attached as Exhibit O to the Complaint, that the patent is titled "LFA-1 Inhibitor and Methods of Preparation and Polymorph Thereof," and that the patent bears an issue date of July 21, 2015. All remaining allegations of Paragraph 386 are denied.

387. Micro Labs lacks the knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 387, and on that basis denies these allegations.

388. Micro Labs lacks the knowledge or information sufficient to form a belief as to the truth of the allegations contained in paragraph 388, and on that basis denies these allegations.

389. Micro Labs admits that the FDA's Orange Book lists the '553 patent in connection with XIIDRA®. Micro Labs lacks the knowledge or information sufficient to form a belief as to the truth of the remaining allegations contained in paragraph 389, and on that basis denies these allegations.

390. Micro Labs admits that in the First Notice Letter, Micro Labs notified Novartis of the submission of Micro Labs's ANDA to the FDA. Micro Labs further admits that Micro Labs's ANDA contained a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '553 patent. All remaining allegations of Paragraph 390 are denied.

391. Admitted.

392. Denied.

393. Admitted.

394. Admitted.

395. Denied.

396. Denied.

397. Micro Labs intends to sell its ANDA Product at some point in time after approval.

All remaining allegations of Paragraph 397 are denied.

398. Denied.

399. Denied.

400. Denied.

401. Denied.

402. Micro Labs admits that Micro Labs's ANDA contained a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '553 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Micro Labs's ANDA Product. Micro Labs further admits that the Detailed Statements in its Notice Letters contained the factual and legal bases for Micro Labs's contention that the '553 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Micro Labs's ANDA Product. All remaining allegations of Paragraph 402 are denied.

403. Denied.

404. Denied.

405. Denied.

**COUNT XXX – DECLARATORY JUDGMENT OF INFRINGEMENT  
OF THE '553 PATENT**

406. Micro Labs incorporates its Answers to paragraphs 1 through 405 as if fully set forth herein.

407. This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Micro Labs admits only that there is an actual controversy concerning

Micro Labs's noninfringement and invalidity of the '553 patent, but denies any remaining allegations in paragraph 407.

408. Denied.

**PRAYER FOR RELIEF**

Micro Labs denies all allegations not expressly admitted herein. Micro Labs further denies that Plaintiff is entitled to any of the relief requested, and requests Plaintiff's Complaint be dismissed with prejudice and that Micro Labs be awarded its fees and costs incurred defending this suit under 35 U.S.C. § 285.

**SEPARATE DEFENSES**

Without prejudice to the denials set forth in its **ANSWER**, without admitting allegations of the Complaint not otherwise admitted, and without undertaking any of the burdens imposed by law on Plaintiff, Micro Labs avers and asserts the following separate defenses to the Complaint:

**FIRST SEPARATE DEFENSE  
(INVALIDITY OF THE '938 PATENT)**

The claims of the '938 patent are invalid and/or unenforceable under 35 U.S.C. §§ 101, *et seq.* including, *inter alia*, §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation.

**SECOND SEPARATE DEFENSE  
(NO DIRECT INFRINGEMENT OF THE '938 PATENT)**

The manufacture, use, offer for sale, sale, or importation of the products described in Micro Labs's ANDA does not and will not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '938 patent.

**THIRD SEPARATE DEFENSE  
(NO INDIRECT INFRINGEMENT OF THE '938 PATENT)**

The manufacture, use, offer for sale, sale, or importation of the products described in Micro Labs's ANDA does not and will not induce the infringement of, and has not, does not, and will not contribute to the infringement of any valid and enforceable claim of the '938 patent.

**FOURTH SEPARATE DEFENSE  
(INVALIDITY OF THE '460 PATENT)**

The claims of the '460 patent are invalid and/or unenforceable under 35 U.S.C. §§ 101, *et seq.* including, *inter alia*, §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation.

**FIFTH SEPARATE DEFENSE  
(NO DIRECT INFRINGEMENT OF THE '460 PATENT)**

The manufacture, use, offer for sale, sale, or importation of the products described in Micro Labs's ANDA do not and will not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '460 patent.

**SIXTH SEPARATE DEFENSE  
(NO INDIRECT INFRINGEMENT OF THE '460 PATENT)**

The manufacture, use, offer for sale, sale, or importation of the products described in Micro Labs's ANDA does not and will not induce the infringement of, and has not, does not, and will not contribute to the infringement of any valid and enforceable claim of the '460 patent.

**SEVENTH SEPARATE DEFENSE  
(INVALIDITY OF THE '743 PATENT)**

The claims of the '743 patent are invalid and/or unenforceable under 35 U.S.C. §§ 101, *et seq.* including, *inter alia*, §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation.

**EIGHTH SEPARATE DEFENSE  
(NO DIRECT INFRINGEMENT OF THE '743 PATENT)**

The manufacture, use, offer for sale, sale, or importation of the products described in Micro Labs's ANDA does not and will not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '743 patent.

**NINTH SEPARATE DEFENSE  
(NO INDIRECT INFRINGEMENT OF THE '743 PATENT)**

The manufacture, use, offer for sale, sale, or importation of the products described in Micro Labs's ANDA does not and will not induce the infringement of, and has not, does not, and will not contribute to the infringement of any valid and enforceable claim of the '743 patent.

**TENTH SEPARATE DEFENSE  
(INVALIDITY OF THE '122 PATENT)**

The claims of the '122 patent are invalid and/or unenforceable under 35 U.S.C. §§ 101, *et seq.* including, *inter alia*, §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation.

**ELEVENTH SEPARATE DEFENSE  
(NO DIRECT INFRINGEMENT OF THE '122 PATENT)**

The manufacture, use, offer for sale, sale, or importation of the products described in Micro Labs's ANDA does not and will not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '122 patent.

**TWELFTH SEPARATE DEFENSE  
(NO INDIRECT INFRINGEMENT OF THE '122 PATENT)**

The manufacture, use, offer for sale, sale, or importation of the products described in Micro Labs's ANDA does not and will not induce the infringement of, and has not, does not, and will not contribute to the infringement of any valid and enforceable claim of the '122 patent.

**THIRTEENTH SEPARATE DEFENSE  
(INVALIDITY OF THE '174 PATENT)**

The claims of the '174 patent are invalid and/or unenforceable under 35 U.S.C. §§ 101, *et seq.* including, *inter alia*, §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation.

**FOURTEENTH SEPARATE DEFENSE  
(NO DIRECT INFRINGEMENT OF THE '174 PATENT)**

The manufacture, use, offer for sale, sale, or importation of the products described in Micro Labs's ANDA does not and will not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '174 patent.

**FIFTEENTH SEPARATE DEFENSE  
(NO INDIRECT INFRINGEMENT OF THE '174 PATENT)**

The manufacture, use, offer for sale, sale, or importation of the products described in Micro Labs's ANDA does not and will not induce the infringement of, and has not, does not, and will not contribute to the infringement of any valid and enforceable claim of the '174 patent.

**SIXTEENTH SEPARATE DEFENSE  
(INVALIDITY OF THE '000 PATENT)**

The claims of the '000 patent are invalid and/or unenforceable under 35 U.S.C. §§ 101, *et seq.* including, *inter alia*, §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation.

**SEVENTEENTH SEPARATE DEFENSE  
(NO DIRECT INFRINGEMENT OF THE '000 PATENT)**

The manufacture, use, offer for sale, sale, or importation of the products described in Micro Labs's ANDA does not and will not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '000 patent.

**EIGHTEENTH SEPARATE DEFENSE  
(NO INDIRECT INFRINGEMENT OF THE '000 PATENT)**

The manufacture, use, offer for sale, sale, or importation of the products described in Micro Labs's ANDA does not and will not induce the infringement of, and has not, does not, and will not contribute to the infringement of any valid and enforceable claim of the '000 patent.

**NINETEENTH SEPARATE DEFENSE  
(INVALIDITY OF THE '047 PATENT)**

The claims of the '047 patent are invalid and/or unenforceable under 35 U.S.C. §§ 101, *et seq.* including, *inter alia*, §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation.

**TWENTIETH SEPARATE DEFENSE  
(NO DIRECT INFRINGEMENT OF THE '047 PATENT)**

The manufacture, use, offer for sale, sale, or importation of the products described in Micro Labs's ANDA does not and will not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '047 patent.

**TWENTY FIRST SEPARATE DEFENSE  
(NO INDIRECT INFRINGEMENT OF THE '047 PATENT)**

The manufacture, use, offer for sale, sale, or importation of the products described in Micro Labs's ANDA does not and will not induce the infringement of, and has not, does not, and will not contribute to the infringement of any valid and enforceable claim of the '047 patent.

**TWENTY SECOND SEPARATE DEFENSE  
(INVALIDITY OF THE '450 PATENT)**

The claims of the '450 patent are invalid and/or unenforceable under 35 U.S.C. §§ 101, *et seq.* including, *inter alia*, §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation.

**TWENTY THIRD SEPARATE DEFENSE  
(NO DIRECT INFRINGEMENT OF THE '450 PATENT)**

The manufacture, use, offer for sale, sale, or importation of the products described in Micro Labs's ANDA does not and will not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '450 patent.

**TWENTY FOURTH SEPARATE DEFENSE  
(NO INDIRECT INFRINGEMENT OF THE '450 PATENT)**

The manufacture, use, offer for sale, sale, or importation of the products described in Micro Labs's ANDA does not and will not induce the infringement of, and has not, does not, and will not contribute to the infringement of any valid and enforceable claim of the '450 patent.

**TWENTY FIFTH SEPARATE DEFENSE  
(INVALIDITY OF THE '655 PATENT)**

The claims of the '655 patent are invalid and/or unenforceable under 35 U.S.C. §§ 101, *et seq.* including, *inter alia*, §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation.

**TWENTY SIXTH SEPARATE DEFENSE  
(NO DIRECT INFRINGEMENT OF THE '655 PATENT)**

The manufacture, use, offer for sale, sale, or importation of the products described in Micro Labs's ANDA does not and will not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '655 patent.

**TWENTY SEVENTH SEPARATE DEFENSE  
(NO INDIRECT INFRINGEMENT OF THE '655 PATENT)**

The manufacture, use, offer for sale, sale, or importation of the products described in Micro Labs's ANDA does not and will not induce the infringement of, and has not, does not, and will not contribute to the infringement of any valid and enforceable claim of the '655 patent.

**TWENTY EIGHTH SEPARATE DEFENSE  
(INVALIDITY OF THE '701 PATENT)**

The claims of the '701 patent are invalid and/or unenforceable under 35 U.S.C. §§ 101, *et seq.* including, *inter alia*, §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation.

**TWENTY NINTH SEPARATE DEFENSE  
(NO DIRECT INFRINGEMENT OF THE '701 PATENT)**

The manufacture, use, offer for sale, sale, or importation of the products described in Micro Labs's ANDA does not and will not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '701 patent.

**THIRTIETH SEPARATE DEFENSE  
(NO INDIRECT INFRINGEMENT OF THE '701 PATENT)**

The manufacture, use, offer for sale, sale, or importation of the products described in Micro Labs's ANDA does not and will not induce the infringement of, and has not, does not, and will not contribute to the infringement of any valid and enforceable claim of the '701 patent.

**THIRTY FIRST SEPARATE DEFENSE  
(INVALIDITY OF THE '077 PATENT)**

The claims of the '077 patent are invalid and/or unenforceable under 35 U.S.C. §§ 101, *et seq.* including, *inter alia*, §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation.

**THIRTY SECOND SEPARATE DEFENSE  
(NO DIRECT INFRINGEMENT OF THE '077 PATENT)**

The manufacture, use, offer for sale, sale, or importation of the products described in Micro Labs's ANDA does not and will not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '077 patent.

**THIRTY THIRD SEPARATE DEFENSE  
(NO INDIRECT INFRINGEMENT OF THE '077 PATENT)**

The manufacture, use, offer for sale, sale, or importation of the products described in Micro Labs's ANDA does not and will not induce the infringement of, and has not, does not, and will not contribute to the infringement of any valid and enforceable claim of the '077 patent.

**THIRTY FOURTH SEPARATE DEFENSE  
(INVALIDITY OF THE '574 PATENT)**

The claims of the '574 patent are invalid and/or unenforceable under 35 U.S.C. §§ 101, *et seq.* including, *inter alia*, §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation.

**THIRTY FIFTH SEPARATE DEFENSE  
(NO DIRECT INFRINGEMENT OF THE '574 PATENT)**

The manufacture, use, offer for sale, sale, or importation of the products described in Micro Labs's ANDA does not and will not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '574 patent.

**THIRTY SIXTH SEPARATE DEFENSE  
(NO INDIRECT INFRINGEMENT OF THE '574 PATENT)**

The manufacture, use, offer for sale, sale, or importation of the products described in Micro Labs's ANDA does not and will not induce the infringement of, and has not, does not, and will not contribute to the infringement of any valid and enforceable claim of the '574 patent.

**THIRTY SEVENTH SEPARATE DEFENSE  
(INVALIDITY OF THE '088 PATENT)**

The claims of the '088 patent are invalid and/or unenforceable under 35 U.S.C. §§ 101, *et seq.* including, *inter alia*, §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation.

**THIRTY EIGHTH SEPARATE DEFENSE  
(NO DIRECT INFRINGEMENT OF THE '088 PATENT)**

The manufacture, use, offer for sale, sale, or importation of the products described in Micro Labs's ANDA does not and will not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '088 patent.

**THIRTY NINTH SEPARATE DEFENSE  
(NO INDIRECT INFRINGEMENT OF THE '088 PATENT)**

The manufacture, use, offer for sale, sale, or importation of the products described in Micro Labs's ANDA does not and will not induce the infringement of, and has not, does not, and will not contribute to the infringement of any valid and enforceable claim of the '088 patent.

**FOURTIETH SEPARATE DEFENSE  
(INVALIDITY OF THE '141 PATENT)**

The claims of the '141 patent are invalid and/or unenforceable under 35 U.S.C. §§ 101, *et seq.* including, *inter alia*, §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation.

**FOURTY FIRST SEPARATE DEFENSE  
(NO DIRECT INFRINGEMENT OF THE '141 PATENT)**

The manufacture, use, offer for sale, sale, or importation of the products described in Micro Labs's ANDA does not and will not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '141 patent.

**FOURTY SECOND SEPARATE DEFENSE  
(NO INDIRECT INFRINGEMENT OF THE '141 PATENT)**

The manufacture, use, offer for sale, sale, or importation of the products described in Micro Labs's ANDA does not and will not induce the infringement of, and has not, does not, and will not contribute to the infringement of any valid and enforceable claim of the '141 patent.

**FOURTY THIRD SEPARATE DEFENSE  
(INVALIDITY OF THE '553 PATENT)**

The claims of the '553 patent are invalid and/or unenforceable under 35 U.S.C. §§ 101, *et seq.* including, *inter alia*, §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation.

**FOURTY FOURTH SEPARATE DEFENSE  
(NO DIRECT INFRINGEMENT OF THE '553 PATENT)**

The manufacture, use, offer for sale, sale, or importation of the products described in Micro Labs's ANDA does not and will not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '553 patent.

**FOURTY FIFTH SEPARATE DEFENSE  
(NO INDIRECT INFRINGEMENT OF THE '553 PATENT)**

The manufacture, use, offer for sale, sale, or importation of the products described in Micro Labs's ANDA does not and will not induce the infringement of, and has not, does not, and will not contribute to the infringement of any valid and enforceable claim of the '553 patent.

**FOURTY SIXTH SEPARATE DEFENSE  
(FAILURE TO STATE A CLAIM)**

Plaintiff's Complaint, in whole and/or in part, fails to state a claim upon which relief can be granted.

**FOURTY SEVENTH SEPARATE DEFENSE  
(LACK OF SUBJECT MATTER JURISDICTION)**

Plaintiff's Complaint lacks subject matter jurisdiction over any and all claims asserted under 35 U.S.C. § 271(a), (b), (c), and/or (g).

**FOURTY EIGHTH SEPARATE DEFENSE  
(FAILURE TO STATE A CLAIM FOR EXCEPTIONAL OR WILLFUL  
INFRINGEMENT)**

Plaintiff fails to state a proper claim for an exceptional case and/or willful infringement.

**RESERVATION OF ADDITIONAL SEPARATE DEFENSES**

Micro Labs reserves the right to plead additional separate defenses or counterclaims that may be revealed through the course of discovery, including unenforceability.

## **COUNTERCLAIMS**

Pursuant to Rule 13 of the Federal Rules of Civil Procedure, Micro Labs Limited and Micro Labs USA Inc. (collectively, “Micro Labs”), by way of its attorneys, hereby states for its Counterclaims against Plaintiff Novartis Pharmaceuticals Corporation (“Plaintiff” or “Novartis”), the following:

1. Micro Labs repeats and incorporates by reference each of the foregoing paragraphs of Micro Labs’ Answer and Affirmative Defenses to the Complaint.

## **PARTIES**

2. Micro Labs Limited is a company organized and existing under the laws of India, and has a principal place of business at 31, Race Course Road, Bangalore-560 001, India.

3. Micro Labs USA Inc. is a New Jersey corporation having a place of business at 106 Allen Rd., Suite 102, Basking Ridge, New Jersey 07920.

4. Upon information and belief, Plaintiff Novartis Pharmaceuticals Corporation is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 1 Health Plaza, East Hanover, NJ 07936.

## **JURISDICTION**

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

6. This Court has original jurisdiction over the subject matter of these Counterclaims under 28 U.S.C. §§ 1331 and 1338(a); under the Declaratory Judgment Act, and 28 U.S.C. §§ 2201 and 2202.

7. This court has subject matter jurisdiction over these Counterclaims for declaratory judgment pursuant to 28 U.S.C. §§ 1331, 1337(a), 1338(a), 2201(a) and (b), and 2202, based on

an actual controversy between Micro Labs and Plaintiff/Counterclaim-Defendant, arising under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*

8. This court has personal jurisdiction over Plaintiff/Counterclaim-Defendant based, *inter alia*, on the filing of this lawsuit in this jurisdiction and because Plaintiff/Counterclaim-Defendant is doing business in this jurisdiction.

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

#### **FACTUAL BACKGROUND**

10. This is an action for a declaratory judgment of non-infringement and invalidity of one or more claims of U.S. Patent No. 7,314,938 (“the ’938 patent”); U.S. Patent No. 7,745,460 (“the ’460 patent”); U.S. Patent No. 7,790,743 (“the ’743 patent”); U.S. Patent No. 7,928,122 (“the ’122 patent”); U.S. Patent No. 9,216,174 (“the ’174 patent”); U.S. Patent No. 10,124,000 (“the ’000 patent”); U.S. Patent No. 8,084,047 (“the ’047 patent”); U.S. Patent No. 8,592,450 (“the ’450 patent”); U.S. Patent No. 8,168,655 (“the ’655 patent”); U.S. Patent No. 8,367,701 (“the ’701 patent”); U.S. Patent No. 9,447,077 (“the ’077 patent”); U.S. Patent No. 8,927,574 (“the ’574 patent”); U.S. Patent No. 9,353,088 (“the ’088 patent”); U.S. Patent No. 9,890,141 (“the ’141 patent”); and U.S. Patent No. 9,085,553 (“the ’553 patent”) (collectively, the “Asserted Patents”).

11. Upon information and belief, true and correct copies of the Patents-in-Suit are attached to Plaintiff’s/Counterclaim-Defendant’s Complaint as Exhibits A-O, respectively.

12. The ’938 patent, which the Counterclaim-Defendant alleges is attached to the Complaint as Exhibit A, on its face is titled “Modulators of Cellular Adhesion,” and lists an issue date of January 1, 2008. The face of the ’938 patent identifies Novartis as assignee.

13. The '460 patent, which the Counterclaim-Defendant alleges is attached to the Complaint as Exhibit B, on its face is titled "Modulators of Cellular Adhesion," and lists an issue date of June 29, 2010. The face of the '460 patent identifies Novartis as assignee.

14. The '743 patent, which the Counterclaim-Defendant alleges is attached to the Complaint as Exhibit C, on its face is titled "Modulators of Cellular Adhesion," and lists an issue date of September 7, 2010. The face of the '743 patent identifies Novartis as assignee.

15. The '122 patent, which the Counterclaim-Defendant alleges is attached to the Complaint as Exhibit D, on its face is titled "Modulators of Cellular Adhesion," and lists an issue date of April 19, 2011. The face of the '122 patent identifies Novartis as assignee.

16. The '174 patent, which the Counterclaim-Defendant alleges is attached to the Complaint as Exhibit E, on its face is titled "Modulators of Cellular Adhesion," and lists an issue date of December 22, 2015. The face of the '174 patent identifies Novartis as assignee.

17. The '000 patent, which the Counterclaim-Defendant alleges is attached to the Complaint as Exhibit F, on its face is titled "Compositions and Methods for Treatment of Eye Disorders," and lists an issue date of November 13, 2018. The face of the '000 patent identifies Novartis as assignee.

18. The '047 patent, which the Counterclaim-Defendant alleges is attached to the Complaint as Exhibit G, on its face is titled "Compositions and Methods for Treatment of Eye Disorders," and lists an issue date of December 27, 2011. The face of the '047 patent identifies Novartis as assignee.

19. The '655 patent, which the Counterclaim-Defendant alleges is attached to the Complaint as Exhibit H, on its face is titled "Compositions and Methods for Treatment of Eye

Disorders,” and lists an issue date of May 1, 2012. The face of the ’655 patent identifies Novartis as assignee.

20. The ’450 patent, which the Counterclaim-Defendant alleges is attached to the Complaint as Exhibit I, on its face is titled “Compositions and Methods for Treatment of Eye Disorders,” and lists an issue date of November 26, 2013. The face of the ’450 patent identifies Novartis as assignee.

21. The ’701 patent, which the Counterclaim-Defendant alleges is attached to the Complaint as Exhibit J, on its face is titled “Crystalline Pharmaceutical and Methods of Preparation and Use Thereof,” and lists an issue date of February 5, 2013. The face of the ’701 patent identifies Novartis as assignee.

22. The ’077 patent, which the Counterclaim-Defendant alleges is attached to the Complaint as Exhibit K, on its face is titled “Crystalline Pharmaceutical and Methods of Preparation and Use Thereof,” and lists an issue date of September 20, 2016. The face of the ’077 patent identifies Novartis as assignee.

23. The ’574 patent, which the Counterclaim-Defendant alleges is attached to the Complaint as Exhibit L, on its face is titled “Crystalline Pharmaceutical and Methods of Preparation and Use Thereof,” and lists an issue date of January 6, 2015. The face of the ’574 patent identifies Novartis as assignee.

24. The ’088 patent, which the Counterclaim-Defendant alleges is attached to the Complaint as Exhibit M, on its face is titled “Crystalline Pharmaceutical and Methods of Preparation and Use Thereof,” and lists an issue date of May 31, 2016. The face of the ’088 patent identifies Novartis as assignee.

25. The '141 patent, which the Counterclaim-Defendant alleges is attached to the Complaint as Exhibit N, on its face is titled "Crystalline Pharmaceutical and Methods of Preparation and Use Thereof," and lists an issue date of May 31, 2016. The face of the '141 patent identifies Novartis as assignee.

26. The '553 patent, which the Counterclaim-Defendant alleges is attached to the Complaint as Exhibit O, on its face is titled "LFA-1 inhibitor and methods of preparation and polymorph thereof," and lists an issue date of July 21, 2015. The face of the '553 patent identifies Novartis as assignee.

27. Novartis Pharmaceuticals Corporation is the holder of New Drug Application ("NDA") No. 208073 for the manufacture and sale of lifitegrast ophthalmic solution 5%, which has been approved by the FDA.

28. Plaintiff/Counterclaim-Defendant purports and claims to have the right to enforce the Asserted Patents, and have listed or caused to be listed the Asserted Patents in the FDA's *Approved Drug Products and Therapeutic Equivalence Evaluations* (the "Orange Book") for XIIDRA®.

29. Micro Labs has filed the Abbreviated New Drug Application ("ANDA") No. 215081 with the U.S. Food and Drug Administration (the "FDA") seeking approval for Micro Labs's proposed lifitegrast intravenous solution product described therein ("Micro Labs's ANDA Product"), identifying NDA No. 208073 as the Reference Listed Drug.

30. Micro Labs's ANDA seeks FDA approval to market the ANDA Product described within ANDA No. 215081 before the expiration of the Asserted Patents listed in the Orange Book, and Micro Labs's ANDA includes a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (also called a "Paragraph IV Certification") as to the Asserted Patents.

31. Plaintiff/Counterclaim-Defendant sued Micro Labs in this District for alleged infringement of the Asserted Patents.

**COUNT I**  
**Declaratory Judgment of Invalidity of the '938 Patent**

32. Micro Labs re-alleges and incorporates by reference the allegations of paragraphs 1-31 as though fully set forth herein.

33. There is an actual, substantial, and continuing case or controversy between Micro Labs and the Plaintiff/Counterclaim-Defendant regarding, *inter alia*, the invalidity of the '938 Patent.

34. The claims of the '938 Patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code, or under judicially-created bases for invalidation.

35. The claims of the '938 Patent are obvious to a person of ordinary skill in the art because each and every element of each and every claim of the '938 patent was disclosed expressly or inherently in one or more references and/or products which were publicly available before the earliest possible priority date of the '938 patent, including, but not limited to, those references and/or products disclosed in Micro Labs's Notice Letters dated September 3, 2020 and May 20, 2021 (collectively, "Micro Labs's Notice Letters"). The claims of the '938 Patent are obvious over the references and/or products because the person of ordinary skill in the art would have been motivated to combine those references and/or products as of the earliest possible priority date of the '938 Patent, and would have had a reasonable expectation of success in doing so.

36. There is no objective evidence of non-obviousness of the claims of the '938 Patent, nor would any such evidence, should it exist, have any nexus to the claimed purported inventions of the '938 Patent.

37. Micro Labs is entitled to a judicial declaration that the claims of the '938 Patent are invalid.

**COUNT II**  
**Declaratory Judgment of Noninfringement of the '938 Patent**

38. Micro Labs re-alleges and incorporates by reference the allegations of paragraphs 1-37 as though fully set forth herein.

39. There is an actual, substantial, and continuing case or controversy between Micro Labs and the Plaintiff/Counterclaim-Defendant regarding, *inter alia*, non-infringement of the claims of the '938 Patent.

40. The manufacture, use, offer for sale, sale, importation, and/or marketing of Micro Labs's ANDA Product described in Micro Labs's ANDA has not infringed, does not infringe, and would not—if made, used, sold, offered for sale, imported or marketed—infringe, either directly or indirectly, the claims of the '938 Patent, either literally or under the doctrine of equivalents, that do not cover Micro Labs's ANDA Product.

41. Micro Labs is entitled to a judicial declaration that the manufacture, use, offer for sale, sale, importation, and/or marketing of Micro Labs's ANDA Product described in Micro Labs's ANDA has not infringed, does not infringe, and would not—if made, used, sold, offered for sale, imported or marketed—infringe, either directly or indirectly, any valid or enforceable claim of the '938 Patent, either literally or under the doctrine of equivalents.

**COUNT III**  
**Declaratory Judgment of Invalidity of the '460 Patent**

42. Micro Labs re-alleges and incorporates by reference the allegations of paragraphs 1-41 as though fully set forth herein.

43. There is an actual, substantial, and continuing case or controversy between Micro Labs and the Plaintiff/Counterclaim-Defendant regarding, *inter alia*, the invalidity of the '460 Patent.

44. The claims of the '460 Patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code, or under judicially-created bases for invalidation.

45. The claims of the '460 Patent are obvious to a person of ordinary skill in the art because each and every element of each and every claim of the '460 patent was disclosed expressly or inherently in one or more references and/or products which were publicly available before the earliest possible priority date of the '460 patent, including, but not limited to, those references and/or products disclosed in Micro Labs's Notice Letters. The claims of the '460 Patent are obvious over the references and/or products because the person of ordinary skill in the art would have been motivated to combine those references and/or products as of the earliest possible priority date of the '460 Patent, and would have had a reasonable expectation of success in doing so.

46. There is no objective evidence of non-obviousness of the claims of the '460 Patent, nor would any such evidence, should it exist, have any nexus to the claimed purported inventions of the '460 Patent.

47. Micro Labs is entitled to a judicial declaration that the claims of the '460 Patent are invalid.

**COUNT IV**  
**Declaratory Judgment of Noninfringement of the '460 Patent**

48. Micro Labs re-alleges and incorporates by reference the allegations of paragraphs 1-47 as though fully set forth herein.

49. There is an actual, substantial, and continuing case or controversy between Micro Labs and the Plaintiff/Counterclaim-Defendant regarding, *inter alia*, non-infringement of the claims of the '460 Patent.

50. The manufacture, use, offer for sale, sale, importation, and/or marketing of Micro Labs's ANDA Product described in Micro Labs's ANDA has not infringed, does not infringe, and would not—if made, used, sold, offered for sale, imported or marketed—infringe, either directly or indirectly, the claims of the '460 Patent, either literally or under the doctrine of equivalents, that do not cover Micro Labs's ANDA Product.

51. Micro Labs is entitled to a judicial declaration that the manufacture, use, offer for sale, sale, importation, and/or marketing of Micro Labs's ANDA Product described in Micro Labs's ANDA has not infringed, does not infringe, and would not—if made, used, sold, offered for sale, imported or marketed—infringe, either directly or indirectly, any valid or enforceable claim of the '460 Patent, either literally or under the doctrine of equivalents.

**COUNT V**  
**Declaratory Judgment of Invalidity of the '743 Patent**

52. Micro Labs re-alleges and incorporates by reference the allegations of paragraphs 1-51 as though fully set forth herein.

53. There is an actual, substantial, and continuing case or controversy between Micro Labs and the Plaintiff/Counterclaim-Defendant regarding, *inter alia*, the invalidity of the '743 Patent.

54. The claims of the '743 Patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code, or under judicially-created bases for invalidation.

55. The claims of the '743 Patent are obvious to a person of ordinary skill in the art because each and every element of each and every claim of the '743 patent was disclosed expressly or inherently in one or more references and/or products which were publicly available before the earliest possible priority date of the '743 patent, including, but not limited to, those references and/or products disclosed in Micro Labs's Notice Letters. The claims of the '743 Patent are obvious over the references and/or products because the person of ordinary skill in the art would have been motivated to combine those references and/or products as of the earliest possible priority date of the '743 Patent, and would have had a reasonable expectation of success in doing so.

56. There is no objective evidence of non-obviousness of the claims of the '743 Patent, nor would any such evidence, should it exist, have any nexus to the claimed purported inventions of the '743 Patent.

57. Micro Labs is entitled to a judicial declaration that the claims of the '743 Patent are invalid.

**COUNT VI**  
**Declaratory Judgment of Noninfringement of the '743 Patent**

58. Micro Labs re-alleges and incorporates by reference the allegations of paragraphs 1-57 as though fully set forth herein.

59. There is an actual, substantial, and continuing case or controversy between Micro Labs and the Plaintiff/Counterclaim-Defendant regarding, *inter alia*, non-infringement of the claims of the '743 Patent.

60. The manufacture, use, offer for sale, sale, importation, and/or marketing of Micro Labs's ANDA Product described in Micro Labs's ANDA has not infringed, does not infringe, and would not—if made, used, sold, offered for sale, imported or marketed—Infringe, either directly

or indirectly, the claims of the '743 Patent, either literally or under the doctrine of equivalents, that do not cover Micro Labs's ANDA Product.

61. Micro Labs is entitled to a judicial declaration that the manufacture, use, offer for sale, sale, importation, and/or marketing of Micro Labs's ANDA Product described in Micro Labs's ANDA has not infringed, does not infringe, and would not—if made, used, sold, offered for sale, imported or marketed—infringe, either directly or indirectly, any valid or enforceable claim of the '743 Patent, either literally or under the doctrine of equivalents.

**COUNT VII**  
**Declaratory Judgment of Invalidity of the '122 Patent**

62. Micro Labs re-alleges and incorporates by reference the allegations of paragraphs 1-61 as though fully set forth herein.

63. There is an actual, substantial, and continuing case or controversy between Micro Labs and the Plaintiff/Counterclaim-Defendant regarding, *inter alia*, the invalidity of the '122 Patent.

64. The claims of the '122 Patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code, or under judicially-created bases for invalidation.

65. The claims of the '122 Patent are obvious to a person of ordinary skill in the art because each and every element of each and every claim of the '122 patent was disclosed expressly or inherently in one or more references and/or products which were publicly available before the earliest possible priority date of the '122 patent, including, but not limited to, those references and/or products disclosed in Micro Labs's Notice Letters. The claims of the '122 Patent are obvious over the references and/or products because the person of ordinary skill in the art would

have been motivated to combine those references and/or products as of the earliest possible priority date of the '122 Patent, and would have had a reasonable expectation of success in doing so.

66. There is no objective evidence of non-obviousness of the claims of the '122 Patent, nor would any such evidence, should it exist, have any nexus to the claimed purported inventions of the '122 Patent.

67. Micro Labs is entitled to a judicial declaration that the claims of the '122 Patent are invalid.

**COUNT VIII**  
**Declaratory Judgment of Noninfringement of the '122 Patent**

68. Micro Labs re-alleges and incorporates by reference the allegations of paragraphs 1-67 as though fully set forth herein.

69. There is an actual, substantial, and continuing case or controversy between Micro Labs and the Plaintiff/Counterclaim-Defendant regarding, *inter alia*, non-infringement of the claims of the '122 Patent.

70. The manufacture, use, offer for sale, sale, importation, and/or marketing of Micro Labs's ANDA Product described in Micro Labs's ANDA has not infringed, does not infringe, and would not—if made, used, sold, offered for sale, imported or marketed—infringe, either directly or indirectly, the claims of the '122 Patent, either literally or under the doctrine of equivalents, that do not cover Micro Labs's ANDA Product.

71. Micro Labs is entitled to a judicial declaration that the manufacture, use, offer for sale, sale, importation, and/or marketing of Micro Labs's ANDA Product described in Micro Labs's ANDA has not infringed, does not infringe, and would not—if made, used, sold, offered for sale, imported or marketed—infringe, either directly or indirectly, any valid or enforceable claim of the '122 Patent, either literally or under the doctrine of equivalents.

**COUNT IX**  
**Declaratory Judgment of Invalidity of the '174 Patent**

72. Micro Labs re-alleges and incorporates by reference the allegations of paragraphs 1-71 as though fully set forth herein.

73. There is an actual, substantial, and continuing case or controversy between Micro Labs and the Plaintiff/Counterclaim-Defendant regarding, *inter alia*, the invalidity of the '174 Patent.

74. The claims of the '174 Patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code, or under judicially-created bases for invalidation.

75. The claims of the '174 Patent are obvious to a person of ordinary skill in the art because each and every element of each and every claim of the '174 patent was disclosed expressly or inherently in one or more references and/or products which were publicly available before the earliest possible priority date of the '174 patent, including, but not limited to, those references and/or products disclosed in Micro Labs's Notice Letters. The claims of the '174 Patent are obvious over the references and/or products because the person of ordinary skill in the art would have been motivated to combine those references and/or products as of the earliest possible priority date of the '174 Patent, and would have had a reasonable expectation of success in doing so.

76. There is no objective evidence of non-obviousness of the claims of the '174 Patent, nor would any such evidence, should it exist, have any nexus to the claimed purported inventions of the '174 Patent.

77. Micro Labs is entitled to a judicial declaration that the claims of the '174 Patent are invalid.

**COUNT X**  
**Declaratory Judgment of Noninfringement of the '174 Patent**

78. Micro Labs re-alleges and incorporates by reference the allegations of paragraphs 1-77 as though fully set forth herein.

79. There is an actual, substantial, and continuing case or controversy between Micro Labs and the Plaintiff/Counterclaim-Defendant regarding, *inter alia*, non-infringement of the claims of the '174 Patent.

80. The manufacture, use, offer for sale, sale, importation, and/or marketing of Micro Labs's ANDA Product described in Micro Labs's ANDA has not infringed, does not infringe, and would not—if made, used, sold, offered for sale, imported or marketed—infringe, either directly or indirectly, the claims of the '174 Patent, either literally or under the doctrine of equivalents, that do not cover Micro Labs's ANDA Product.

81. Micro Labs is entitled to a judicial declaration that the manufacture, use, offer for sale, sale, importation, and/or marketing of Micro Labs's ANDA Product described in Micro Labs's ANDA has not infringed, does not infringe, and would not—if made, used, sold, offered for sale, imported or marketed—infringe, either directly or indirectly, any valid or enforceable claim of the '174 Patent, either literally or under the doctrine of equivalents.

**COUNT XI**  
**Declaratory Judgment of Invalidity of the '000 Patent**

82. Micro Labs re-alleges and incorporates by reference the allegations of paragraphs 1-81 as though fully set forth herein.

83. There is an actual, substantial, and continuing case or controversy between Micro Labs and the Plaintiff/Counterclaim-Defendant regarding, *inter alia*, the invalidity of the '000 Patent.

84. The claims of the '000 Patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code, or under judicially-created bases for invalidation.

85. The claims of the '000 Patent are obvious to a person of ordinary skill in the art because each and every element of each and every claim of the '000 patent was disclosed expressly or inherently in one or more references and/or products which were publicly available before the earliest possible priority date of the '000 patent, including, but not limited to, those references and/or products disclosed in Micro Labs's Notice Letters. The claims of the '000 Patent are obvious over the references and/or products because the person of ordinary skill in the art would have been motivated to combine those references and/or products as of the earliest possible priority date of the '000 Patent, and would have had a reasonable expectation of success in doing so.

86. There is no objective evidence of non-obviousness of the claims of the '000 Patent, nor would any such evidence, should it exist, have any nexus to the claimed purported inventions of the '000 Patent.

87. Micro Labs is entitled to a judicial declaration that the claims of the '000 Patent are invalid.

**COUNT XII**  
**Declaratory Judgment of Noninfringement of the '000 Patent**

88. Micro Labs re-alleges and incorporates by reference the allegations of paragraphs 1-87 as though fully set forth herein.

89. There is an actual, substantial, and continuing case or controversy between Micro Labs and the Plaintiff/Counterclaim-Defendant regarding, *inter alia*, non-infringement of the claims of the '000 Patent.

90. The manufacture, use, offer for sale, sale, importation, and/or marketing of Micro Labs's ANDA Product described in Micro Labs's ANDA has not infringed, does not infringe, and would not—if made, used, sold, offered for sale, imported or marketed—infringe, either directly or indirectly, the claims of the '000 Patent, either literally or under the doctrine of equivalents, that do not cover Micro Labs's ANDA Product.

91. Micro Labs is entitled to a judicial declaration that the manufacture, use, offer for sale, sale, importation, and/or marketing of Micro Labs's ANDA Product described in Micro Labs's ANDA has not infringed, does not infringe, and would not—if made, used, sold, offered for sale, imported or marketed—infringe, either directly or indirectly, any valid or enforceable claim of the '000 Patent, either literally or under the doctrine of equivalents.

**COUNT XIII**  
**Declaratory Judgment of Invalidity of the '047 Patent**

92. Micro Labs re-alleges and incorporates by reference the allegations of paragraphs 1-91 as though fully set forth herein.

93. There is an actual, substantial, and continuing case or controversy between Micro Labs and the Plaintiff/Counterclaim-Defendant regarding, *inter alia*, the invalidity of the '047 Patent.

94. The claims of the '047 Patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code, or under judicially-created bases for invalidation.

95. The claims of the '047 Patent are obvious to a person of ordinary skill in the art because each and every element of each and every claim of the '047 patent was disclosed expressly or inherently in one or more references and/or products which were publicly available before the earliest possible priority date of the '047 patent, including, but not limited to, those references

and/or products disclosed in Micro Labs's Notice Letters. The claims of the '047 Patent are obvious over the references and/or products because the person of ordinary skill in the art would have been motivated to combine those references and/or products as of the earliest possible priority date of the '047 Patent, and would have had a reasonable expectation of success in doing so.

96. There is no objective evidence of non-obviousness of the claims of the '047 Patent, nor would any such evidence, should it exist, have any nexus to the claimed purported inventions of the '047 Patent.

97. Micro Labs is entitled to a judicial declaration that the claims of the '047 Patent are invalid.

**COUNT XIV**  
**Declaratory Judgment of Noninfringement of the '047 Patent**

98. Micro Labs re-alleges and incorporates by reference the allegations of paragraphs 1-97 as though fully set forth herein.

99. There is an actual, substantial, and continuing case or controversy between Micro Labs and the Plaintiff/Counterclaim-Defendant regarding, *inter alia*, non-infringement of the claims of the '047 Patent.

100. The manufacture, use, offer for sale, sale, importation, and/or marketing of Micro Labs's ANDA Product described in Micro Labs's ANDA has not infringed, does not infringe, and would not—if made, used, sold, offered for sale, imported or marketed—infringe, either directly or indirectly, the claims of the '047 Patent, either literally or under the doctrine of equivalents, that do not cover Micro Labs's ANDA Product.

101. Micro Labs is entitled to a judicial declaration that the manufacture, use, offer for sale, sale, importation, and/or marketing of Micro Labs's ANDA Product described in Micro Labs's ANDA has not infringed, does not infringe, and would not—if made, used, sold, offered

for sale, imported or marketed— infringe, either directly or indirectly, any valid or enforceable claim of the '047 Patent, either literally or under the doctrine of equivalents.

**COUNT XV**  
**Declaratory Judgment of Invalidity of the '655 Patent**

102. Micro Labs re-alleges and incorporates by reference the allegations of paragraphs 1-101 as though fully set forth herein.

103. There is an actual, substantial, and continuing case or controversy between Micro Labs and the Plaintiff/Counterclaim-Defendant regarding, *inter alia*, the invalidity of the '655 Patent.

104. The claims of the '655 Patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code, or under judicially-created bases for invalidation.

105. The claims of the '655 Patent are obvious to a person of ordinary skill in the art because each and every element of each and every claim of the '655 patent was disclosed expressly or inherently in one or more references and/or products which were publicly available before the earliest possible priority date of the '655 patent, including, but not limited to, those references and/or products disclosed in Micro Labs's Notice Letters. The claims of the '655 Patent are obvious over the references and/or products because the person of ordinary skill in the art would have been motivated to combine those references and/or products as of the earliest possible priority date of the '655 Patent, and would have had a reasonable expectation of success in doing so.

106. There is no objective evidence of non-obviousness of the claims of the '655 Patent, nor would any such evidence, should it exist, have any nexus to the claimed purported inventions of the '655 Patent.

107. Micro Labs is entitled to a judicial declaration that the claims of the '655 Patent are invalid.

**COUNT XVI**  
**Declaratory Judgment of Noninfringement of the '655 Patent**

108. Micro Labs re-alleges and incorporates by reference the allegations of paragraphs 1-107 as though fully set forth herein.

109. There is an actual, substantial, and continuing case or controversy between Micro Labs and the Plaintiff/Counterclaim-Defendant regarding, *inter alia*, non-infringement of the claims of the '655 Patent.

110. The manufacture, use, offer for sale, sale, importation, and/or marketing of Micro Labs's ANDA Product described in Micro Labs's ANDA has not infringed, does not infringe, and would not—if made, used, sold, offered for sale, imported or marketed—infringe, either directly or indirectly, the claims of the '655 Patent, either literally or under the doctrine of equivalents, that do not cover Micro Labs's ANDA Product.

111. Micro Labs is entitled to a judicial declaration that the manufacture, use, offer for sale, sale, importation, and/or marketing of Micro Labs's ANDA Product described in Micro Labs's ANDA has not infringed, does not infringe, and would not—if made, used, sold, offered for sale, imported or marketed—infringe, either directly or indirectly, any valid or enforceable claim of the '655 Patent, either literally or under the doctrine of equivalents.

**COUNT XVII**  
**Declaratory Judgment of Invalidity of the '450 Patent**

112. Micro Labs re-alleges and incorporates by reference the allegations of paragraphs 1-111 as though fully set forth herein.

113. There is an actual, substantial, and continuing case or controversy between Micro Labs and the Plaintiff/Counterclaim-Defendant regarding, *inter alia*, the invalidity of the '450 Patent.

114. The claims of the '450 Patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code, or under judicially-created bases for invalidation.

115. The claims of the '450 Patent are obvious to a person of ordinary skill in the art because each and every element of each and every claim of the '450 patent was disclosed expressly or inherently in one or more references and/or products which were publicly available before the earliest possible priority date of the '450 patent, including, but not limited to, those references and/or products disclosed in Micro Labs's Notice Letters. The claims of the '450 Patent are obvious over the references and/or products because the person of ordinary skill in the art would have been motivated to combine those references and/or products as of the earliest possible priority date of the '450 Patent, and would have had a reasonable expectation of success in doing so.

116. There is no objective evidence of non-obviousness of the claims of the '450 Patent, nor would any such evidence, should it exist, have any nexus to the claimed purported inventions of the '450 Patent.

117. Micro Labs is entitled to a judicial declaration that the claims of the '450 Patent are invalid.

**COUNT XVIII**  
**Declaratory Judgment of Noninfringement of the '450 Patent**

118. Micro Labs re-alleges and incorporates by reference the allegations of paragraphs 1-117 as though fully set forth herein.

119. There is an actual, substantial, and continuing case or controversy between Micro Labs and the Plaintiff/Counterclaim-Defendant regarding, *inter alia*, non-infringement of the claims of the '450 Patent.

120. The manufacture, use, offer for sale, sale, importation, and/or marketing of Micro Labs's ANDA Product described in Micro Labs's ANDA has not infringed, does not infringe, and would not—if made, used, sold, offered for sale, imported or marketed—infringe, either directly or indirectly, the claims of the '450 Patent, either literally or under the doctrine of equivalents, that do not cover Micro Labs's ANDA Product.

121. Micro Labs is entitled to a judicial declaration that the manufacture, use, offer for sale, sale, importation, and/or marketing of Micro Labs's ANDA Product described in Micro Labs's ANDA has not infringed, does not infringe, and would not—if made, used, sold, offered for sale, imported or marketed—infringe, either directly or indirectly, any valid or enforceable claim of the '450 Patent, either literally or under the doctrine of equivalents.

**COUNT XIX**  
**Declaratory Judgment of Invalidity of the '701 Patent**

122. Micro Labs re-alleges and incorporates by reference the allegations of paragraphs 1-121 as though fully set forth herein.

123. There is an actual, substantial, and continuing case or controversy between Micro Labs and the Plaintiff/Counterclaim-Defendant regarding, *inter alia*, the invalidity of the '701 Patent.

124. The claims of the '701 Patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code, or under judicially-created bases for invalidation.

125. The claims of the '701 Patent are obvious to a person of ordinary skill in the art because each and every element of each and every claim of the '701 patent was disclosed expressly or inherently in one or more references and/or products which were publicly available before the earliest possible priority date of the '701 patent, including, but not limited to, those references and/or products disclosed in Micro Labs's Notice Letters. The claims of the '701 Patent are obvious over the references and/or products because the person of ordinary skill in the art would have been motivated to combine those references and/or products as of the earliest possible priority date of the '701 Patent, and would have had a reasonable expectation of success in doing so.

126. There is no objective evidence of non-obviousness of the claims of the '701 Patent, nor would any such evidence, should it exist, have any nexus to the claimed purported inventions of the '701 Patent.

127. Micro Labs is entitled to a judicial declaration that the claims of the '701 Patent are invalid.

**COUNT XX**  
**Declaratory Judgment of Noninfringement of the '701 Patent**

128. Micro Labs re-alleges and incorporates by reference the allegations of paragraphs 1-127 as though fully set forth herein.

129. There is an actual, substantial, and continuing case or controversy between Micro Labs and the Plaintiff/Counterclaim-Defendant regarding, *inter alia*, non-infringement of the claims of the '701 Patent.

130. The manufacture, use, offer for sale, sale, importation, and/or marketing of Micro Labs's ANDA Product described in Micro Labs's ANDA has not infringed, does not infringe, and would not—if made, used, sold, offered for sale, imported or marketed—Infringe, either directly

or indirectly, the claims of the '701 Patent, either literally or under the doctrine of equivalents, that do not cover Micro Labs's ANDA Product.

131. Micro Labs is entitled to a judicial declaration that the manufacture, use, offer for sale, sale, importation, and/or marketing of Micro Labs's ANDA Product described in Micro Labs's ANDA has not infringed, does not infringe, and would not—if made, used, sold, offered for sale, imported or marketed—infringe, either directly or indirectly, any valid or enforceable claim of the '701 Patent, either literally or under the doctrine of equivalents.

**COUNT XXI**  
**Declaratory Judgment of Invalidity of the '077 Patent**

132. Micro Labs re-alleges and incorporates by reference the allegations of paragraphs 1-131 as though fully set forth herein.

133. There is an actual, substantial, and continuing case or controversy between Micro Labs and the Plaintiff/Counterclaim-Defendant regarding, *inter alia*, the invalidity of the '077 Patent.

134. The claims of the '077 Patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code, or under judicially-created bases for invalidation.

135. The claims of the '077 Patent are obvious to a person of ordinary skill in the art because each and every element of each and every claim of the '077 patent was disclosed expressly or inherently in one or more references and/or products which were publicly available before the earliest possible priority date of the '077 patent, including, but not limited to, those references and/or products disclosed in Micro Labs's Notice Letters. The claims of the '077 Patent are obvious over the references and/or products because the person of ordinary skill in the art would

have been motivated to combine those references and/or products as of the earliest possible priority date of the '077 Patent, and would have had a reasonable expectation of success in doing so.

136. There is no objective evidence of non-obviousness of the claims of the '077 Patent, nor would any such evidence, should it exist, have any nexus to the claimed purported inventions of the '077 Patent.

137. Micro Labs is entitled to a judicial declaration that the claims of the '077 Patent are invalid.

**COUNT XXII**  
**Declaratory Judgment of Noninfringement of the '077 Patent**

138. Micro Labs re-alleges and incorporates by reference the allegations of paragraphs 1-137 as though fully set forth herein.

139. There is an actual, substantial, and continuing case or controversy between Micro Labs and the Plaintiff/Counterclaim-Defendant regarding, *inter alia*, non-infringement of the claims of the '077 Patent.

140. The manufacture, use, offer for sale, sale, importation, and/or marketing of Micro Labs's ANDA Product described in Micro Labs's ANDA has not infringed, does not infringe, and would not—if made, used, sold, offered for sale, imported or marketed—infringe, either directly or indirectly, the claims of the '077 Patent, either literally or under the doctrine of equivalents, that do not cover Micro Labs's ANDA Product.

141. Micro Labs is entitled to a judicial declaration that the manufacture, use, offer for sale, sale, importation, and/or marketing of Micro Labs's ANDA Product described in Micro Labs's ANDA has not infringed, does not infringe, and would not—if made, used, sold, offered for sale, imported or marketed—infringe, either directly or indirectly, any valid or enforceable claim of the '077 Patent, either literally or under the doctrine of equivalents.

**COUNT XXIII**  
**Declaratory Judgment of Invalidity of the '574 Patent**

142. Micro Labs re-alleges and incorporates by reference the allegations of paragraphs 1-141 as though fully set forth herein.

143. There is an actual, substantial, and continuing case or controversy between Micro Labs and the Plaintiff/Counterclaim-Defendant regarding, *inter alia*, the invalidity of the '574 Patent.

144. The claims of the '574 Patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code, or under judicially-created bases for invalidation.

145. The claims of the '574 Patent are obvious to a person of ordinary skill in the art because each and every element of each and every claim of the '574 patent was disclosed expressly or inherently in one or more references and/or products which were publicly available before the earliest possible priority date of the '574 patent, including, but not limited to, those references and/or products disclosed in Micro Labs's Notice Letters. The claims of the '574 Patent are obvious over the references and/or products because the person of ordinary skill in the art would have been motivated to combine those references and/or products as of the earliest possible priority date of the '574 Patent, and would have had a reasonable expectation of success in doing so.

146. There is no objective evidence of non-obviousness of the claims of the '574 Patent, nor would any such evidence, should it exist, have any nexus to the claimed purported inventions of the '574 Patent.

147. Micro Labs is entitled to a judicial declaration that the claims of the '574 Patent are invalid.

**COUNT XXIV**  
**Declaratory Judgment of Noninfringement of the '574 Patent**

148. Micro Labs re-alleges and incorporates by reference the allegations of paragraphs 1-147 as though fully set forth herein.

149. There is an actual, substantial, and continuing case or controversy between Micro Labs and the Plaintiff/Counterclaim-Defendant regarding, *inter alia*, non-infringement of the claims of the '574 Patent.

150. The manufacture, use, offer for sale, sale, importation, and/or marketing of Micro Labs's ANDA Product described in Micro Labs's ANDA has not infringed, does not infringe, and would not—if made, used, sold, offered for sale, imported or marketed—infringe, either directly or indirectly, the claims of the '574 Patent, either literally or under the doctrine of equivalents, that do not cover Micro Labs's ANDA Product.

151. Micro Labs is entitled to a judicial declaration that the manufacture, use, offer for sale, sale, importation, and/or marketing of Micro Labs's ANDA Product described in Micro Labs's ANDA has not infringed, does not infringe, and would not—if made, used, sold, offered for sale, imported or marketed—infringe, either directly or indirectly, any valid or enforceable claim of the '574 Patent, either literally or under the doctrine of equivalents.

**COUNT XXV**  
**Declaratory Judgment of Invalidity of the '088 Patent**

152. Micro Labs re-alleges and incorporates by reference the allegations of paragraphs 1-151 as though fully set forth herein.

153. There is an actual, substantial, and continuing case or controversy between Micro Labs and the Plaintiff/Counterclaim-Defendant regarding, *inter alia*, the invalidity of the '088 Patent.

154. The claims of the '088 Patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code, or under judicially-created bases for invalidation.

155. The claims of the '088 Patent are obvious to a person of ordinary skill in the art because each and every element of each and every claim of the '088 patent was disclosed expressly or inherently in one or more references and/or products which were publicly available before the earliest possible priority date of the '088 patent, including, but not limited to, those references and/or products disclosed in Micro Labs's Notice Letters. The claims of the '088 Patent are obvious over the references and/or products because the person of ordinary skill in the art would have been motivated to combine those references and/or products as of the earliest possible priority date of the '088 Patent, and would have had a reasonable expectation of success in doing so.

156. There is no objective evidence of non-obviousness of the claims of the '088 Patent, nor would any such evidence, should it exist, have any nexus to the claimed purported inventions of the '088 Patent.

157. Micro Labs is entitled to a judicial declaration that the claims of the '088 Patent are invalid.

**COUNT XXVI**  
**Declaratory Judgment of Noninfringement of the '088 Patent**

158. Micro Labs re-alleges and incorporates by reference the allegations of paragraphs 1-157 as though fully set forth herein.

159. There is an actual, substantial, and continuing case or controversy between Micro Labs and the Plaintiff/Counterclaim-Defendant regarding, *inter alia*, non-infringement of the claims of the '088 Patent.

160. The manufacture, use, offer for sale, sale, importation, and/or marketing of Micro Labs's ANDA Product described in Micro Labs's ANDA has not infringed, does not infringe, and would not—if made, used, sold, offered for sale, imported or marketed—infringe, either directly or indirectly, the claims of the '088 Patent, either literally or under the doctrine of equivalents, that do not cover Micro Labs's ANDA Product.

161. Micro Labs is entitled to a judicial declaration that the manufacture, use, offer for sale, sale, importation, and/or marketing of Micro Labs's ANDA Product described in Micro Labs's ANDA has not infringed, does not infringe, and would not—if made, used, sold, offered for sale, imported or marketed—infringe, either directly or indirectly, any valid or enforceable claim of the '088 Patent, either literally or under the doctrine of equivalents.

**COUNT XXVII**  
**Declaratory Judgment of Invalidity of the '141 Patent**

162. Micro Labs re-alleges and incorporates by reference the allegations of paragraphs 1-161 as though fully set forth herein.

163. There is an actual, substantial, and continuing case or controversy between Micro Labs and the Plaintiff/Counterclaim-Defendant regarding, *inter alia*, the invalidity of the '141 Patent.

164. The claims of the '141 Patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code, or under judicially-created bases for invalidation.

165. The claims of the '141 Patent are obvious to a person of ordinary skill in the art because each and every element of each and every claim of the '141 patent was disclosed expressly or inherently in one or more references and/or products which were publicly available before the earliest possible priority date of the '141 patent, including, but not limited to, those references

and/or products disclosed in Micro Labs's Notice Letters. The claims of the '141 Patent are obvious over the references and/or products because the person of ordinary skill in the art would have been motivated to combine those references and/or products as of the earliest possible priority date of the '141 Patent, and would have had a reasonable expectation of success in doing so.

166. There is no objective evidence of non-obviousness of the claims of the '141 Patent, nor would any such evidence, should it exist, have any nexus to the claimed purported inventions of the '141 Patent.

167. Micro Labs is entitled to a judicial declaration that the claims of the '141 Patent are invalid.

**COUNT XXVIII**  
**Declaratory Judgment of Noninfringement of the '141 Patent**

168. Micro Labs re-alleges and incorporates by reference the allegations of paragraphs 1-167 as though fully set forth herein.

169. There is an actual, substantial, and continuing case or controversy between Micro Labs and the Plaintiff/Counterclaim-Defendant regarding, *inter alia*, non-infringement of the claims of the '141 Patent.

170. The manufacture, use, offer for sale, sale, importation, and/or marketing of Micro Labs's ANDA Product described in Micro Labs's ANDA has not infringed, does not infringe, and would not—if made, used, sold, offered for sale, imported or marketed—infringe, either directly or indirectly, the claims of the '141 Patent, either literally or under the doctrine of equivalents, that do not cover Micro Labs's ANDA Product.

171. Micro Labs is entitled to a judicial declaration that the manufacture, use, offer for sale, sale, importation, and/or marketing of Micro Labs's ANDA Product described in Micro Labs's ANDA has not infringed, does not infringe, and would not—if made, used, sold, offered

for sale, imported or marketed— infringe, either directly or indirectly, any valid or enforceable claim of the '141 Patent, either literally or under the doctrine of equivalents.

**COUNT XXIX**  
**Declaratory Judgment of Invalidity of the '553 Patent**

172. Micro Labs re-alleges and incorporates by reference the allegations of paragraphs 1-171 as though fully set forth herein.

173. There is an actual, substantial, and continuing case or controversy between Micro Labs and the Plaintiff/Counterclaim-Defendant regarding, *inter alia*, the invalidity of the '553 Patent.

174. The claims of the '553 Patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code, or under judicially-created bases for invalidation.

175. The claims of the '553 Patent are obvious to a person of ordinary skill in the art because each and every element of each and every claim of the '553 patent was disclosed expressly or inherently in one or more references and/or products which were publicly available before the earliest possible priority date of the '553 patent, including, but not limited to, those references and/or products disclosed in Micro Labs's Notice Letters. The claims of the '553 Patent are obvious over the references and/or products because the person of ordinary skill in the art would have been motivated to combine those references and/or products as of the earliest possible priority date of the '553 Patent, and would have had a reasonable expectation of success in doing so.

176. There is no objective evidence of non-obviousness of the claims of the '553 Patent, nor would any such evidence, should it exist, have any nexus to the claimed purported inventions of the '553 Patent.

177. Micro Labs is entitled to a judicial declaration that the claims of the '553 Patent are invalid.

**COUNT XXX**  
**Declaratory Judgment of Noninfringement of the '553 Patent**

178. Micro Labs re-alleges and incorporates by reference the allegations of paragraphs 1-177 as though fully set forth herein.

179. There is an actual, substantial, and continuing case or controversy between Micro Labs and the Plaintiff/Counterclaim-Defendant regarding, *inter alia*, non-infringement of the claims of the '553 Patent.

180. The manufacture, use, offer for sale, sale, importation, and/or marketing of Micro Labs's ANDA Product described in Micro Labs's ANDA has not infringed, does not infringe, and would not—if made, used, sold, offered for sale, imported or marketed—infringe, either directly or indirectly, the claims of the '553 Patent, either literally or under the doctrine of equivalents, that do not cover Micro Labs's ANDA Product.

181. Micro Labs is entitled to a judicial declaration that the manufacture, use, offer for sale, sale, importation, and/or marketing of Micro Labs's ANDA Product described in Micro Labs's ANDA has not infringed, does not infringe, and would not—if made, used, sold, offered for sale, imported or marketed—infringe, either directly or indirectly, any valid or enforceable claim of the '553 Patent, either literally or under the doctrine of equivalents.

**PRAYER FOR RELIEF**

WHEREFORE, Micro Labs respectfully prays for judgment in its favor and against Plaintiff/Counterclaim-Defendant:

- A. Declaring that the manufacture, use, sale, offer for sale, importation, and/or marketing of the Micro Labs's ANDA Product in Micro Labs's ANDA No. 215081 has not infringed, does not infringe, and would not—if made, used, sold, offered for sale, imported, or marketed—Infringe, either directly or indirectly, any claim of the Asserted Patents, either literally or under the doctrine of equivalents;
- B. Declaring that the claims of the Asserted Patents are invalid;
- C. Ordering that Plaintiff/Counterclaim-Defendant's Complaint be dismissed with prejudice and judgment entered in favor of Micro Labs;
- D. If the facts so demonstrate, declaring this case exceptional and awarding Micro Labs its reasonable attorneys' fees, expenses, and costs under 35 U.S.C. § 285, this Court's inherent authority and/or any other applicable authority;
- E. Ordering that Plaintiff/Counterclaim-Defendant, and its officers, agents, servants, employees, attorneys, successors and any person who acts in concert or participation with it or any of them, be preliminarily and permanently enjoined from using any one or more of the Asserted Patents to block, hamper, hinder, or obstruct FDA approval of the products described in Micro Labs's ANDA; and
- F. Awarding such other and further relief as the Court may deem just and proper.

Dated: August 4, 2021

PHILLIPS, MCLAUGHLIN & HALL, P.A.

/s/ John C. Phillips, Jr.

John C. Phillips, Jr. (#110)  
Megan C. Haney (#5016)  
1200 North Broom Street  
Wilmington, DE 19806  
(302) 655-4200  
jcp@pmhdelaw.com  
mch@pmhdelaw.com

OF COUNSEL:

Stephen R. Auten  
Philip Y. Kouyoumdjian  
Jaimin H. Shah  
TAFT STETTINIUS & HOLLISTER LLP  
111 East Wacker Drive  
Suite 2800  
Chicago, IL 60601  
(312) 527-4000

*Attorneys for Defendants Micro Labs USA Inc.  
and Micro Labs Limited*