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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

SUPERNUS PHARMACEUTICALS, INC. Plaintiffs, v. ZENARA PHARMA PRIVATE LIMITED and BIOPHORE PHARMA INC. Defendants.	Civil Action No. 2:25-cv-13207 (MEF)(MAH) Document Filed Electronically

DEFENDANTS ZENARA PHARMA PRIVATE LIMITED AND BIOPHORE PHARMA INC.'S ANSWER AND AFFIRMATIVE DEFENSES

Defendants Zenara Pharma Private Limited and Biophore Pharma Inc. ("Biophore") (collectively, "Zenara" or "Defendants") respond to the allegations in the Complaint by Plaintiff Supernus Pharmaceuticals, Inc. ("Plaintiff" or "Supernus"). Zenara bases its responses on its knowledge as to its own activities, and on information and belief as to the activities of others. The numbered paragraphs below correspond to the numbered paragraphs in Plaintiff's Complaint. To the extent that the section headings in the Complaint contain allegations, those allegations are denied. If not specifically admitted, the allegations of the Complaint are denied.

NATURE OF THE ACTION

1. Paragraph 1 of the Complaint contains legal conclusion to which no answer is required. To the extent an answer to Paragraph 1 of the Complaint is required, Zenara admits that the Complaint purports to set forth claims of alleged infringement under the patent laws of the United States. Zenara admits that this action purports to relate to United States Patent Nos. 9,358,204 ("the '204 patent"); 9,603,853 ("the '853 patent"); 9,662,338 ("the '338 patent"); 11,324,753 ("the '753 patent"); 11,458,143 ("the '143 patent"); and 12,121,523 ("the '523 patent") (collectively, the "patents-in-suit"). Zenara denies any allegations of infringement of the patents-in-suit.

THE PARTIES

2. Zenara is without sufficient information to admit or deny the allegations in Paragraph 2 of the Complaint, and therefore denies those allegations.

3. Admitted.

4. Admitted that Zenara filed ANDA No. 220376 seeking approval from the FDA to market Zenara's ANDA Products in the United States. Zenara denies any remaining allegations of this paragraph.

5. Admitted that Zenara filed ANDA No. 220376 seeking approval from the FDA to market Zenara's ANDA Products in the United States. Zenara denies any remaining allegations of this paragraph.

6. Admitted that Biophore's principal place of business is 4262 US-1 Suite A, Monmouth Junction, New Jersey 08852. Zenara denies any remaining allegations of this paragraph.

7. Admitted that Biophore Pharma Inc. is Zenara Pharma Private Limited's U.S. agent with respect to the filing of ANDA No. 220376. Zenara denies any remaining allegations of this paragraph.

8. Admitted that Biophore Pharma Inc. is Zenara Pharma Private Limited's U.S. agent with respect to the filing of ANDA No. 220376. Zenara denies any remaining allegations of this paragraph.

9. Admitted that Biophore Pharma Inc. is Zenara Pharma Private Limited's U.S. agent with respect to the filing of ANDA No. 220376. Zenara denies any remaining allegations of this paragraph.

10. Biophore Pharma Inc. is Zenara Pharma Private Limited's U.S. agent with respect to the filing of ANDA No. 220376, which seeks approval from the FDA to market Zenara's ANDA Products in the United States. Zenara denies any remaining allegations of this paragraph.

11. Admitted that Zenara filed ANDA No. 220376 seeking approval from the FDA to market Zenara's ANDA Products in the United States. Admitted that Biophore Pharma Inc. is Zenara Pharma Private Limited's U.S. agent with respect to the filing of ANDA No. 220376. Zenara denies any remaining allegations of this paragraph.

12. Admitted that Zenara filed ANDA No. 220376 seeking approval from the FDA to market Zenara's ANDA Products in the United States. Zenara denies any remaining allegations of this paragraph.

13. Admitted that Zenara filed ANDA No. 220376 seeking approval from the FDA to market Zenara's ANDA Products in the United States. Zenara denies any remaining allegations of this paragraph.

JURISDICTION AND VENUE

14. Paragraph 14 of the Complaint states a legal conclusion to which no response is required. Zenara will not contest that this Court has subject matter jurisdiction for the limited purpose of this action only. Zenara denies any remaining allegations of this paragraph.

15. Paragraph 15 of the Complaint states a legal conclusion to which no response is required. Zenara will not contest that this Court has personal jurisdiction for the limited purpose of this action only. Zenara denies any remaining allegations of this paragraph.

16. Paragraph 16 of the Complaint states a legal conclusion to which no response is required. Zenara will not contest that this Court has personal jurisdiction for the limited purpose of this action only. Zenara denies any remaining allegations of this paragraph.

17. Paragraph 17 of the Complaint states a legal conclusion to which no response is required. Zenara will not contest that this Court has personal jurisdiction for the limited purpose of this action only. Zenara denies any remaining allegations of this paragraph.

18. Paragraph 18 of the Complaint states a legal conclusion to which no response is required. Zenara will not contest that this Court has personal jurisdiction for the limited purpose of this action only. Zenara denies any remaining allegations of this paragraph.

19. Admitted that Zenara filed ANDA No. 220376 seeking approval from the FDA to market Zenara's ANDA Products in the United States. Zenara denies any remaining allegations of this paragraph.

20. Admitted that Zenara filed ANDA No. 220376 seeking approval from the FDA to market Zenara's ANDA Products in the United States. Zenara denies any remaining allegations of this paragraph.

21. Paragraph 21 of the Complaint states a legal conclusion to which no response is required. Zenara will not contest that this Court has personal jurisdiction for the limited purpose

of this action only. Zenara denies any remaining allegations of this paragraph.

22. Paragraph 22 of the Complaint states a legal conclusion to which no response is required. Zenara will not contest that this Court has personal jurisdiction for the limited purpose of this action only. Zenara denies any remaining allegations of this paragraph.

23. Paragraph 23 of the Complaint states a legal conclusion to which no response is required. Zenara will not contest that this Court has personal jurisdiction for the limited purpose of this action only. Zenara denies any remaining allegations of this paragraph.

24. Paragraph 24 of the Complaint states a legal conclusion to which no response is required. Zenara will not contest that this Court has personal jurisdiction for the limited purpose of this action only. Zenara denies any remaining allegations of this paragraph.

25. Paragraph 25 of the Complaint states a legal conclusion to which no response is required. Zenara will not contest that this Court has personal jurisdiction for the limited purpose of this action only. Zenara denies any remaining allegations of this paragraph.

26. Paragraph 18 of the Complaint states a legal conclusion to which no response is required. Zenara will not contest that venue is proper in this Court for the limited purpose of this action only. Zenara denies any remaining allegations of this paragraph.

FACTS COMMON TO ALL COUNTS

27. Admitted that Zenara sent a letter to Supernus that included certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the patents-in-suit. Zenara denies any remaining allegations of this paragraph.

28. Admitted.

29. Admitted to the extent Plaintiff and Zenara engaged in negotiation over the terms of the Offer of Confidential Access and that they did not reach an agreement. Zenara denies any

remaining allegations of this paragraph.

30. Admitted.

31. Admitted.

32. Admitted.

33. Paragraph 33 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, admitted that Zenara filed ANDA No. 220376 seeking approval from the FDA to market Zenara's ANDA Products in the United States. Also, Zenara will not contest that this Court has personal jurisdiction for the limited purpose of this action only. Zenara denies any remaining allegations of this paragraph.

34. Paragraph 34 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, admitted that Zenara filed ANDA No. 220376 seeking approval from the FDA to market Zenara's ANDA Products in the United States. Also, Zenara will not contest that this Court has personal jurisdiction for the limited purpose of this action only. Zenara denies any remaining allegations of this paragraph.

35. Paragraph 35 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, admitted that Zenara filed ANDA No. 220376 seeking approval from the FDA to market Zenara's ANDA Products in the United States. Also, Zenara will not contest that this Court has personal jurisdiction for the limited purpose of this action only. Zenara denies any remaining allegations of this paragraph.

36. Paragraph 36 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, admitted that Zenara filed ANDA No. 220376 seeking approval from the FDA to market Zenara's ANDA Products in the United States. Also, Zenara will not contest that this Court has personal jurisdiction for the limited purpose of this

action only. Zenara denies any remaining allegations of this paragraph.

37. Paragraph 37 of the Complaint states a legal conclusion to which no response is required. Zenara denies any remaining allegations of this paragraph.

38. Paragraph 38 of the Complaint states a legal conclusion to which no response is required. Zenara denies any remaining allegations of this paragraph.

39. Denied.

40. Denied.

41. Paragraph 41 of the Complaint states a legal conclusion to which no response is required. Zenara denies any remaining allegations of this paragraph.

42. Zenara is without sufficient information to admit or deny the allegations in Paragraph 42 of the Complaint, and therefore denies those allegations.

43. Zenara is without sufficient information to admit or deny the allegations in Paragraph 43 of the Complaint, and therefore denies those allegations.

44. Admitted that the Highlights of Prescribing Information for QELBREE® (revised 1/2025) contain the following section:

----------DOSAGE AND ADMINISTRATION----------

- *Pediatric patients 6 to 11 years of age*: Recommended starting dosage is 100 mg once daily. May titrate in increments of 100 mg weekly to the maximum recommended dosage of 400 mg once daily (2.2)
- *Pediatric patients 12 to 17 years of age*: Recommended starting dosage is 200 mg once daily. May titrate after 1 week, by an increment of 200mg, to the maximum recommended dosage of 400 mg once daily (2.2)
- *Adult patients*: Recommended starting dosage is 200 mg once daily. May titrate in increments of 200 mg weekly, to maximum recommended dosage of 600 mg once daily (2.2)
- Capsules may be swallowed whole or opened and the entire contents sprinkled onto applesauce or pudding (2.3)
- Severe Renal Impairment: Initial dosage is 100 mg once daily. Titrate in weekly increments of 50 mg to 100 mg to a maximum recommended dosage of 200 mg once daily (2.4, 8.6)

Zenara denies any remaining allegations of this paragraph.

45. Admitted that the electronic version of Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations at https://www.accessdata.fda.gov/scripts/cder/ob/patent_info.cfm?Product_No=001&Appl_No=211964&Appl_type=N lists the patents-in-suit. Zenara denies any remaining allegations of this paragraph.

46. Zenara admits that, on its face, the '204 patent is titled "Formulations of Viloxazine," is assigned to Supernus and was issued by the United States Patent & Trademark Office on June 7, 2016. Zenara denies that the '204 patent was duly and legally issued. Zenara is without information sufficient to admit or deny the remaining allegations in Paragraph 46 of the Complaint and therefore denies those allegations.

47. Zenara admits that, on its face, the '853 patent is titled "Formulations of Viloxazine," is assigned to Supernus and was issued by the United States Patent & Trademark Office on March 28, 2017. Zenara denies that the '853 patent was duly and legally issued. Zenara is without information sufficient to admit or deny the remaining allegations in Paragraph 47 of the Complaint and therefore denies those allegations.

48. Zenara admits that, on its face, the '338 patent is titled "Formulations of Viloxazine," is assigned to Supernus and was issued by the United States Patent & Trademark Office on May 30, 2017. Zenara denies that the '338 patent was duly and legally issued. Zenara is without information sufficient to admit or deny the remaining allegations in Paragraph 48 of the Complaint and therefore denies those allegations.

49. Zenara admits that, on its face, the '753 patent is titled "Method of Treatment of Attention Deficit/Hyperactivity Disorder (ADHD)," is assigned to Supernus and was issued by the United States Patent & Trademark Office on May 10, 2022. Zenara denies that the '753 patent was

duly and legally issued. Zenara is without information sufficient to admit or deny the remaining allegations in Paragraph 49 of the Complaint and therefore denies those allegations.

50. Zenara admits that, on its face, the '143 patent is titled "Method of Treatment of Attention Deficit/Hyperactivity Disorder (ADHD)," is assigned to Supernus and was issued by the United States Patent & Trademark Office on October 4, 2022. Zenara denies that the '143 patent was duly and legally issued. Zenara is without information sufficient to admit or deny the remaining allegations in Paragraph 50 of the Complaint and therefore denies those allegations.

51. Zenara admits that, on its face, the '523 patent is titled "Method of Treatment of Attention Deficit/Hyperactivity Disorder (ADHD)," is assigned to Supernus and was issued by the United States Patent & Trademark Office on October 22, 2024. Zenara denies that the '523 patent was duly and legally issued. Zenara is without information sufficient to admit or deny the remaining allegations in Paragraph 51 of the Complaint and therefore denies those allegations.

52. Admitted that Qelbree® is cited in the ANDA No. 220376 as a proprietary name for the active ingredient viloxazine hydrochloride with respect to NDA No. 211964. Zenara denies any remaining allegations of this paragraph.

53. Admitted that the proposed ANDA products described in ANDA No. 220376 contain 1-[2-(2-ethoxyphenoxy)ethyl]pyrrolidine as an active pharmaceutical ingredient. Zenara denies any remaining allegations of this paragraph.

54. Zenara admits that the patents-in-suit are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (also known as the "Orange Book") for Qelbree®, 100 mg, 150 mg and 200 mg capsules. Zenara denies any remaining allegations in Paragraph 54 of the Complaint.

55. Paragraph 55 of the Complaint states a legal conclusion to which no response is

required. Zenara denies any remaining allegations of this paragraph.

56. Paragraph 56 of the Complaint states a legal conclusion to which no response is required. Zenara denies any remaining allegations of this paragraph.

57. Paragraph 57 of the Complaint states a legal conclusion to which no response is required. Zenara denies any remaining allegations of this paragraph.

58. Paragraph 58 of the Complaint states a legal conclusion to which no response is required. Zenara denies any remaining allegations of this paragraph.

59. Paragraph 59 of the Complaint states a legal conclusion to which no response is required. Zenara denies any remaining allegations of this paragraph.

60. Paragraph 60 of the Complaint states a legal conclusion to which no response is required. Zenara denies any remaining allegations of this paragraph.

61. Paragraph 61 of the Complaint states a legal conclusion to which no response is required. Zenara denies any remaining allegations of this paragraph.

62. Paragraph 62 of the Complaint states a legal conclusion to which no response is required. Zenara denies any remaining allegations of this paragraph.

63. Admitted that Zenara filed ANDA No. 220376 seeking approval from the FDA to market Zenara's ANDA Products in the United States. Zenara denies any remaining allegations of this paragraph.

FIRST COUNT
(Defendants' [Alleged] Infringement of the '204 Patent)

64. Zenara incorporates its responses to Paragraphs 1 to 63 of the Complaint as if fully set forth herein.

65. Admitted that Zenara filed ANDA No. 220376 seeking approval from the FDA to market Zenara's ANDA Products in the United States. Zenara denies any remaining allegations of

this paragraph.

66. Paragraph 66 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, admitted that Zenara filed ANDA No. 220376 seeking approval from the FDA to market Zenara's ANDA Products in the United States. Zenara denies any remaining allegations of this paragraph.

67. Paragraph 67 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, admitted that Biophore Pharma Inc. is Zenara Pharma Private Limited's U.S. agent with respect to the filing of ANDA No. 220376. Zenara denies any remaining allegations of this paragraph.

68. Denied.

69. Admitted that Zenara filed ANDA No. 220376 seeking approval from the FDA to market Zenara's ANDA Products in the United States. Zenara denies any remaining allegations of this paragraph.

70. Paragraph 70 of the Complaint states a legal conclusion to which no response is required. Zenara denies any remaining allegations of this paragraph.

71. Admitted that Zenara sent a letter to Supernus that included certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the patents-in-suit. Zenara denies any remaining allegations of this paragraph.

72. Paragraph 72 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Zenara's filing of an ANDA with the FDA is merely a technical act of infringement and does not carry with it any implications of infringement, contributory infringement, or inducement of infringement under 35 U.S.C. § 271(a), (b), and/or (c). Zenara denies any remaining allegations of this paragraph.

73. Admitted that Zenara filed ANDA No. 220376 seeking approval from the FDA to market Zenara's ANDA Products in the United States. Zenara denies any remaining allegations of this paragraph.

74. Denied.

75. Denied.

76. Denied.

77. Denied.

78. Denied.

79. Denied.

80. Denied.

81. Denied.

82. Denied.

83. Denied.

84. Denied.

85. Denied.

SECOND COUNT
(Defendants' [Alleged] Infringement of the '853 Patent)

86. Zenara incorporates its responses to Paragraphs 1 to 85 of the Complaint as if fully set forth herein.

87. Admitted that Zenara filed ANDA No. 220376 seeking approval from the FDA to market Zenara's ANDA Products in the United States. Zenara denies any remaining allegations of this paragraph.

88. Paragraph 88 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, admitted that Zenara filed ANDA No. 220376

seeking approval from the FDA to market Zenara's ANDA Products in the United States. Zenara denies any remaining allegations of this paragraph.

89. Paragraph 89 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, admitted that Biophore Pharma Inc. is Zenara Pharma Private Limited's U.S. agent with respect to the filing of ANDA No. 220376. Zenara denies any remaining allegations of this paragraph.

90. Denied.

91. Admitted that Zenara filed ANDA No. 220376 seeking approval from the FDA to market Zenara's ANDA Products in the United States. Zenara denies any remaining allegations of this paragraph.

92. Paragraph 92 of the Complaint states a legal conclusion to which no response is required. Zenara denies any remaining allegations of this paragraph.

93. Admitted that Zenara sent a letter to Supernus that included certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the patents-in-suit. Zenara denies any remaining allegations of this paragraph.

94. Paragraph 94 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Zenara's filing of an ANDA with the FDA is merely a technical act of infringement and does not carry with it any implications of infringement, contributory infringement, or inducement of infringement under 35 U.S.C. § 271(a), (b), and/or (c). Zenara denies any remaining allegations of this paragraph.

95. Admitted that Zenara filed ANDA No. 220376 seeking approval from the FDA to market Zenara's ANDA Products in the United States. Zenara denies any remaining allegations of this paragraph.

96. Denied.

97. Denied.

98. Denied.

99. Denied.

100. Denied.

101. Denied.

102. Denied.

103. Denied.

104. Denied.

105. Denied.

106. Denied.

107. Denied.

THIRD COUNT
(Defendants' [Alleged] Infringement of the '338 Patent)

108. Zenara incorporates its responses to Paragraphs 1 to 107 of the Complaint as if fully set forth herein.

109. Admitted that Zenara filed ANDA No. 220376 seeking approval from the FDA to market Zenara's ANDA Products in the United States. Zenara denies any remaining allegations of this paragraph.

110. Paragraph 110 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, admitted that Zenara filed ANDA No. 220376 seeking approval from the FDA to market Zenara's ANDA Products in the United States. Zenara denies any remaining allegations of this paragraph.

111. Paragraph 111 of the Complaint states a legal conclusion to which no response is

required. To the extent a response is required, admitted that Biophore Pharma Inc. is Zenara Pharma Private Limited's U.S. agent with respect to the filing of ANDA No. 220376. Zenara denies any remaining allegations of this paragraph.

112. Denied.

113. Admitted that Zenara filed ANDA No. 220376 seeking approval from the FDA to market Zenara's ANDA Products in the United States. Zenara denies any remaining allegations of this paragraph.

114. Paragraph 114 of the Complaint states a legal conclusion to which no response is required. Zenara denies any remaining allegations of this paragraph.

115. Admitted that Zenara sent a letter to Supernus that included certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the patents-in-suit. Zenara denies any remaining allegations of this paragraph.

116. Paragraph 116 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Zenara's filing of an ANDA with the FDA is merely a technical act of infringement and does not carry with it any implications of infringement, contributory infringement, or inducement of infringement under 35 U.S.C. § 271(a), (b), and/or (c). Zenara denies any remaining allegations of this paragraph.

117. Admitted that Zenara filed ANDA No. 220376 seeking approval from the FDA to market Zenara's ANDA Products in the United States. Zenara denies any remaining allegations of this paragraph.

118. Denied.

119. Denied.

120. Denied.

121. Denied.

122. Denied.

123. Denied.

124. Denied.

125. Denied.

126. Denied.

127. Denied.

128. Denied.

129. Denied.

FOURTH COUNT
(Defendants' [Alleged] Infringement of the '753 Patent)

130. Zenara incorporates its responses to Paragraphs 1 to 129 of the Complaint as if fully set forth herein.

131. Admitted that Zenara filed ANDA No. 220376 seeking approval from the FDA to market Zenara's ANDA Products in the United States. Zenara denies any remaining allegations of this paragraph.

132. Paragraph 132 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, admitted that Zenara filed ANDA No. 220376 seeking approval from the FDA to market Zenara's ANDA Products in the United States. Zenara denies any remaining allegations of this paragraph.

133. Paragraph 133 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, admitted that Biophore Pharma Inc. is Zenara Pharma Private Limited's U.S. agent with respect to the filing of ANDA No. 220376. Zenara denies any remaining allegations of this paragraph.

134. Denied.

135. Admitted that Zenara filed ANDA No. 220376 seeking approval from the FDA to market Zenara's ANDA Products in the United States. Zenara denies any remaining allegations of this paragraph.

136. Paragraph 136 of the Complaint states a legal conclusion to which no response is required. Zenara denies any remaining allegations of this paragraph.

137. Admitted that Zenara sent a letter to Supernus that included certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the patents-in-suit. Zenara denies any remaining allegations of this paragraph.

138. Paragraph 138 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Zenara's filing of an ANDA with the FDA is merely a technical act of infringement and does not carry with it any implications of infringement, contributory infringement, or inducement of infringement under 35 U.S.C. § 271(a), (b), and/or (c). Zenara denies any remaining allegations of this paragraph.

139. Admitted that Zenara filed ANDA No. 220376 seeking approval from the FDA to market Zenara's ANDA Products in the United States. Zenara denies any remaining allegations of this paragraph.

140. Denied.

141. Denied.

142. Denied.

143. Denied.

144. Denied.

145. Denied.

146. Denied.

147. Denied.

148. Denied.

149. Denied.

150. Denied.

151. Denied.

FIFTH COUNT
(Defendants' [Alleged] Infringement of the '143 Patent)

152. Zenara incorporates its responses to Paragraphs 1 to 151 of the Complaint as if fully set forth herein.

153. Admitted that Zenara filed ANDA No. 220376 seeking approval from the FDA to market Zenara's ANDA Products in the United States. Zenara denies any remaining allegations of this paragraph.

154. Paragraph 154 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, admitted that Zenara filed ANDA No. 220376 seeking approval from the FDA to market Zenara's ANDA Products in the United States. Zenara denies any remaining allegations of this paragraph.

155. Paragraph 155 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, admitted that Biophore Pharma Inc. is Zenara Pharma Private Limited's U.S. agent with respect to the filing of ANDA No. 220376. Zenara denies any remaining allegations of this paragraph.

156. Denied.

157. Admitted that Zenara filed ANDA No. 220376 seeking approval from the FDA to market Zenara's ANDA Products in the United States. Zenara denies any remaining allegations of

this paragraph.

158. Paragraph 158 of the Complaint states a legal conclusion to which no response is required. Zenara denies any remaining allegations of this paragraph.

159. Admitted that Zenara sent a letter to Supernus that included certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the patents-in-suit. Zenara denies any remaining allegations of this paragraph.

160. Paragraph 160 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Zenara's filing of an ANDA with the FDA is merely a technical act of infringement and does not carry with it any implications of infringement, contributory infringement, or inducement of infringement under 35 U.S.C. § 271(a), (b), and/or (c). Zenara denies any remaining allegations of this paragraph.

161. Admitted that Zenara filed ANDA No. 220376 seeking approval from the FDA to market Zenara's ANDA Products in the United States. Zenara denies any remaining allegations of this paragraph.

162. Denied.

163. Denied.

164. Denied.

165. Denied.

166. Denied.

167. Denied.

168. Denied.

169. Denied.

170. Denied.

171. Denied.

172. Denied.

173. Denied.

SIXTH COUNT
(Defendants' [Alleged] Infringement of the '523 Patent)

174. Zenara incorporates its responses to Paragraphs 1 to 173 of the Complaint as if fully set forth herein.

175. Admitted that Zenara filed ANDA No. 220376 seeking approval from the FDA to market Zenara's ANDA Products in the United States. Zenara denies any remaining allegations of this paragraph.

176. Paragraph 176 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, admitted that Zenara filed ANDA No. 220376 seeking approval from the FDA to market Zenara's ANDA Products in the United States. Zenara denies any remaining allegations of this paragraph.

177. Paragraph 177 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, admitted that Biophore Pharma Inc. is Zenara Pharma Private Limited's U.S. agent with respect to the filing of ANDA No. 220376. Zenara denies any remaining allegations of this paragraph.

178. Denied.

179. Admitted that Zenara filed ANDA No. 220376 seeking approval from the FDA to market Zenara's ANDA Products in the United States. Zenara denies any remaining allegations of this paragraph.

180. Paragraph 180 of the Complaint states a legal conclusion to which no response is

required. Zenara denies any remaining allegations of this paragraph.

181. Admitted that Zenara sent a letter to Supernus that included certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the patents-in-suit. Zenara denies any remaining allegations of this paragraph.

182. Paragraph 182 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Zenara's filing of an ANDA with the FDA is merely a technical act of infringement and does not carry with it any implications of infringement, contributory infringement, or inducement of infringement under 35 U.S.C. § 271(a), (b), and/or (c). Zenara denies any remaining allegations of this paragraph.

183. Admitted that Zenara filed ANDA No. 220376 seeking approval from the FDA to market Zenara's ANDA Products in the United States. Zenara denies any remaining allegations of this paragraph.

184. Denied.

185. Denied.

186. Denied.

187. Denied.

188. Denied.

189. Denied.

190. Denied.

191. Denied.

192. Denied.

193. Denied.

194. Denied.

195. Denied.

[ANSWER TO] PRAYER FOR RELIEF

Zenara denies that Plaintiffs are entitled to judgment and any relief sought by the Complaint in paragraphs (i)-(ix) of their prayer for relief or otherwise.

AFFIRMATIVE DEFENSES

Zenara, without prejudice to the denials set forth in its Answer, further alleges the following defenses to Plaintiff's Complaint. Zenara reserves the right to supplement this Answer, including the right to assert additional defenses as more information is learned through discovery, claim construction, and/or any further investigation in this case. Zenara does not assume the burden of proof with respect to those matters as to on which, pursuant to law, Plaintiff bears the burden of proof.

FIRST DEFENSE
(Non-infringement of the Patents-in-suit)

The manufacture, use, offer for sale, sale, or importation of the Zenara ANDA Products that are the subject of ANDA No. 220376 has not, does not, and will not infringe any valid and enforceable claim of the '204 patent, '853 patent, '338 patent, '753 patent, '143 patent, and '523 patent directly, indirectly, by inducement, contributorily, literally, under the doctrine of equivalents, or in any manner.

SECOND DEFENSE
(Invalidity and/or Unenforceability of the Patents-in-Suit)

Each claim of the claims of the '204 patent, '853 patent, '338 patent, '753 patent, '143 patent, and '523 patent is invalid and/or unenforceable for failure to meet the requirements of patentability set forth in 35 U.S.C. §§ 1 *et seq*., including, without limitation, §§ 101, 102, 103, 112, and/or 116, or other judicially created bases for invalidity and/or unenforceability, such as

obviousness-type double patenting, and the rules, regulations, and laws pertaining thereto.

THIRD DEFENSE
(Prosecution History Estoppel)

Plaintiff's claims are barred in whole or in part by the doctrine of prosecution history estoppel. Under the doctrine of prosecution history estoppel, Plaintiffs cannot use the doctrine of equivalents to reclaim claim scope surrendered during prosecution.

FOURTH DEFENSE
(Failure to State a Claim)

The Complaint fails to state a claim upon which relief may be granted and must be dismissed to the extent Zenara has not infringed and will not infringe any valid and enforceable claim of the '204 patent, '853 patent, '338 patent, '753 patent, '143 patent, and '523 patent.

FIFTH DEFENSE
(Not an Exceptional Case)

Plaintiffs are not entitled to a finding that this case is exceptional or to attorneys' fees under 35 U.S.C. § 285, pursuant to the Court's inherent power or pursuant to any other basis.

SIXTH DEFENSE
(No Injunctive Relief)

Plaintiffs are not entitled to injunctive relief because Plaintiffs cannot prove: (i) that they have suffered irreparable injury; (ii) that there is no adequate remedy at law; (iii) that a remedy in equity is warranted; and (iv) that the public interest warrants an injunction.

SEVENTH DEFENSE
(Reservation of Rights)

Zenara specifically reserves the right to assert each and every other defense that may become evident in the course of discovery.

PRAYER FOR RELIEF

WHEREFORE, Zenara respectfully prays that this Court enter judgment in Zenara's favor

and grant the following relief:

A. Dismiss Plaintiff's Complaint with prejudice and deny each and every prayer for relief contained therein;

B. A declaration that Zenara does not infringe the claims of the Patents-in-Suit;

C. A declaration that the claims of the Patents-in-Suit are invalid or unenforceable;

D. Award the costs of this action against Plaintiff;

E. A declaration that this is an exceptional case within the meaning of 35 U.S.C. § 285, and that Zenara is entitled to recover reasonable attorney fees and costs upon prevailing in this action;

F. A declaration that the effective date of any FDA approval of Zenara's ANDA Products shall not be stayed thirty months from the date of Plaintiffs' receipt of Zenara's Notice Letter, in accordance with 21 U.S.C. § 355(j)(5)(B)(iii);

G. An award to Zenara of such further and other relief as this Court deems necessary, just, and proper.

Date: September 16, 2025

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that, on September 16, 2025, the above DEFENDANTS ZENARA PHARMA PRIVATE LIMITED AND BIOPHORE PHARMA INC.'S ANSWER AND AFFIRMATIVE DEFENSES was served on all parties who have made an appearance via ECF and by email.

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