IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

INTERCEPT PHARMACEUTICALS, INC. and INTERCEPT PHARMA EUROPE LTD., Plaintiffs, v. LUPIN LIMITED and LUPIN PHARMACEUTICALS, INC., Defendants.	Civil Action No. 20-cv-01155-MN

DEFENDANTS, LUPIN LIMITED AND LUPIN PHARMACEUTICALS, INC'S ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS

Defendants Lupin Limited ("Lupin Ltd.") and Lupin Pharmaceuticals, Inc. (collectively, "Defendants"), by and through their counsel, hereby answer and respond to each of the allegations in the First Amended Complaint of Plaintiffs Intercept Pharmaceuticals, Inc. ("Intercept Pharmaceuticals") and Intercept Pharma Europe Limited ("IPEL") (collectively "Intercept" or "Plaintiffs") (D.I. 11), and assert their separate defenses, and Lupin Ltd. asserts its separate counterclaims, as follows. Defendants deny all allegations not expressly admitted herein.

NATURE OF THE ACTION

1. Paragraph 1 states legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, Defendants admit that the First Amended Complaint purports to state claims for infringement of U.S. Patent Nos. RE48,286 ("the RE286 patent"); 9,238,673 ("the '673 patent"); 10,047,117 ("the '117 patent"); 10,052,337 ("the '337 patent"); 10,174,073 ("the '073 patent"); and 10,758,549 ("the '549 patent") (collectively the

"patents-in-suit") arising under the United States patent laws, 35 U.S.C. § 1, et seq. Defendants further admit that Lupin Ltd., as the sole applicant, submitted Abbreviated New Drug Application ("ANDA") No. 214980 (hereinafter, "the Lupin ANDA") with the U.S Food and Drug Administration ("FDA") seeking approval for obeticholic acid tablets, 5 mg and 10 mg. Defendants deny any remaining allegations of Paragraph 1.

2. Paragraph 2 states legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, Defendants admit that the First Amended Complaint purports to state claims for infringement of the patents-in-suit arising under the United States patent laws, 35 U.S.C. § 1, et seq. Defendants deny any remaining allegations of Paragraph 2.

THE PARTIES

3. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 3, and therefore deny them.

4. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 4, and therefore deny them.

5. Defendants admit that Lupin Ltd. is an entity organized and existing under the laws of India, with a place of business at 3rd Floor, Kalpataru Inspire, Off Wertern Express Highway, Santacruz (E), Mumbai 400 055, India. Defendants deny any remaining allegations of Paragraph 5.

6. Defendants admit that Lupin Pharmaceuticals, Inc. is an indirect, wholly-owned subsidiary of Lupin Ltd. Defendants further admit that Lupin Pharmaceuticals, Inc. is a Delaware corporation with a place of business at 111 South Calvert Street, Harborplace Tower, 21st Floor,

Baltimore, Maryland 21202. Defendants deny that Lupin Pharmaceuticals, Inc. is a proper party to this action.

7. Paragraph 7 states legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, Defendants admit that Lupin Pharmaceuticals, Inc. is an indirect, wholly-owned subsidiary of Lupin Ltd. Defendants deny that Lupin Pharmaceuticals, Inc. is a proper party to this action. Defendants deny any remaining allegations of Paragraph 7.

8. Paragraph 8 states legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, Defendants admit that Lupin Pharmaceuticals, Inc. is an indirect, wholly-owned subsidiary of Lupin Ltd. Defendants deny that Lupin Pharmaceuticals, Inc. is a proper party to this action. Defendants deny any remaining allegations of Paragraph 8.

9. Paragraph 9 states legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, Defendants admit that Lupin Pharmaceuticals, Inc. is an indirect, wholly-owned subsidiary of Lupin Ltd. Defendants deny that Lupin Pharmaceuticals, Inc. is a proper party to this action. Defendants deny any remaining allegations of Paragraph 9.

10. Defendants admit that Lupin Ltd., as the sole applicant, submitted the Lupin ANDA with the FDA seeking approval for obeticholic acid tablets, 5 mg and 10 mg. Defendants deny any remaining allegations of Paragraph 10.

11. Defendants admit that Lupin Ltd., as the sole applicant, submitted the Lupin ANDA with the FDA seeking approval for obeticholic acid tablets, 5 mg and 10 mg. Defendants deny any remaining allegations of Paragraph 11.

JURISDICTION AND VENUE

12. Paragraph 12 states legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, Defendants admit that the First Amended Complaint purports to state claims for infringement under the patent laws of the United States, including 35 U.S.C. § 271. Defendants deny that the First Amended Complaint states a proper claim for infringement and/or that any such claim has any merit. Defendants admit that this Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338 solely for the claims directed against Lupin Ltd. under 35 U.S.C. § 271(e)(2). Defendants deny any remaining allegations of Paragraph 12.

13. Paragraph 13 states legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, Defendants do not contest personal jurisdiction over Lupin Ltd. in this Court for purposes of this action only. Defendants deny any remaining allegations of Paragraph 13.

14. Defendants admit that Lupin Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware. Defendants deny that Lupin Pharmaceuticals, Inc. is a proper party to this action. Defendants deny any remaining allegations of Paragraph 14.

15. Paragraph 15 states legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, Defendants do not contest personal jurisdiction over Lupin Ltd. in this Court for purposes of this action only. Defendants deny that Lupin Pharmaceuticals, Inc. is a proper party to this action. Defendants deny any remaining allegations of Paragraph 15.

16. Paragraph 16 states legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, Defendants do not contest personal

jurisdiction over Lupin Ltd. in this Court for purposes of this action only. Defendants deny that Lupin Pharmaceuticals, Inc. is a proper party to this action. Defendants deny any remaining allegations of Paragraph 16.

17. Denied.

18. Paragraph 18 states legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, Defendants do not contest personal jurisdiction over Lupin Ltd. in this Court for purposes of this action only. Defendants deny that Lupin Pharmaceuticals, Inc. is a proper party to this action. Defendants deny any remaining allegations of Paragraph 18.

19. Paragraph 19 states legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, Defendants do not contest personal jurisdiction over Lupin Ltd. in this Court for purposes of this action only. Defendants deny that Lupin Pharmaceuticals, Inc. is a proper party to this action. Defendants deny any remaining allegations of Paragraph 19.

20. Paragraph 20 states legal conclusions and allegations to which no answer is required. Defendants admit that Lupin Ltd. did not contest personal jurisdiction in *Otsuka Pharmaceuticals Co., Ltd. et al. v. Lupin Limited et al.*, No. 19-1988 (LPS) (D. Del. Feb. 10, 2020); *CyDex Pharmaceuticals, Inc. v. Lupin Limited et al.*, No. 19-2043 (LPS) (D. Del. Dec. 11, 2019); *Merck Sharp & Dohme Corp. v. Lupin Limited et al.*, No. 19-347 (RGA) (D. Del. Apr. 22, 2019); *Genentech, Inc. v. Lupin Ltd. et al.*, No. 19-109 (RGA) (D. Del. Mar. 15, 2019). Defendants deny that Lupin Pharmaceuticals, Inc. is a proper party to this action. Defendants deny any remaining allegations of Paragraph 20.

21. Paragraph 21 states legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, Defendants do not contest personal jurisdiction over Lupin Ltd. in this Court for purposes of this action only. Defendants deny any remaining allegations of Paragraph 21.

22. Paragraph 22 states legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, Defendants do not contest venue over Lupin Ltd. in this Court for purposes of this action only. Defendants deny that Lupin Pharmaceuticals, Inc. is a proper party to this action. Defendants deny any remaining allegations of Paragraph 22.

23. Paragraph 23 states legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, Defendants do not contest venue over Lupin Ltd. in this Court for purposes of this action only. Defendants deny any remaining allegations of Paragraph 23.

INTERCEPT'S APPROVED OCALIVA® DRUG PRODUCT AND PATENTS

24. Upon information and belief, Defendants admit that the "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book") currently lists Intercept Pharmaceuticals as the holder of New Drug Application ("NDA") No. 207999 for obeticholic acid 5 mg and 10 mg under the name OCALIVA®. Defendants further admit that Plaintiffs purport to attach the prescribing label for OCALIVA® as Exhibit A to the First Amended Complaint. Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 24, and therefore deny them.

25. Upon information and belief, Defendants admit that the Orange Book currently lists Intercept Pharmaceuticals as the holder of NDA No. 207999 for obeticholic acid 5 mg and 10

mg under the name OCALIVA®. Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 25, and therefore deny them.

26. Upon information and belief, Defendants admit that the patents-in-suit are listed in the Orange Book as purportedly associated with OCALIVA®. Defendants lack knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 26, and therefore deny them.

27. Defendants admit that Plaintiffs purport to attach a copy of the RE286 patent to the First Amended Complaint as Exhibit B. Defendants admit that the face of the RE286 patent states that it issued on October 27, 2020. Defendants further admit that the RE286 patent is titled "Steroids as Agonists for FXR." Defendants deny any remaining allegations of Paragraph 27, including any suggestion or implication that the RE286 patent was duly and lawfully issued or is valid or enforceable.

28. Defendants admit that Plaintiffs purport to attach a copy of the '673 patent to the First Amended Complaint as Exhibit C. Defendants admit that the face of the '673 patent states that it issued on January 19, 2016. Defendants further admit that the '673 patent is titled "Preparations and Uses of Obeticholic Acid." Defendants deny any remaining allegations of Paragraph 28, including any suggestion or implication that the '673 patent was duly and lawfully issued or is valid or enforceable.

29. Defendants admit that Plaintiffs purport to attach a copy of the '117 patent to the First Amended Complaint as Exhibit D. Defendants admit that the face of the '117 patent states that it issued on August 14, 2018. Defendants further admit that the '117 patent is titled "Preparations and Uses of Obeticholic Acid." Defendants deny any remaining allegations of

Paragraph 29, including any suggestion or implication that the '117 patent was duly and lawfully issued or is valid or enforceable.

30. Defendants admit that Plaintiffs purport to attach a copy of the '337 patent to the First Amended Complaint as Exhibit E. Defendants admit that the face of the '337 patent states that it issued on August 21, 2018. Defendants further admit that the '337 patent is titled "Compositions of Obeticholic Acid and Methods of Use." Defendants deny any remaining allegations of Paragraph 30, including any suggestion or implication that the '337 patent was duly and lawfully issued or is valid or enforceable.

31. Defendants admit that Plaintiffs purport to attach a copy of the '073 patent to the First Amended Complaint as Exhibit F. Defendants admit that the face of the '073 patent states that it issued on January 8, 2019. Defendants further admit that the '073 patent is titled "Preparations and Uses of Obeticholic Acid." Defendants deny any remaining allegations of Paragraph 31, including any suggestion or implication that the '073 patent was duly and lawfully issued or is valid or enforceable.

32. Defendants admit that Plaintiffs purport to attach a copy of the '549 patent to the First Amended Complaint as Exhibit G. Defendants admit that the face of the '549 patent states that it issued on September 1, 2020. Defendants further admit that the '549 patent is titled "Compositions of Obeticholic Acid and Methods of Use." Defendants deny any remaining allegations of Paragraph 32, including any suggestion or implication that the '549 patent was duly and lawfully issued or is valid or enforceable.

LUPIN'S ANDA

33. Paragraph 33 states legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, Defendants admit that Lupin Ltd. as the

sole applicant, submitted ANDA No. 214980 to the FDA seeking approval for its proposed obeticholic acid tablets, 5 mg and 10 mg, prior to the expiration of the patents-in-suit. Defendants deny any remaining allegations of Paragraph 33.

34. Paragraph 34 states legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, Defendants admit that Lupin Ltd. sent a Notice Letter dated July 15, 2020 to Intercept that notified them that Lupin Ltd., as the sole applicant, submitted ANDA No. 214980 to the FDA seeking approval for its proposed obeticholic acid tablets, 5 mg and 10 mg, which contained Paragraph IV certifications to U.S. Patent Nos. 7,138,390; 9,238,673; 10,047,117; 10,052,337; and 10,174,073. Defendants state that the July 15, 2020 Notice Letter speaks for itself, and Defendants deny the allegations of Paragraph 34 to the extent they deviate from or otherwise do not accurately reflect or describe the July 15, 2020 Notice Letter or Lupin Ltd.'s proposed obeticholic acid tablets, 5 mg and 10 mg. Defendants deny the remaining allegations of Paragraph 34.

35. Paragraph 35 states legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, Defendants admit that Lupin Ltd. sent a Notice Letter dated July 15, 2020 to Intercept that notified them that Lupin Ltd., as the sole applicant, submitted ANDA No. 214980 to the FDA seeking approval for its proposed obeticholic acid tablets, 5 mg and 10 mg, which contained Paragraph IV certifications to U.S. Patent Nos. 7,138,390; 9,238,673; 10,047,117; 10,052,337; and 10,174,073. Defendants state that the July 15, 2020 Notice Letter speaks for itself, and Defendants deny the allegations of Paragraph 35 to the extent they deviate from or otherwise do not accurately reflect or describe the July 15, 2020 Notice Letter or Lupin Ltd.'s proposed obeticholic acid tablets, 5 mg and 10 mg. Defendants deny the remaining allegations of Paragraph 35.

36. Paragraph 36 states legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, Defendants admit that Lupin Ltd. sent a Notice Letter dated July 15, 2020 to Intercept that notified them that Lupin Ltd., as the sole applicant, submitted ANDA No. 214980 to the FDA seeking approval for its proposed obeticholic acid tablets, 5 mg and 10 mg, which contained Paragraph IV certifications to U.S. Patent Nos. 7,138,390; 9,238,673; 10,047,117; 10,052,337; and 10,174,073. Defendants state that the July 15, 2020 Notice Letter speaks for itself, and Defendants deny the allegations of Paragraph 36 to the extent they deviate from or otherwise do not accurately reflect or describe the July 15, 2020 Notice Letter or Lupin Ltd.'s proposed obeticholic acid tablets, 5 mg and 10 mg. Defendants deny the remaining allegations of Paragraph 36.

37. Paragraph 37 states legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, Defendants admit that Lupin Ltd. sent a Notice Letter dated September 28, 2020 to Intercept that notified them that Lupin Ltd., as the sole applicant, submitted ANDA No. 214980 to the FDA seeking approval for its proposed obeticholic acid tablets, 5 mg and 10 mg, which contained Paragraph IV certifications to U.S. Patent No. 10,758,549. Defendants state that the September 28, 2020 Notice Letter speaks for itself, and Defendants deny the allegations of Paragraph 37 to the extent they deviate from or otherwise do not accurately reflect or describe the September 28, 2020 Notice Letter or Lupin Ltd.'s proposed obeticholic acid tablets, 5 mg and 10 mg. Defendants deny the remaining allegations of Paragraph 37.

38. Paragraph 38 states legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, Defendants admit that Lupin Ltd. sent a Notice Letter dated September 28, 2020 to Intercept that notified them that Lupin Ltd., as the sole

applicant, submitted ANDA No. 214980 to the FDA seeking approval for its proposed obeticholic acid tablets, 5 mg and 10 mg, which contained Paragraph IV certifications to U.S. Patent No. 10,758,549. Defendants state that the September 28, 2020 Notice Letter speaks for itself, and Defendants deny the allegations of Paragraph 38 to the extent they deviate from or otherwise do not accurately reflect or describe the September 28, 2020 Notice Letter or Lupin Ltd.'s proposed obeticholic acid tablets, 5 mg and 10 mg. Defendants deny the remaining allegations of Paragraph 38.

39. Paragraph 39 states legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, Defendants admit that Lupin Ltd. sent a Notice Letter dated September 28, 2020 to Intercept that notified them that Lupin Ltd., as the sole applicant, submitted ANDA No. 214980 to the FDA seeking approval for its proposed obeticholic acid tablets, 5 mg and 10 mg, which contained Paragraph IV certifications to U.S. Patent No. 10,758,549. Defendants state that the September 28, 2020 Notice Letter speaks for itself, and Defendants deny the allegations of Paragraph 39 to the extent they deviate from or otherwise do not accurately reflect or describe the September 28, 2020 Notice Letter or Lupin Ltd.'s proposed obeticholic acid tablets, 5 mg and 10 mg. Defendants deny the remaining allegations of Paragraph 39.

40. Paragraph 40 states legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, Defendants admit that Lupin Ltd. sent a Notice Letter dated November 10, 2020 to Intercept that notified them that Lupin Ltd., as the sole applicant, submitted ANDA No. 214980 to the FDA seeking approval for its proposed obeticholic acid tablets, 5 mg and 10 mg, which contained Paragraph IV certifications to U.S. Patent No. RE48,286. Defendants state that the November 10, 2020 Notice Letter speaks for itself, and

Defendants deny the allegations of Paragraph 40 to the extent they deviate from or otherwise do not accurately reflect or describe the November 10, 2020 Notice Letter or Lupin Ltd.'s proposed obeticholic acid tablets, 5 mg and 10 mg. Defendants deny the remaining allegations of Paragraph 40.

41. Paragraph 41 states legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, Defendants admit that Lupin Ltd. sent a Notice Letter dated November 10, 2020 to Intercept that notified them that Lupin Ltd., as the sole applicant, submitted ANDA No. 214980 to the FDA seeking approval for its proposed obeticholic acid tablets, 5 mg and 10 mg, which contained Paragraph IV certifications to U.S. Patent No. RE48,286. Defendants state that the November 10, 2020 Notice Letter speaks for itself, and Defendants deny the allegations of Paragraph 41 to the extent they deviate from or otherwise do not accurately reflect or describe the November 10, 2020 Notice Letter or Lupin Ltd.'s proposed obeticholic acid tablets, 5 mg and 10 mg. Defendants deny the remaining allegations of Paragraph 41.

42. Paragraph 42 states legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, Defendants admit that Lupin Ltd. sent a Notice Letter dated November 10, 2020 to Intercept that notified them that Lupin Ltd., as the sole applicant, submitted ANDA No. 214980 to the FDA seeking approval for its proposed obeticholic acid tablets, 5 mg and 10 mg, which contained Paragraph IV certifications to U.S. Patent No. RE48,286. Defendants state that the November 10, 2020 Notice Letter speaks for itself, and Defendants deny the allegations of Paragraph 42 to the extent they deviate from or otherwise do not accurately reflect or describe the November 10, 2020 Notice Letter or Lupin Ltd.'s proposed

obeticholic acid tablets, 5 mg and 10 mg. Defendants deny the remaining allegations of Paragraph 42.

43. Defendants admit that Lupin Ltd., as the sole applicant, submitted ANDA No. 214980 to the FDA seeking approval for its proposed obeticholic acid tablets, 5 mg and 10 mg. Defendants further state that ANDA No. 214980 speaks for itself. Defendants deny the remaining allegations of Paragraph 43.

44. Defendants admit that Lupin Ltd., as the sole applicant, submitted ANDA No. 214980 to the FDA seeking approval for its proposed obeticholic acid tablets, 5 mg and 10 mg. Defendants further state that ANDA No. 214980 speaks for itself. Defendants deny the remaining allegations of Paragraph 44.

45. Paragraph 45 states legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, Defendants admit that Lupin Ltd., as the sole applicant, submitted ANDA No. 214980 to the FDA seeking approval for its proposed obeticholic acid tablets, 5 mg and 10 mg. Defendants further state that ANDA No. 214980 speaks for itself. Defendants deny the remaining allegations of Paragraph 45.

46. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 46, and therefore deny them.

COUNT I

INFRINGEMENT OF THE RE286 PATENT

47. Defendants reassert and incorporate by reference their responses to paragraphs 1-46 in full herein.

48. Defendants admit that Lupin Ltd., as the sole applicant, submitted ANDA No. 214980 to the FDA seeking approval for its proposed obeticholic acid tablets, 5 mg and 10 mg. Defendants deny the remaining allegations of Paragraph 48.

49. Denied.

50. Denied.

51. Denied.

52. Denied.

53. Denied.

54. Denied.

COUNT II

DECLARATORY JUDGMENT OF INFRINGEMENT OF THE RE286 PATENT

55. Defendants reassert and incorporate by reference their responses to paragraphs 1-54 in full herein.

56. Denied.

57. Defendants admit that Lupin Ltd., as the sole applicant, submitted ANDA No. 214980 to the FDA seeking approval for its proposed obeticholic acid tablets, 5 mg and 10 mg. Defendants deny the remaining allegations of Paragraph 57.

58. Denied.

59. Denied.

60. Denied.

61. Denied.

62. Denied.

COUNT III

INFRINGEMENT OF THE '673 PATENT

63. Defendants reassert and incorporate by reference their responses to paragraphs 1-62 in full herein.

64. Defendants admit that Lupin Ltd., as the sole applicant, submitted ANDA No. 214980 to the FDA seeking approval for its proposed obeticholic acid tablets, 5 mg and 10 mg. Defendants deny the remaining allegations of Paragraph 64.

65. Denied.

66. Denied.

67. Denied.

68. Denied.

69. Denied.

70. Denied.

COUNT IV

DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '673 PATENT

71. Defendants reassert and incorporate by reference their responses to paragraphs 1-70 in full herein.

72. Denied.

73. Defendants admit that Lupin Ltd., as the sole applicant, submitted ANDA No. 214980 to the FDA seeking approval for its proposed obeticholic acid tablets, 5 mg and 10 mg. Defendants deny the remaining allegations of Paragraph 73.

74. Denied.

75. Denied.

76. Denied.

77. Denied.

78. Denied.

COUNT V

INFRINGEMENT OF THE '117 PATENT

79. Defendants reassert and incorporate by reference their responses to paragraphs 1-78 in full herein.

80. Defendants admit that Lupin Ltd., as the sole applicant, submitted ANDA No. 214980 to the FDA seeking approval for its proposed obeticholic acid tablets, 5 mg and 10 mg. Defendants deny the remaining allegations of Paragraph 80.

81. Denied.

82. Denied.

83. Denied.

84. Denied.

85. Denied.

86. Denied.

COUNT VI

DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '117 PATENT

87. Defendants reassert and incorporate by reference their responses to paragraphs 1-86 in full herein.

88. Denied.

89. Defendants admit that Lupin Ltd., as the sole applicant, submitted ANDA No. 214980 to the FDA seeking approval for its proposed obeticholic acid tablets, 5 mg and 10 mg. Defendants deny the remaining allegations of Paragraph 89.

90. Denied.

91. Denied.

92. Denied.

93. Denied.

94. Denied.

COUNT VII

INFRINGEMENT OF THE '337 PATENT

95. Defendants reassert and incorporate by reference their responses to paragraphs 1-94 in full herein.

96. Defendants admit that Lupin Ltd., as the sole applicant, submitted ANDA No. 214980 to the FDA seeking approval for its proposed obeticholic acid tablets, 5 mg and 10 mg. Defendants deny the remaining allegations of Paragraph 96.

97. Denied.

98. Denied.

99. Denied.

100. Denied.

101. Denied.

102. Denied.

COUNT VIII

DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '337 PATENT

103. Defendants reassert and incorporate by reference their responses to paragraphs 1-102 in full herein.

104. Denied.

105. Defendants admit that Lupin Ltd., as the sole applicant, submitted ANDA No. 214980 to the FDA seeking approval for its proposed obeticholic acid tablets, 5 mg and 10 mg. Defendants deny the remaining allegations of Paragraph 105.

106. Denied.

107. Denied.

108. Denied.

109. Denied.

110. Denied.

COUNT IX

INFRINGEMENT OF THE '073 PATENT

111. Defendants reassert and incorporate by reference their responses to paragraphs 1-110 in full herein.

112. Defendants admit that Lupin Ltd., as the sole applicant, submitted ANDA No. 214980 to the FDA seeking approval for its proposed obeticholic acid tablets, 5 mg and 10 mg. Defendants deny the remaining allegations of Paragraph 112.

113. Denied.

114. Denied.

115. Denied.

116. Denied.

117. Denied.

118. Denied.

COUNT X

DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '073 PATENT

119. Defendants reassert and incorporate by reference their responses to paragraphs 1-118 in full herein.

120. Denied.

121. Defendants admit that Lupin Ltd., as the sole applicant, submitted ANDA No. 214980 to the FDA seeking approval for its proposed obeticholic acid tablets, 5 mg and 10 mg. Defendants deny the remaining allegations of Paragraph 121.

122. Denied.

123. Denied.

124. Denied.

125. Denied.

126. Denied.

COUNT XI

INFRINGEMENT OF THE '549 PATENT

127. Defendants reassert and incorporate by reference their responses to paragraphs 1-126 in full herein.

128. Defendants admit that Lupin Ltd., as the sole applicant, submitted ANDA No. 214980 to the FDA seeking approval for its proposed obeticholic acid tablets, 5 mg and 10 mg. Defendants deny the remaining allegations of Paragraph 128.

129. Denied.

130. Denied.

131. Denied.

132. Denied.

133. Denied.

134. Denied.

COUNT XII

DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '549 PATENT

135. Defendants reassert and incorporate by reference their responses to paragraphs 1-134 in full herein.

136. Denied.

137. Defendants admit that Lupin Ltd., as the sole applicant, submitted ANDA No. 214980 to the FDA seeking approval for its proposed obeticholic acid tablets, 5 mg and 10 mg. Defendants deny the remaining allegations of Paragraph 137.

138. Denied.

139. Denied.

140. Denied.

141. Denied.

142. Denied.

RESPONSE TO PRAYER FOR RELIEF

All remaining allegations not specifically admitted herein are denied. Defendants further deny that Plaintiffs are entitled to any judgment or relief against Defendants and, therefore, specifically deny paragraphs A through I of Plaintiffs' Prayer for Relief.

GENERAL DENIAL

Defendants deny all remaining allegations not specifically admitted herein. Defendants further deny that Plaintiffs are entitled to any judgment or relief requested in the First Amended Complaint, or to any relief whatsoever. Defendants respectfully request that the Court: (a) dismiss the First Amended Complaint with prejudice; (b) enter judgment in favor of Defendants; (c) award Defendants the reasonable attorneys' fees and costs of defending this action pursuant to 35 U.S.C. § 285; and (d) award Defendants such further relief as the Court deems just and appropriate.

DEFENDANTS' AFFIRMATIVE DEFENSES

Without prejudice to the responses and denials set forth in Defendants' Answer, without admitting any allegations of the First Amended Complaint not expressly admitted, and without assuming the burden of proof on any such defense that would otherwise rest with Plaintiffs, Defendants assert the following separate defenses to the First Amended Complaint:

FIRST AFFIRMATIVE DEFENSE

The First Amended Complaint, in whole or in part, fails to state a claim upon which relief can be granted.

SECOND AFFIRMATIVE DEFENSE

The claims of the patents-in-suit are invalid and/or unenforceable for failure to comply with and/or satisfy one or more of the conditions and requirements of Title 35 of the United States Code, including, but not limited to, one or more of 35 U.S.C. §§ 101, 102, 103, 112, and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b).

THIRD AFFIRMATIVE DEFENSE

Defendants do not, have not, and will not infringe, literally or under the doctrine of equivalents, willfully or otherwise, any valid, enforceable, and properly construed claim of the patents-in-suit, either directly, indirectly, contributorily, by inducement, or in any other manner. The manufacture, use, offer for sale, sale, and/or importation of the product that is the subject of Lupin Ltd.'s ANDA No. 214980 does not, has not, and will not infringe, literally or under the doctrine of equivalents, willfully or otherwise, any valid, enforceable, and properly construed claim of the patents-in-suit, either directly, indirectly, contributorily, by inducement, or in any other manner.

FOURTH AFFIRMATIVE DEFENSE

The First Amended Complaint fails to state a claim for exceptional case and/or willful infringement under 25 U.S.C. § 285 and/or 35 U.S.C. § 271(e)(4). Moreover, Lupin's actions in defending this case do not constitute an exceptional case under 35 U.S.C. § 285.

FIFTH AFFIRMATIVE DEFENSE

Lupin reserves the right to present any additional defenses or counterclaims that discovery may reveal.

SIXTH AFFIRMATIVE DEFENSE

Lupin Pharmaceuticals, Inc. is not a proper party to this action.

COUNTERCLAIMS BY LUPIN LTD.

Counterclaim-Plaintiff Lupin Ltd., for its Counterclaims against Plaintiffs/Counterclaim-Defendants Intercept Pharmaceuticals, Inc. ("Intercept Pharmaceuticals") and Intercept Pharma Europe Limited ("IPEL") (collectively "Intercept"), allege as follows:

1. This is a counterclaim action for declaratory judgment of noninfringement and/or invalidity of one or more claims of U.S. Patent Nos. RE48,286 ("the RE286 patent"); 9,238,673 ("the '673 patent"); 10,047,117 ("the '117 patent"); 10,052,337 ("the '337 patent"); 10,174,073 ("the '073 patent"); 10,758,549 ("the '549 patent"); and 10,751,349 ("the '349 patent").

THE PARTIES

2. Lupin Ltd. is a corporation organized and existing under the laws of India, having a place of business at 3rd Floor, Kalpataru Inspire, Off Wertern Express Highway, Santacruz (E), Mumbai 400 055, India.

3. On information and belief, and based on the allegations in the First Amended Complaint, Intercept Pharmaceuticals is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 10 Hudson Yards, 37th Floor, New York, New York 10001, and purports to be the assignee of the RE286, '673, '117, '337, '073, '549 and '349 patents.

4. On information and belief, and based on the allegations in the First Amended Complaint, IPEL is a limited corporation organized under the laws of the United Kingdom, having a principal place of business at One Glass Wharf, Bristol, BS2 0ZX United Kingdom, and purports to be the exclusive licensee of the RE286, '673, '117, '337, '073, '549 and '349 patents.

JURISDICTION AND VENUE

5. Lupin Ltd. seeks a declaratory judgment pursuant to 28 U.S.C. §§ 2201 and 2202.

6. The Court has jurisdiction over these counterclaims pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, 2202, and/or 35 U.S.C. § 271(e)(2).

7. This is an action based on an actual controversy between Lupin Ltd. and Intercept concerning the noninfringement and/or invalidity of the RE286, '673, '117, '337, '073, '549 and

'349 patents arising under the Patent Laws of the United States, 35 U.S.C. §§ 100 *et seq.*, and Lupin Ltd.'s right to continue to seek approval by the Food and Drug Administration ("FDA") of Abbreviated New Drug Application ("ANDA") No. 214980, and upon FDA approval, to manufacture, use, sell, and offer to sell within, and/or import into, the United States the obeticholic acid tablets, 5 mg and 10 mg, that are the subject of Lupin Ltd.'s ANDA No. 214980 ("Lupin Ltd.'s ANDA Product").

8. The Court has personal jurisdiction over Intercept because, on information and belief, Intercept transacts business within the State of Delaware and/or has engaged in systematic and continuous business contacts within the State of Delaware. Further, Intercept has subjected itself to the jurisdiction of this Court by virtue of filing its First Amended Complaint.

9. Venue is legally proper in this District under 28 U.S.C. § 1391, § 1400(b), 21 U.S.C. § 355(j)(5)(C)(i)(II), and/or by Intercept's choice of forum.

BACKGROUND

10. On information and belief, on or about October 27, 2020, the United States Patent and Trademark Office ("USPTO") issued the RE286 patent, titled "Steroids as Agonists for FXR," to Intercept Pharmaceuticals. The RE286 patent is attached as Exhibit B to the First Amended Complaint.

11. On information and belief, on or about January 19, 2016, the USPTO issued the '673 patent, titled "Preparations and Uses of Obeticholic Acid," to Intercept Pharmaceuticals. The '673 patent is attached as Exhibit C to the First Amended Complaint.

12. On information and belief, on or about August 14, 2018, the USPTO issued the '117 patent, titled "Preparations and Uses of Obeticholic Acid," to Intercept Pharmaceuticals. The '117 patent is attached as Exhibit D to the First Amended Complaint.

13. On information and belief, on or about August 21, 2018, the USPTO issued the '337 patent, titled "Compositions of Obeticholic Acid and Methods of Use," to Intercept Pharmaceuticals. The '337 patent is attached as Exhibit E to the First Amended Complaint.

14. On information and belief, on or about January 8, 2019, the USPTO issued the '073 patent, titled "Preparations and Uses of Obeticholic Acid," to Intercept Pharmaceuticals. The '073 patent is attached as Exhibit F to the First Amended Complaint.

15. On information and belief, on or about September 1, 2020, the USPTO issued the '549 patent, titled "Compositions of Obeticholic Acid and Methods of Use," to Intercept Pharmaceuticals. The '549 patent is attached as Exhibit G to the First Amended Complaint.

16. On information and belief, on or about August 25, 2020, the USPTO issued the '349 patent, titled "Compositions of Obeticholic Acid and Methods of Use," to Intercept Pharmaceuticals. The '349 patent is attached as Exhibit A to these Counterclaims.

17. On information and belief, IPEL is the exclusive licensee of the RE286, '673, '117, '337, '073, '549 and '349 patents.

18. On information and belief, and according to the United States Food and Drugs Administration (FDA) publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations" ("the Orange Book"), Intercept Pharmaceuticals is the holder of NDA No. 207999 and caused the FDA to list the RE286, '673, '117, '337, '073, '549 and '349 patents in the Orange Book in connection with NDA No. 207999.

19. By maintaining the listing of the RE286, '673, '117, '337, '073, '549 and '349 patents in the Orange Book, Intercept Pharmaceuticals represents that a claim of infringement of the RE286, '673, '117, '337, '073, '549 and '349 patents "could reasonably be asserted if a

person not licensed by the owner engaged in the manufacture, use, or sale of the drug." *See* 21 U.S.C. § 355(b)(1)(G).

20. On information and belief, Intercept Pharmaceuticals has not caused the FDA to remove the RE286, '673, '117, '337, '073, '549 and '349 patents from the Orange Book in connection with NDA No. 207999.

21. By Notice Letter dated July 15, 2020 (hereinafter, "Lupin Ltd.'s First Notice Letter"), Lupin Ltd. timely notified Intercept Pharmaceuticals that it had submitted ANDA No. 214980 to the FDA with a Paragraph IV certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '390, '673, '117, '337 and '073 patents. Lupin Ltd.'s First Notice Letter met the statutory and regulatory requirements for such notice letters, and included a detailed statement of the factual and legal bases for Lupin Ltd.'s opinion that the claims of the '390, '673, '117, '337 and '073 patents are invalid, unenforceable, and/or will not be infringed by the manufacture, use, sale, offer for sale, and/or importation of Lupin Ltd.'s ANDA Product. Lupin Ltd. incorporates by reference its First Notice Letter.

22. By Notice Letter dated September 28, 2020 (hereinafter, "Lupin Ltd.'s Second Notice Letter"), Lupin Ltd. timely notified Intercept Pharmaceuticals that it had submitted ANDA No. 214980 to the FDA with a Paragraph IV certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '549 and '349 patents. Lupin Ltd.'s Second Notice Letter met the statutory and regulatory requirements for such notice letters, and included a detailed statement of the factual and legal bases for Lupin Ltd.'s opinion that the claims of the '549 and '349 patents are invalid, unenforceable, and/or will not be infringed by the manufacture, use, sale, offer for sale, and/or importation of Lupin Ltd.'s ANDA Product. Lupin Ltd. incorporates by reference its Second Notice Letter.

23. By Notice Letter dated November 10, 2020 (hereinafter, "Lupin Ltd.'s Third Notice Letter"), Lupin Ltd. timely notified Intercept Pharmaceuticals that it had submitted ANDA No. 214980 to the FDA with a Paragraph IV certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the RE286 patent.[1] Lupin Ltd.'s Third Notice Letter met the statutory and regulatory requirements for such notice letters, and included a detailed statement of the factual and legal bases for Lupin Ltd.'s opinion that the claims of the RE286 patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, sale, offer for sale, and/or importation of Lupin Ltd.'s ANDA Product. Lupin Ltd. incorporates by reference its Third Notice Letter.

24. On August 28, 2020, Intercept filed an infringement action against Lupin Ltd. alleging infringement of the '390, '673, '117, '337 and '073 patents. (*See* D.I. 1). On November 12, 2020, Intercept filed a First Amended Complaint against Lupin Ltd. alleging infringement of the RE286, '673, '117, '337,'073 and '549 patents. (*See* D.I. 11). Intercept did not assert an infringement claim against Lupin Ltd. with respect to the '349 patent. In its First, Second and Third Notice Letters, Lupin Ltd. granted Intercept Pharmaceuticals an Offer of Confidential Access to Lupin Ltd.'s ANDA No. 214980 for the purpose of Intercept making a determination of whether an infringement action could be brought with respect to the RE286, '673, '117, '337, '073, '549 and '349 patents. As such, Lupin Ltd. is statutorily entitled to institute—and this Court has constitutional authority to adjudicate—a declaratory judgment action against Intercept for the RE286, '673, '117, '337, '073, '549 and '349 patents. 35 U.S.C. § 271(e)(5).

25. In view of the foregoing, there has been, and is now, an actual, substantial, and continuing, justiciable controversy between Lupin Ltd. and Intercept having sufficient immediacy

[1] The RE286 patent is a reissue of U.S. Patent No. 7,138,390, which was asserted in the original Complaint (D.I. 1).

and reality to warrant the issuance of a declaration of rights by the Court with respect to noninfringement and/or invalidity of the RE286, ’673, ’117, ’337, ’073, ’549 and ’349 patents, and as to Lupin Ltd.’s right to obtain FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of Lupin Ltd.’s ANDA Product.

COUNT I

Declaratory Judgment of Noninfringement of the RE286 Patent

26. Lupin Ltd. repeats and incorporates by reference each of the foregoing paragraphs 1-25 of its Counterclaims.

27. Lupin Ltd. has not, does not, and will not, infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid, enforceable, properly construed claim of the RE286 patent, including for at least the reasons set forth in the detailed statement included with Lupin Ltd.’s Third Notice Letter.

28. The manufacture, use, sale, or offer for sale within, and/or importation into, the United States of Lupin Ltd.’s ANDA Product will not constitute infringement (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), of any valid, enforceable, properly construed claim of the RE286 patent, including for at least the reasons set forth in the detailed statement included with Lupin Ltd.’s Third Notice Letter.

29. Lupin Ltd. is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of Lupin Ltd.’s ANDA Product does not, and would not if marketed, infringe any valid and/or enforceable claim of the RE286 patent, including for at least the reasons set forth in the detailed statement included with Lupin Ltd.’s Third Notice Letter.

COUNT II

Declaratory Judgment of Invalidity of the RE286 Patent

30. Lupin Ltd. repeats and incorporates by reference each of the foregoing paragraphs 1-29 of its Counterclaims.

31. The claims of the RE286 patent are invalid for failure to comply with one or more of the requirements of patentability specified in Title 35 of the United States Code, including, but not limited to, 35 U.S.C. §§ 101, 102, 103, 112, and/or double patenting, and/or based on other judicially-created bases for invalidation, including for at least the reasons set forth in the detailed statement included with Lupin Ltd.'s Third Notice Letter.

32. The RE286 patent describes and claims an alleged invention, the making of which did not involve the inventive faculty, but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains, including for at least the reasons set forth in the detailed statement included with Lupin Ltd.'s Third Notice Letter.

33. Lupin Ltd. is entitled to a judicial declaration that the claims of the RE286patent are invalid.

COUNT III

Declaratory Judgment of Noninfringement of the '673 Patent

34. Lupin Ltd. repeats and incorporates by reference each of the foregoing paragraphs 1-33 of its Counterclaims.

35. Lupin Ltd. has not, does not, and will not, infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid,

enforceable, properly construed claim of the '673 patent, including for at least the reasons set forth in the detailed statement included with Lupin Ltd.'s First Notice Letter.

36. The manufacture, use, sale, or offer for sale within, and/or importation into, the United States of Lupin Ltd.'s ANDA Product will not constitute infringement (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), of any valid, enforceable, properly construed claim of the '673 patent, including for at least the reasons set forth in the detailed statement included with Lupin Ltd.'s First Notice Letter.

37. Lupin Ltd. is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of Lupin Ltd.'s ANDA Product does not, and would not if marketed, infringe any valid and/or enforceable claim of the '673 patent, including for at least the reasons set forth in the detailed statement included with Lupin Ltd.'s First Notice Letter.

COUNT IV

Declaratory Judgment of Invalidity of the '673 Patent

38. Lupin Ltd. repeats and incorporates by reference each of the foregoing paragraphs 1-37 of its Counterclaims.

39. The claims of the '673 patent are invalid for failure to comply with one or more of the requirements of patentability specified in Title 35 of the United States Code, including but not limited to, 35 U.S.C. §§ 101, 102, 103, 112, and/or double patenting, and/or based on other judicially-created bases for invalidation, including for at least the reasons set forth in the detailed statement included with Lupin Ltd.'s First Notice Letter.

40. The '673 patent describes and claims an alleged invention, the making of which did not involve the inventive faculty, but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains,

including for at least the reasons set forth in the detailed statement included with Lupin Ltd.'s First Notice Letter.

41. Lupin Ltd. is entitled to a judicial declaration that the claims of the '673 patent are invalid.

COUNT V

Declaratory Judgment of Noninfringement of the '117 Patent

42. Lupin Ltd. repeats and incorporates by reference each of the foregoing paragraphs 1-41 of its Counterclaims.

43. Lupin Ltd. has not, does not, and will not, infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid, enforceable, properly construed claim of the '117 patent, including for at least the reasons set forth in the detailed statement included with Lupin Ltd.'s First Notice Letter.

44. The manufacture, use, sale, or offer for sale within, and/or importation into, the United States of Lupin Ltd.'s ANDA Product will not constitute infringement (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), of any valid, enforceable, properly construed claim of the '117 patent, including for at least the reasons set forth in the detailed statement included with Lupin Ltd.'s First Notice Letter.

45. Lupin Ltd. is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of Lupin Ltd.'s ANDA Product does not, and would not if marketed, infringe any valid and/or enforceable claim of the '117 patent, including for at least the reasons set forth in the detailed statement included with Lupin Ltd.'s First Notice Letter.

COUNT VI

Declaratory Judgment of Invalidity of the '117 Patent

46. Lupin Ltd. repeats and incorporates by reference each of the foregoing paragraphs 1-45 of its Counterclaims.

47. The claims of the '117 patent are invalid for failure to comply with one or more of the requirements of patentability specified in Title 35 of the United States Code, including, but not limited to, 35 U.S.C. §§ 101, 102, 103, 112, and/or double patenting, and/or based on other judicially-created bases for invalidation, including for at least the reasons set forth in the detailed statement included with Lupin Ltd.'s First Notice Letter.

48. The '117 patent describes and claims an alleged invention, the making of which did not involve the inventive faculty, but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains, including for at least the reasons set forth in the detailed statement included with Lupin Ltd.'s First Notice Letter.

49. Lupin Ltd. is entitled to a judicial declaration that the claims of the '117 patent are invalid.

COUNT VII

Declaratory Judgment of Noninfringement of the '337 Patent

50. Lupin Ltd. repeats and incorporates by reference each of the foregoing paragraphs 1-49 of its Counterclaims.

51. Lupin Ltd. has not, does not, and will not, infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid,

enforceable, properly construed claim of the ’337 patent, including for at least the reasons set forth in the detailed statement included with Lupin Ltd.’s First Notice Letter.

52. The manufacture, use, sale, or offer for sale within, and/or importation into, the United States of Lupin Ltd.’s ANDA Product will not constitute infringement (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), of any valid, enforceable, properly construed claim of the ’337 patent, including for at least the reasons set forth in the detailed statement included with Lupin Ltd.’s First Notice Letter.

53. Lupin Ltd. is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of Lupin Ltd.’s ANDA Product does not, and would not if marketed, infringe any valid and/or enforceable claim of the ’337 patent, including for at least the reasons set forth in the detailed statement included with Lupin Ltd.’s First Notice Letter.

COUNT VIII

Declaratory Judgment of Invalidity of the ’337 Patent

54. Lupin Ltd. repeats and incorporates by reference each of the foregoing paragraphs 1-53 of its Counterclaims.

55. The claims of the ’337 patent are invalid for failure to comply with one or more of the requirements of patentability specified in Title 35 of the United States Code, including, but not limited to, 35 U.S.C. §§ 101, 102, 103, 112, and/or double patenting, and/or based on other judicially-created bases for invalidation, including for at least the reasons set forth in the detailed statement included with Lupin Ltd.’s First Notice Letter.

56. The ’337 patent describes and claims an alleged invention, the making of which did not involve the inventive faculty, but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains,

including for at least the reasons set forth in the detailed statement included with Lupin Ltd.'s First Notice Letter.

57. Lupin Ltd. is entitled to a judicial declaration that the claims of the '337 patent are invalid.

COUNT IX

Declaratory Judgment of Noninfringement of the '073 Patent

58. Lupin Ltd. repeats and incorporates by reference each of the foregoing paragraphs 1-57 of its Counterclaims.

59. Lupin Ltd. has not, does not, and will not, infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid, enforceable, properly construed claim of the '073 patent, including for at least the reasons set forth in the detailed statement included with Lupin Ltd.'s First Notice Letter.

60. The manufacture, use, sale, or offer for sale within, and/or importation into, the United States of Lupin Ltd.'s ANDA Product will not constitute infringement (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), of any valid, enforceable, properly construed claim of the '073 patent, including for at least the reasons set forth in the detailed statement included with Lupin Ltd.'s First Notice Letter.

61. Lupin Ltd. is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of Lupin Ltd.'s ANDA Product does not, and would not if marketed, infringe any valid and/or enforceable claim of the '073 patent, including for at least the reasons set forth in the detailed statement included with Lupin Ltd.'s First Notice Letter.

COUNT X

Declaratory Judgment of Invalidity of the '073 Patent

62. Lupin Ltd. repeats and incorporates by reference each of the foregoing paragraphs 1-61 of its Counterclaims.

63. The claims of the '073 patent are invalid for failure to comply with one or more of the requirements of patentability specified in Title 35 of the United States Code, including, but not limited to, 35 U.S.C. §§ 101, 102, 103, 112, and/or double patenting, and/or based on other judicially-created bases for invalidation, including for at least the reasons set forth in the detailed statement included with Lupin Ltd.'s First Notice Letter.

64. The '073 patent describes and claims an alleged invention, the making of which did not involve the inventive faculty, but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains, including for at least the reasons set forth in the detailed statement included with Lupin Ltd.'s First Notice Letter.

65. Lupin Ltd. is entitled to a judicial declaration that the claims of the '073 patent are invalid.

COUNT XI

Declaratory Judgment of Noninfringement of the '549 Patent

66. Lupin Ltd. repeats and incorporates by reference each of the foregoing paragraphs 1-65 of its Counterclaims.

67. Lupin Ltd. has not, does not, and will not, infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid,

enforceable, properly construed claim of the ’549 patent, including for at least the reasons set forth in the detailed statement included with Lupin Ltd.’s Second Notice Letter.

68. The manufacture, use, sale, or offer for sale within, and/or importation into, the United States of Lupin Ltd.’s ANDA Product will not constitute infringement (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), of any valid, enforceable, properly construed claim of the ’549 patent, including for at least the reasons set forth in the detailed statement included with Lupin Ltd.’s Second Notice Letter.

69. Lupin Ltd. is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of Lupin Ltd.’s ANDA Product does not, and would not if marketed, infringe any valid and/or enforceable claim of the ’549 patent, including for at least the reasons set forth in the detailed statement included with Lupin Ltd.’s Second Notice Letter.

COUNT XII

Declaratory Judgment of Invalidity of the ’549 Patent

70. Lupin Ltd. repeats and incorporates by reference each of the foregoing paragraphs 1-69 of its Counterclaims.

71. The claims of the ’549 patent are invalid for failure to comply with one or more of the requirements of patentability specified in Title 35 of the United States Code, including, but not limited to, 35 U.S.C. §§ 101, 102, 103, 112, and/or double patenting, and/or based on other judicially-created bases for invalidation, including for at least the reasons set forth in the detailed statement included with Lupin Ltd.’s Second Notice Letter.

72. The ’549 patent describes and claims an alleged invention, the making of which did not involve the inventive faculty, but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains,

including for at least the reasons set forth in the detailed statement included with Lupin Ltd.'s Second Notice Letter.

73. Lupin Ltd. is entitled to a judicial declaration that the claims of the '549 patent are invalid.

COUNT XIII

Declaratory Judgment of Noninfringement of the '349 Patent

74. Lupin Ltd. repeats and incorporates by reference each of the foregoing paragraphs 1-73 of its Counterclaims.

75. Lupin Ltd. has not, does not, and will not, infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid, enforceable, properly construed claim of the '349 patent, including for at least the reasons set forth in the detailed statement included with Lupin Ltd.'s Second Notice Letter.

76. The manufacture, use, sale, or offer for sale within, and/or importation into, the United States of Lupin Ltd.'s ANDA Product will not constitute infringement (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), of any valid, enforceable, properly construed claim of the '349 patent, including for at least the reasons set forth in the detailed statement included with Lupin Ltd.'s Second Notice Letter.

77. Lupin Ltd. is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of Lupin Ltd.'s ANDA Product does not, and would not if marketed, infringe any valid and/or enforceable claim of the '349 patent, including for at least the reasons set forth in the detailed statement included with Lupin Ltd.'s Second Notice Letter.

COUNT XIV

Declaratory Judgment of Invalidity of the '349 Patent

78. Lupin Ltd. repeats and incorporates by reference each of the foregoing paragraphs 1-77 of its Counterclaims.

79. The claims of the '349 patent are invalid for failure to comply with one or more of the requirements of patentability specified in Title 35 of the United States Code, including, but not limited to, 35 U.S.C. §§ 101, 102, 103, 112, and/or double patenting, and/or based on other judicially-created bases for invalidation, including for at least the reasons set forth in the detailed statement included with Lupin Ltd.'s Second Notice Letter.

80. The '349 patent describes and claims an alleged invention, the making of which did not involve the inventive faculty, but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains, including for at least the reasons set forth in the detailed statement included with Lupin Ltd.'s Second Notice Letter.

81. Lupin Ltd. is entitled to a judicial declaration that the claims of the '349 patent are invalid.

EXCEPTIONAL CASE

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

PRAYER FOR RELIEF

WHEREFORE, Lupin Ltd. prays that the Court enter judgment in its favor and against Intercept as follows:

a) Dismissing the First Amended Complaint with prejudice and denying each request for relief made by Intercept therein;

b) Declaring that the claims of the RE286, ’673, ’117, ’337, ’073, ’549 and ’349 patents are invalid;

c) Declaring that the submission of Lupin Ltd.’s ANDA seeking FDA approval to market the obeticholic acid tablets, 5 mg and 10 mg, that are the subject of Lupin Ltd.’s ANDA No. 214980 prior to the expiration of the RE286, ’673, ’117, ’337, ’073, ’549 and ’349 patents has not infringed and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid, enforceable, properly construed claim of the RE286, ’673, ’117, ’337, ’073, ’549 and ’349 patents;

d) Declaring that the manufacture, use, sale, offer for sale, and/or importation of the obeticholic acid tablets, 5 mg and 10 mg, that are the subject of Lupin Ltd.’s ANDA No. 214980 will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid, enforceable, properly construed claim of the RE286, ’673, ’117, ’337, ’073, ’549 and ’349 patents;

e) A declaration that Plaintiff/Counterclaim Defendant is not entitled to injunctive relief;

f) Granting Lupin Ltd. judgment in its favor on Intercept’s claims;

g) Granting Lupin Ltd. judgment in its favor on its own Counterclaims;

h) Declaring that this is an exceptional case in favor of Lupin Ltd. pursuant to 35 U.S.C. § 285;

i) Declaring that Lupin Ltd. is the prevailing party and awarding costs, attorneys’ fees, and expenses to Lupin Ltd.; and

j) Awarding Lupin Ltd. such other and further relief to which it may be entitled.

Date: November 30, 2020

PHILLIPS, MCLAUGHLIN & HALL, P.A.

John C. Phillips, Jr.
John C. Phillips, Jr. (No. 110)
Megan C. Haney (No. 5016)
1200 North Broom Street
Wilmington, Delaware 19806-4204
Phone: (302) 655-4200
jcp@pmhdelaw.com
mch@pmhdelaw.com

Attorneys for Defendants
Lupin Limited and Lupin Pharmaceuticals, Inc.

Of Counsel:

Deepro R. Mukerjee
Lance Soderstrom
KATTEN MUCHIN ROSENMAN LLP
575 Madison Avenue
New York, NY 10022-2585
(212) 940-8800
deepro.mukerjee@katten.com
lance.soderstrom@katten.com

Jitendra Malik
KATTEN MUCHIN ROSENMAN LLP
550 S. Tryon Street, Suite 2900
Charlotte, NC 28202-4213
(704) 444-2000
jitty.malik@katten.com

Guylaine Haché
KATTEN MUCHIN ROSENMAN LLP
525 W. Monroe Street
Chicago, IL 60661-3693
(312) 902-5200
guylaine.hache@katten.com