

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

INTERCEPT PHARMACEUTICALS, INC.
and INTERCEPT PHARMA EUROPE LTD.,

Plaintiffs,

v.

OPTIMUS PHARMA PVT. LTD. and
OPTIMUS DRUGS PRIVATE LTD.,

Defendants.

C.A. No. 1:20-cv-01215-MN

**DEFENDANTS' ANSWER TO PLAINTIFFS' FIRST AMENDED COMPLAINT,
AFFIRMATIVE DEFENSES AND COUNTERCLAIMS**

Defendants Optimus Pharma Pvt. Ltd. and Optimus Drugs Private Ltd., (collectively, "Optimus" or "Defendants") for its answers, affirmative defenses and counterclaims to the First Amended Complaint for Patent Infringement of Plaintiffs Intercept Pharmaceuticals Inc. and Intercept Pharma Europe Ltd. (collectively, "Intercept" or "Plaintiffs") (D.I. 17), by and through its counsel responds as follows. To the extent not expressly admitted or qualified below in response to the correspondingly numbered paragraphs of the First Amended Complaint, each and every allegation of the First Amended Complaint is denied.

NATURE OF THE ACTION

1. Paragraph 1 of the First Amended Complaint contains conclusions of law to which no response is required. To the extent a response is required, Optimus admits that the First Amended Complaint purports to be an action for patent infringement under the patent laws of the United States, Title 35 of the United States Code, arising from Optimus' filing of Abbreviated New Drug Application ("ANDA") No. 214935 ("the Optimus ANDA") with the U.S. Food and Drug Administration ("FDA") seeking approval to commercially manufacture and market generic versions of the 5 mg and 10 mg OCALIVA[®] drug product ("the Optimus

'935 ANDA Product”), prior to the expiration 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, “patents in suit”). Optimus lacks information sufficient to form a belief as to the remaining allegations of paragraph 1 and thus denies any remaining allegations contained in this paragraph of the First Amended Complaint.

2. Paragraph 2 of the First Amended Complaint contains conclusions of law to which no response is required. To the extent a response is required, Optimus, the allegations contained in this paragraph of the First Amended Complaint are denied.

THE PARTIES

3. Optimus lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained this paragraph of the First Amended Complaint and therefore denies them.

4. Optimus lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained this paragraph of the First Amended Complaint and therefore denies them.

5. Optimus admits that Optimus Pharma Pvt. Ltd. is a corporation organized and existing under the laws of the Republic of India, having its principal place of business at 2nd Floor, Sy No. 37/A & 37/P, Plot No. 6P, Signature Towers, Kothaguda, Kondapur, Hyderabad 500 084, Telangana, India.

6. Optimus admits that Optimus Drugs Private Ltd. is a limited corporation organized and existing under the laws of the Republic of India, having its principal place of business at 2nd Floor, Sy No. 37/A & 37/P, Plot No. 6P, Signature Towers, Kothaguda, Kondapur, Hyderabad 500 084, Telangana, India. Optimus admits that Optimus Drugs Private Ltd. is an affiliate of Optimus Pharma Pvt. Ltd.

7. Optimus admits that it is the holder of FDA Drug Master File No. 33960 for obeticholic acid.

8. Optimus admits that Defendants collaborate with respect to the development, regulatory approval, marketing, sale, and/or distribution of pharmaceutical products. Optimus admits that Defendants are agents of each other and/or operate in concert as integrated parts of the same business group and enter into agreements with each other that are nearer than arm's length.

9. Optimus admits that it prepared and submitted ANDA No. 214935 (the "Optimus ANDA") and continue to seek FDA approval of that application.

10. Optimus admits that it intends to commercially manufacture, market, offer for sale, and sell the products described in the Optimus ANDA (the "Optimus ANDA Products" or "ANDA Products") throughout the United States, including in the State of Delaware, in the event the FDA approves the Optimus ANDA.

JURISDICTION AND VENUE

11. Paragraph 11 of the First Amended Complaint contains legal conclusions to which no response is required. To the extent a response is required, Optimus admits that this action purports to arise under the patent laws of the United States. Optimus admits that this Court has subject matter jurisdiction.

12. Paragraph 12 of the First Amended Complaint contains legal conclusions to which no response is required. To the extent a response is required, the allegations contained in this paragraph of the First Amended Complaint are denied. Optimus further avers, however, that for the purposes of this case only, it does not contest this Court's personal jurisdiction over Optimus.

13. Optimus admits that Defendants are in the business of manufacturing, marketing, importing, distributing, and selling pharmaceutical drug products, including generic

drug products, either directly or through subsidiaries, agents, and/or alter egos, which Defendants manufacture, distribute, market and/or sell throughout the United States and in this judicial district. Optimus denies any remaining allegations contained in this paragraph of the First Amended Complaint.

14. Optimus admits that Defendants are licensed to sell generic and proprietary pharmaceutical products in Delaware, either directly or through one or more of their wholly owned subsidiaries, agents, and/or alter egos. Optimus denies any remaining allegations contained in this paragraph of the First Amended Complaint.

15. Paragraph 15 of the First Amended Complaint contains legal conclusions to which no response is required. To the extent a response is required, Optimus admits that it indicated by a letter dated July 27, 2020 sent by Optimus Pharma Pvt. Ltd. to Intercept Pharmaceuticals pursuant to 21 U.S.C. § 355(j)(2)(b), Defendants prepared and filed the Optimus ANDA with the intention of seeking to market the Optimus ANDA Products nationwide. Optimus denies any remaining allegations contained in this paragraph of the First Amended Complaint. Optimus further avers, however, that for the purposes of this case only, it does not contest this Court's personal jurisdiction over Optimus.

16. Optimus admits that Defendants plan to sell the Optimus ANDA Products in Delaware, list the Optimus ANDA Products on Delaware's prescription drug formulary, and seek Medicaid reimbursements for sales of the Optimus ANDA Products in the State of Delaware, either directly or through one or more of their wholly owned subsidiaries, agents, and/or alter egos. Optimus denies any remaining allegations contained in this paragraph of the First Amended Complaint.

17. Paragraph 17 of the First Amended Complaint contains legal conclusions to which no response is required. To the extent a response is required, the allegations contained in this paragraph of the First Amended Complaint are denied. Optimus further avers, however,

that for the purposes of this case only, it does not contest this Court's personal jurisdiction over Optimus. Optimus denies any remaining allegations contained in this paragraph of the First Amended Complaint.

18. Paragraph 18 of the First Amended Complaint contains legal conclusions to which no response is required. To the extent a response is required, Optimus admits filing of ANDA No. 214935 and that it has engaged in patent litigation concerning FDA-approved drug products in this judicial district. Optimus further avers, however, that for the purposes of this case only, it does not contest this Court's personal jurisdiction over Optimus. Optimus denies any remaining allegations contained in this paragraph of the First Amended Complaint.

19. Paragraph 19 of the First Amended Complaint contains legal conclusions to which no response is required. To the extent a response is required, the allegations contained in this paragraph of the First Amended Complaint are denied. Optimus further avers, however, that for the purposes of this case only, it does not contest this Court's personal jurisdiction over Optimus.

20. Paragraph 20 of the First Amended Complaint contains legal conclusions to which no response is required. To the extent a response is required, the allegations contained in this paragraph of the First Amended Complaint are denied. Optimus further avers, however, that for the purposes of this case only, it does not contest this Court's personal jurisdiction over Optimus.

21. Paragraph 21 of the First Amended Complaint contains legal conclusions to which no response is required. To the extent a response is required, the allegations contained in this paragraph of the First Amended Complaint are denied. Optimus further avers, however, that for the purposes of this case only, it does not contest this Court's personal jurisdiction over Optimus.

INTERCEPT'S APPROVED OCALIVA® DRUG PRODUCT AND PATENTS

22. Paragraph 22 of the First Amended Complaint contains statements to which no response is required. To the extent a response is required, Optimus denies any allegations in this paragraph of the First Amended Complaint.

23. Paragraph 23 of the First Amended Complaint contains statements to which no response is required. To the extent a response is required, Optimus denies any allegations in this paragraph of the First Amended Complaint

24. Paragraph 24 of the First Amended Complaint contains statements to which no response is required. To the extent a response is required, Optimus denies any allegations in this paragraph of the First Amended Complaint.

25. Paragraph 25 of the First Amended Complaint contains statements to which no response is required. To the extent a response is required, Optimus denies any allegations in this paragraph of the First Amended Complaint.

26. Paragraph 26 of the First Amended Complaint contains statements to which no response is required. To the extent a response is required, Optimus denies any allegations in this paragraph of the First Amended Complaint.

27. Paragraph 27 of the First Amended Complaint contains statements to which no response is required. To the extent a response is required, Optimus denies any allegations in this paragraph of the First Amended Complaint.

28. Paragraph 28 of the First Amended Complaint contains statements to which no response is required. To the extent a response is required, Optimus denies any allegations in this paragraph of the First Amended Complaint.

29. Paragraph 29 of the First Amended Complaint contains statements to which no response is required. To the extent a response is required, Optimus denies any allegations in this paragraph of the First Amended Complaint.

30. Paragraph 30 of the First Amended Complaint contains statements to which no response is required. To the extent a response is required, Optimus denies any allegations in this paragraph of the First Amended Complaint.

OPTIMUS' ANDA

31. Admitted.

32. Admitted.

33. Admitted.

34. Admitted.

35. Admitted.

36. Admitted.

37. Admitted.

38. Admitted.

39. Admitted.

40. Paragraph 40 of the First Amended Complaint contains statements to which no response is required. To the extent a response is required, Optimus denies any allegations in this paragraph of the First Amended Complaint.

41. Paragraph 41 of the First Amended Complaint contains statements to which no response is required. To the extent a response is required, Optimus denies any allegations in this paragraph of the First Amended Complaint.

COUNT I
INFRINGEMENT OF THE RE286 PATENT

42. Paragraph 42 of the First Amended Complaint contains statements to which no response is required. To the extent a response is required, Optimus denies any allegations in this paragraph of the First Amended Complaint.

43. Admitted.

44. Paragraph 44 of the First Amended Complaint contains legal conclusions to which no response is required. To the extent a response is required, the allegations contained in this paragraph of the First Amended Complaint are denied.

45. Paragraph 45 of the First Amended Complaint contains legal conclusions to which no response is required. To the extent a response is required, the allegations contained in this paragraph of the First Amended Complaint are denied.

46. Paragraph 46 of the First Amended Complaint contains legal conclusions to which no response is required. To the extent a response is required, the allegations contained in this paragraph of the First Amended Complaint are denied.

47. Paragraph 47 of the First Amended Complaint contains legal conclusions to which no response is required. To the extent a response is required, the allegations contained in this paragraph of the First Amended Complaint are denied.

48. Paragraph 48 of the First Amended Complaint contains legal conclusions to which no response is required. Optimus admits that to the stipulation of “all references to the ’390 [P]tent in Plaintiffs’ First Amended Complaint shall be deemed to refer to the RE286 [P]atent.” To the extent a response is required, the allegations contained in this paragraph of the First Amended Complaint are denied.

49. Paragraph 49 of the First Amended Complaint contains legal conclusions to which no response is required. To the extent a response is required, the allegations contained in this paragraph of the First Amended Complaint are denied.

COUNT II
DECLARATORY JUDGMENT OF INFRINGEMENT OF THE RE286 PATENT

50. Paragraph 50 of the First Amended Complaint contains statements to which no response is required. To the extent a response is required, Optimus denies any allegations in this paragraph of the First Amended Complaint.

51. Paragraph 51 of the First Amended Complaint contains legal conclusions to which no response is required. To the extent a response is required, the allegations contained in this paragraph of the First Amended Complaint are denied.

52. Admitted.

53. Paragraph 53 of the First Amended Complaint contains legal conclusions to which no response is required. To the extent a response is required, the allegations contained in this paragraph of the First Amended Complaint are denied.

54. Paragraph 54 of the First Amended Complaint contains legal conclusions to which no response is required. To the extent a response is required, the allegations contained in this paragraph of the First Amended Complaint are denied.

55. Paragraph 55 of the First Amended Complaint contains legal conclusions to which no response is required. To the extent a response is required, the allegations contained in this paragraph of the First Amended Complaint are denied.

56. Paragraph 56 of the First Amended Complaint contains legal conclusions to which no response is required. To the extent a response is required, the allegations contained in this paragraph of the First Amended Complaint are denied.

57. Paragraph 57 of the First Amended Complaint contains legal conclusions to which no response is required. To the extent a response is required, the allegations contained in this paragraph of the First Amended Complaint are denied.

COUNT III
INFRINGEMENT OF THE '673 PATENT

58. Paragraph 58 of the First Amended Complaint contains statements to which no response is required. To the extent a response is required, Optimus denies any allegations in this paragraph of the First Amended Complaint.

59. Admitted.

60. Paragraph 60 of the First Amended Complaint contains legal conclusions to which no response is required. To the extent a response is required, the allegations contained in this paragraph of the First Amended Complaint are denied.

61. Paragraph 61 of the First Amended Complaint contains legal conclusions to which no response is required. To the extent a response is required, the allegations contained in this paragraph of the First Amended Complaint are denied.

62. Paragraph 62 of the First Amended Complaint contains legal conclusions to which no response is required. To the extent a response is required, the allegations contained in this paragraph of the First Amended Complaint are denied.

63. Paragraph 63 of the First Amended Complaint contains legal conclusions to which no response is required. To the extent a response is required, the allegations contained in this paragraph of the First Amended Complaint are denied.

64. Paragraph 64 of the First Amended Complaint contains legal conclusions to which no response is required. To the extent a response is required, the allegations contained in this paragraph of the First Amended Complaint are denied.

65. Paragraph 65 of the First Amended Complaint contains legal conclusions to which no response is required. To the extent a response is required, the allegations contained in this paragraph of the First Amended Complaint are denied.

COUNT IV
DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '673 PATENT

66. Paragraph 66 of the First Amended Complaint contains statements to which no response is required. To the extent a response is required, Optimus denies any allegations in this paragraph of the First Amended Complaint.

67. Paragraph 67 of the First Amended Complaint contains legal conclusions to which no response is required. To the extent a response is required, the allegations contained in this paragraph of the First Amended Complaint are denied.

68. Admitted.

69. Paragraph 69 of the First Amended Complaint contains legal conclusions to which no response is required. To the extent a response is required, the allegations contained in this paragraph of the First Amended Complaint are denied.

70. Paragraph 70 of the First Amended Complaint contains legal conclusions to which no response is required. To the extent a response is required, the allegations contained in this paragraph of the First Amended Complaint are denied.

71. Paragraph 71 of the First Amended Complaint contains legal conclusions to which no response is required. To the extent a response is required, the allegations contained in this paragraph of the First Amended Complaint are denied.

72. Paragraph 72 of the First Amended Complaint contains legal conclusions to which no response is required. To the extent a response is required, the allegations contained in this paragraph of the First Amended Complaint are denied.

73. Paragraph 73 of the First Amended Complaint contains legal conclusions to which no response is required. To the extent a response is required, the allegations contained in this paragraph of the First Amended Complaint are denied.

COUNT V
INFRINGEMENT OF THE '117 PATENT

74. Paragraph 74 of the First Amended Complaint contains statements to which no response is required. To the extent a response is required, Optimus denies any allegations in this paragraph of the First Amended Complaint.

75. Admitted.

76. Paragraph 76 of the First Amended Complaint contains legal conclusions to which no response is required. To the extent a response is required, the allegations contained in this paragraph of the First Amended Complaint are denied.

77. Paragraph 77 of the First Amended Complaint contains legal conclusions to which no response is required. To the extent a response is required, the allegations contained in this paragraph of the First Amended Complaint are denied.

78. Paragraph 78 of the First Amended Complaint contains legal conclusions to which no response is required. To the extent a response is required, the allegations contained in this paragraph of the First Amended Complaint are denied.

79. Paragraph 79 of the First Amended Complaint contains legal conclusions to which no response is required. To the extent a response is required, the allegations contained in this paragraph of the First Amended Complaint are denied.

80. Paragraph 80 of the First Amended Complaint contains legal conclusions to which no response is required. To the extent a response is required, the allegations contained in this paragraph of the First Amended Complaint are denied.

81. Paragraph 81 of the First Amended Complaint contains legal conclusions to which no response is required. To the extent a response is required, the allegations contained in this paragraph of the First Amended Complaint are denied.

COUNT VI
DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '117 PATENT

82. Paragraph 82 of the First Amended Complaint contains statements to which no response is required. To the extent a response is required, Optimus denies any allegations in this paragraph of the First Amended Complaint.

83. Paragraph 83 of the First Amended Complaint contains legal conclusions to which no response is required. To the extent a response is required, the allegations contained in this paragraph of the First Amended Complaint are denied.

84. Admitted.

85. Paragraph 85 of the First Amended Complaint contains legal conclusions to which no response is required. To the extent a response is required, the allegations contained in this paragraph of the First Amended Complaint are denied.

86. Paragraph 86 of the First Amended Complaint contains legal conclusions to which no response is required. To the extent a response is required, the allegations contained in this paragraph of the First Amended Complaint are denied.

87. Paragraph 87 of the First Amended Complaint contains legal conclusions to which no response is required. To the extent a response is required, the allegations contained in this paragraph of the First Amended Complaint are denied.

88. Paragraph 88 of the First Amended Complaint contains legal conclusions to which no response is required. To the extent a response is required, the allegations contained in this paragraph of the First Amended Complaint are denied.

89. Paragraph 89 of the First Amended Complaint contains legal conclusions to which no response is required. To the extent a response is required, the allegations contained in this paragraph of the First Amended Complaint are denied.

COUNT VII
INFRINGEMENT OF THE '337 PATENT

90. Paragraph 90 of the First Amended Complaint contains statements to which no response is required. To the extent a response is required, Optimus denies any allegations in this paragraph of the First Amended Complaint.

91. Admitted.

92. Paragraph 92 of the First Amended Complaint contains legal conclusions to which no response is required. To the extent a response is required, the allegations contained in this paragraph of the First Amended Complaint are denied.

93. Paragraph 93 of the First Amended Complaint contains legal conclusions to which no response is required. To the extent a response is required, the allegations contained in this paragraph of the First Amended Complaint are denied.

94. Paragraph 94 of the First Amended Complaint contains legal conclusions to which no response is required. To the extent a response is required, the allegations contained in this paragraph of the First Amended Complaint are denied.

95. Paragraph 95 of the First Amended Complaint contains legal conclusions to which no response is required. To the extent a response is required, the allegations contained in this paragraph of the First Amended Complaint are denied.

96. Paragraph 96 of the First Amended Complaint contains legal conclusions to which no response is required. To the extent a response is required, the allegations contained in this paragraph of the First Amended Complaint are denied.

97. Paragraph 97 of the First Amended Complaint contains legal conclusions to which no response is required. To the extent a response is required, the allegations contained in this paragraph of the First Amended Complaint are denied.

COUNT VIII
DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '117 PATENT

98. Paragraph 98 of the First Amended Complaint contains statements to which no response is required. To the extent a response is required, Optimus denies any allegations in this paragraph of the First Amended Complaint.

99. Paragraph 99 of the First Amended Complaint contains legal conclusions to which no response is required. To the extent a response is required, the allegations contained in this paragraph of the First Amended Complaint are denied.

100. Admitted.

101. Paragraph 101 of the First Amended Complaint contains legal conclusions to which no response is required. To the extent a response is required, the allegations contained in this paragraph of the First Amended Complaint are denied.

102. Paragraph 102 of the First Amended Complaint contains legal conclusions to which no response is required. To the extent a response is required, the allegations contained in this paragraph of the First Amended Complaint are denied.

103. Paragraph 103 of the First Amended Complaint contains legal conclusions to which no response is required. To the extent a response is required, the allegations contained in this paragraph of the First Amended Complaint are denied.

104. Paragraph 104 of the First Amended Complaint contains legal conclusions to which no response is required. To the extent a response is required, the allegations contained in this paragraph of the First Amended Complaint are denied.

105. Paragraph 105 of the First Amended Complaint contains legal conclusions to which no response is required. To the extent a response is required, the allegations contained in this paragraph of the First Amended Complaint are denied.

COUNT IX
INFRINGEMENT OF THE '073 PATENT

106. Paragraph 106 of the First Amended Complaint contains statements to which no response is required. To the extent a response is required, Optimus denies any allegations in this paragraph of the First Amended Complaint.

107. Admitted.

108. Paragraph 108 of the First Amended Complaint contains legal conclusions to which no response is required. To the extent a response is required, the allegations contained in this paragraph of the First Amended Complaint are denied.

109. Paragraph 109 of the First Amended Complaint contains legal conclusions to which no response is required. To the extent a response is required, the allegations contained in this paragraph of the First Amended Complaint are denied.

110. Paragraph 110 of the First Amended Complaint contains legal conclusions to which no response is required. To the extent a response is required, the allegations contained in this paragraph of the First Amended Complaint are denied.

111. Paragraph 111 of the First Amended Complaint contains legal conclusions to which no response is required. To the extent a response is required, the allegations contained in this paragraph of the First Amended Complaint are denied.

112. Paragraph 112 of the First Amended Complaint contains legal conclusions to which no response is required. To the extent a response is required, the allegations contained in this paragraph of the First Amended Complaint are denied.

113. Paragraph 113 of the First Amended Complaint contains legal conclusions to which no response is required. To the extent a response is required, the allegations contained in this paragraph of the First Amended Complaint are denied.

COUNT X
DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '073 PATENT

114. Paragraph 114 of the First Amended Complaint contains statements to which no response is required. To the extent a response is required, Optimus denies any allegations in this paragraph of the First Amended Complaint.

115. Paragraph 115 of the First Amended Complaint contains legal conclusions to which no response is required. To the extent a response is required, the allegations contained in this paragraph of the First Amended Complaint are denied.

116. Admitted.

117. Paragraph 117 of the First Amended Complaint contains legal conclusions to which no response is required. To the extent a response is required, the allegations contained in this paragraph of the First Amended Complaint are denied.

118. Paragraph 118 of the First Amended Complaint contains legal conclusions to which no response is required. To the extent a response is required, the allegations contained in this paragraph of the First Amended Complaint are denied.

119. Paragraph 119 of the First Amended Complaint contains legal conclusions to which no response is required. To the extent a response is required, the allegations contained in this paragraph of the First Amended Complaint are denied.

120. Paragraph 120 of the First Amended Complaint contains legal conclusions to which no response is required. To the extent a response is required, the allegations contained in this paragraph of the First Amended Complaint are denied.

121. Paragraph 121 of the First Amended Complaint contains legal conclusions to which no response is required. To the extent a response is required, the allegations contained in this paragraph of the First Amended Complaint are denied.

COUNT XI
INFRINGEMENT OF THE '549 PATENT

122. Paragraph 122 of the First Amended Complaint contains statements to which no response is required. To the extent a response is required, Optimus denies any allegations in this paragraph of the First Amended Complaint.

123. Admitted.

124. Paragraph 124 of the First Amended Complaint contains legal conclusions to which no response is required. To the extent a response is required, the allegations contained in this paragraph of the First Amended Complaint are denied.

125. Paragraph 125 of the First Amended Complaint contains legal conclusions to which no response is required. To the extent a response is required, the allegations contained in this paragraph of the First Amended Complaint are denied.

126. Paragraph 126 of the First Amended Complaint contains legal conclusions to which no response is required. To the extent a response is required, the allegations contained in this paragraph of the First Amended Complaint are denied.

127. Paragraph 127 of the First Amended Complaint contains legal conclusions to which no response is required. To the extent a response is required, the allegations contained in this paragraph of the First Amended Complaint are denied.

128. Paragraph 128 of the First Amended Complaint contains legal conclusions to which no response is required. To the extent a response is required, the allegations contained in this paragraph of the First Amended Complaint are denied.

129. Paragraph 129 of the First Amended Complaint contains legal conclusions to which no response is required. To the extent a response is required, the allegations contained in this paragraph of the First Amended Complaint are denied.

COUNT XII
DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '549 PATENT

130. Paragraph 130 of the First Amended Complaint contains statements to which no response is required. To the extent a response is required, Optimus denies any allegations in this paragraph of the First Amended Complaint.

131. Paragraph 131 of the First Amended Complaint contains legal conclusions to which no response is required. To the extent a response is required, the allegations contained in this paragraph of the First Amended Complaint are denied.

132. Admitted.

133. Paragraph 133 of the First Amended Complaint contains legal conclusions to which no response is required. To the extent a response is required, the allegations contained in this paragraph of the First Amended Complaint are denied.

134. Paragraph 134 of the First Amended Complaint contains legal conclusions to which no response is required. To the extent a response is required, the allegations contained in this paragraph of the First Amended Complaint are denied.

135. Paragraph 135 of the First Amended Complaint contains legal conclusions to which no response is required. To the extent a response is required, the allegations contained in this paragraph of the First Amended Complaint are denied.

136. Paragraph 136 of the First Amended Complaint contains legal conclusions to which no response is required. To the extent a response is required, the allegations contained in this paragraph of the First Amended Complaint are denied.

137. Paragraph 137 of the First Amended Complaint contains legal conclusions to which no response is required. To the extent a response is required, the allegations contained in this paragraph of the First Amended Complaint are denied.

FIRST AFFIRMATIVE DEFENSE

138. The manufacture, use, offer to sell, sale or importation of Optimus's ANDA drug product, has not infringed, does not infringe and will not infringe any valid and/or enforceable 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"); and 10,758,549 (the '549 patent) (collectively, "patents in suit"), either directly or indirectly, literally or under the doctrine of equivalents, or in any other manner.

SECOND AFFIRMATIVE DEFENSE

139. Plaintiffs cannot meet their burden of proof to establish direct or indirect infringement of the patents in suit.

THIRD AFFIRMATIVE DEFENSE

140. The claims of the patents in suit are invalid for failure to satisfy or comply with 35 U.S.C. §§ 101, 102, 103, 112 and/or 282, and/or for improper double patenting.

FOURTH AFFIRMATIVE DEFENSE

141. Plaintiffs' claims are barred, in whole or in part, by the doctrine of prosecution history estoppel.

FIFTH AFFIRMATIVE DEFENSE

142. Optimus reserves the right to assert any and all additional defenses and counterclaims that may be developed, whether through discovery, further investigation, and/or otherwise, including defenses or counterclaims of unenforceability.

COUNTERCLAIMS

143. Defendants and Counterclaim-Plaintiffs Optimus Pharma Pvt. Ltd. and Optimus Drugs Private Ltd. (collectively, "Optimus" or "Defendants") for its counterclaims against Plaintiffs and Counterclaim-Defendants Intercept Pharmaceuticals Inc. and Intercept Pharma Europe Ltd. (collectively, "Intercept" or "Plaintiffs"), alleges as follows.

THE PARTIES

144. Optimus Pharma Pvt. Ltd. is an Indian Corporation having its principal place of business at 2nd Floor, Sy No. 37/A & 37/P, Plot No. 6P, Signature Towers, Kothaguda, Kondapur, Hyderabad 500 084, Telangana, India.

145. Optimus Drugs Private Ltd. is a limited corporation organized and existing under the laws of the Republic of India, having its principal place of business at 2nd Floor, Sy No. 37/A & 37/P, Plot No. 6P, Signature Towers, Kothaguda, Kondapur, Hyderabad 500 084, Telangana, India.

146. Intercept Pharmaceuticals Inc. is, on information or belief, 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.

147. Intercept Pharma Europe Ltd. is, on information or belief, a corporation organized under the laws of the United Kingdom, having a principal place of business at One Glass Wharf, Bristol, BS2 OZX United Kingdom.

JURISDICTION AND VENUE

148. These counterclaims are an action for declaratory judgment of patent non-infringement and/or patent invalidity pursuant to 28 U.S.C. §§ 2201 and 2202.

149. These counterclaims arise under the laws of the United States, and this Court has subject matter jurisdiction over these counterclaims pursuant to 28 U.S.C. §§ 1331 and 1338(a).

PERSONAL JURISDICTION

150. This court has personal jurisdiction over Intercept because Intercept filed the Complaint (D.I. 1) in this Court, alleging infringement of the patents-in-suit by Optimus, and because, on information and belief, Intercept is a corporation organized under the laws of Delaware and do business in this District.

VENUE

151. Venue is proper in this District, pursuant to 28 U.S.C. §§ 1391(b) and (c) as Intercept resides in this District and filed the Complaint accusing Optimus of infringement in this District.

BACKGROUND

152. Intercept alleges in the First Amended Complaint that Intercept owns 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, "patents in suit").

153. Intercept alleges in the First Amended Complaint that Intercept is the holder of New Drug Application ("NDA") No. 207999, relating to 5 and 10 mg dosage forms ("OCALIVA® Tablets").

154. The patents in suit are listed in the FDA's "Orange Book" in connection with OCALIVA®.

155. On information and belief, Intercept caused the patents in suit to be listed in the Orange Book in connection with OCALIVA®.

156. Intercept alleges in the First Amended Complaint that Optimus has infringed patents the in suit by filing Abbreviated New Drug Application ("ANDA") No. 214935 seeking approval to market 5 and 10 mg dosage forms obeticholic acid tablets ("Optimus's ANDA drug product") prior to the expiration of the patents the in suit.

157. Intercept alleges in the First Amended Complaint that the commercial manufacture, use, offer to sell, sale or importation of Optimus's ANDA drug product prior to the expiration of the patents in suit, will infringe claims of those patents directly or indirectly, literally or under the doctrine of equivalents.

158. There is an actual, substantial, and justiciable controversy between Optimus and Plaintiffs relating to the infringement and/or validity of the patents the in suit.

COUNT I
(NON-INFRINGEMENT OF THE RE286 PATENT)

159. Optimus re-alleges and incorporates by reference each preceding paragraph of the Counterclaims as if fully set forth herein.

160. Optimus has not, does not and will not infringe one or more claims of the RE286 patent by the manufacture, use, offer to sell, sale or importation of Optimus's ANDA drug product.

161. Optimus is entitled to a judicial declaration that it has not infringed, and that the commercial manufacture, use, offer to sell, sale or importation of Optimus's ANDA drug product will not infringe, one or more claims of the RE286 patent.

COUNT II
(NON-INFRINGEMENT OF THE '673 PATENT)

162. Optimus re-alleges and incorporates by reference each preceding paragraph of the Counterclaims as if fully set forth herein.

163. Optimus has not, does not and will not infringe one or more claims of the '673 patent by the manufacture, use, offer to sell, sale or importation of Optimus's ANDA drug product.

164. Optimus is entitled to a judicial declaration that it has not infringed, and that the commercial manufacture, use, offer to sell, sale or importation of Optimus's ANDA drug product will not infringe, one or more claims of the '673 patent.

COUNT III
(NON-INFRINGEMENT OF THE '117 PATENT)

165. Optimus re-alleges and incorporates by reference each preceding paragraph of the Counterclaims as if fully set forth herein.

166. Optimus has not, does not and will not infringe one or more claims of the '117 patent by the manufacture, use, offer to sell, sale or importation of Optimus's ANDA drug product.

167. Optimus is entitled to a judicial declaration that it has not infringed, and that the commercial manufacture, use, offer to sell, sale or importation of Optimus's ANDA drug product will not infringe, one or more claims of the '117 patent.

COUNT IV
(NON-INFRINGEMENT OF THE '337 PATENT)

168. Optimus re-alleges and incorporates by reference each preceding paragraph of the Counterclaims as if fully set forth herein.

169. Optimus has not, does not and will not infringe one or more claims of the '337 patent by the manufacture, use, offer to sell, sale or importation of Optimus's ANDA drug product.

170. Optimus is entitled to a judicial declaration that it has not infringed, and that the commercial manufacture, use, offer to sell, sale or importation of Optimus's ANDA drug product will not infringe, one or more claims of the '337 patent.

COUNT V
(NON-INFRINGEMENT OF THE '073 PATENT)

171. Optimus re-alleges and incorporates by reference each preceding paragraph of the Counterclaims as if fully set forth herein.

172. Optimus has not, does not and will not infringe one or more claims of the '073 patent by the manufacture, use, offer to sell, sale or importation of Optimus's ANDA drug product.

173. Optimus is entitled to a judicial declaration that it has not infringed, and that the commercial manufacture, use, offer to sell, sale or importation of Optimus's ANDA drug product will not infringe, one or more claims of the '073 patent.

COUNT VI
(NON-INFRINGEMENT OF THE '549 PATENT)

174. Optimus re-alleges and incorporates by reference each preceding paragraph of the Counterclaims as if fully set forth herein.

175. Optimus has not, does not and will not infringe one or more claims of the '549 patent by the manufacture, use, offer to sell, sale or importation of Optimus's ANDA drug product.

176. Optimus is entitled to a judicial declaration that it has not infringed, and that the commercial manufacture, use, offer to sell, sale or importation of Optimus's ANDA drug product will not infringe, one or more claims of the '549 patent.

PRAYER FOR RELIEF

WHEREFORE, Defendants pray that this Court grant the following relief:

1. Dismissing the First Amended Complaint in its entirety with prejudice;
2. Entering judgment in favor of Optimus;
3. A declaration that the manufacture, use, offer to sell, sale or importation of Optimus's ANDA drug product has not, does not, and will not, infringe one or more claims of the RE286, '673, '117, '337, '073 and '549 patents;
4. A declaration that one or more claims of the RE286, '673, '117, '337, '073 and '549 patents are invalid for failure to satisfy or comply with 35 U.S.C. §§ 101, 102, 103, 112 and/or 282, and/or for improper double patenting;
5. Awarding Optimus its reasonable costs and attorney's fees incurred in defending this action pursuant to 35 U.S.C. §285; and
6. Awarding Optimus such other and further relief as the Court deems just and proper.

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Optimus Drugs Private Ltd.*

Dated: December 1, 2020

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

INTERCEPT PHARMACEUTICALS, INC.
and INTERCEPT PHARMA EUROPE LTD.,

Plaintiffs,

v.

OPTIMUS PHARMA PVT. LTD. and
OPTIMUS DRUGS PRIVATE LTD.,

Defendants.

C.A. No. 1:20-cv-01215-MN

CERTIFICATE OF SERVICE

I, R Touhey Myer, Esquire, hereby certify that on the date set forth below I served a true and correct copy of the foregoing *Defendants, Optimus Pharma Pvt. Ltd. and Optimus Drugs Private Ltd. 's Answer to Plaintiffs' First Amended Complaint, Affirmative Defenses and Counterclaims* by ECF only on the below listed Counsel.

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Dated: December 1, 2020