IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BIAL - PORTELA & CA S.A., BIAL - HOLDING, S.A., and SUNOVION PHARMACEUTICALS INC., Plaintiffs, v. DR. REDDY'S LABORATORIES, LTD. and DR. REDDY'S LABORATORIES, INC., Defendants.	C.A. No. 20-784-CFC

DR. REDDY'S LABORATORIES, LTD. AND DR. REDDY'S LABORATORIES, INC.'S ANSWER AND ADDITIONAL DEFENSES TO THE AMENDED COMPLAINT

Defendants Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. (collectively, "DRL"), by and through their undersigned attorneys, hereby answer the Amended Complaint of BIAL - PORTELA & CA S.A., BIAL - HOLDING, S.A. (collectively, "Bial") and Sunovion Pharmaceuticals Inc. ("Sunovion") (collectively, "Plaintiffs") as follows:

GENERAL DENIAL

Pursuant to Fed. R. Civ. P. 8(b)(3), DRL denies all allegations in Plaintiffs' Amended Complaint except those specifically admitted below.

THE PARTIES

1. DRL lacks knowledge or information sufficient to admit or deny the allegations in Paragraph 1 of the Amended Complaint, and therefore denies those allegations.

2. DRL lacks knowledge or information sufficient to admit or deny the allegations in Paragraph 2 of the Amended Complaint, and therefore denies those allegations.

3. DRL admits that APTIOM® is a pharmaceutical product approved for marketing in the United States and indicated for "the treatment of partial-onset seizures in patients 4 years of age and older." DRL lacks knowledge or information sufficient to admit or deny the remaining allegations in Paragraph 3 of the Amended Complaint, and therefore denies those allegations.

4. DRL lacks knowledge or information sufficient to admit or deny the allegations in Paragraph 4 of the Amended Complaint, and therefore denies those allegations.

5. DRL admits that Dr. Reddy's Laboratories, Ltd. is a company organized and existing under the laws of India, having a principal place of business at 8-2-337, Road No. 3, Banjara Hills, Hyderabad, Andhra Pradesh 500034, India. DRL denies the remaining allegations of Paragraph 5 of the Amended Complaint.

6. DRL admits that Dr. Reddy's Laboratories, Ltd. develops, manufactures and markets pharmaceutical products. DRL denies the remaining allegations in Paragraph 6 of the Amended Complaint.

7. Admitted.

8. Admitted.

9. DRL admits that Dr. Reddy's Laboratories, Inc. markets pharmaceutical products in the United States. DRL denies the remaining allegations in Paragraph 9 of the Amended Complaint.

10. DRL admits that Dr. Reddy's Laboratories, Inc. filed Abbreviated New Drug Application ("ANDA") No. 211238 with the United States Food and Drug Administration ("FDA") on behalf of Dr. Reddy's Laboratories, Ltd. for approval of the matters therein. DRL denies the remaining allegations in Paragraph 10 of the Amended Complaint.

11. DRL admits that Dr. Reddy's Laboratories, Inc. filed ANDA No. 211238 with the FDA on behalf of Dr. Reddy's Laboratories, Ltd. for approval of the matters therein. DRL denies the remaining allegations in Paragraph 11 of the Amended Complaint.

NATURE OF THE ACTION

12. DRL admits that the Amended Complaint purports to be a civil action for patent infringement of U.S. Patent Nos. 10,675,287 ("the'287 patent"), 10,695,354 ("the '354 patent"), and 10,702,536 ("the '536 patent") (collectively, "the patents-in-suit") arising under the patent laws of the United States. DRL further admits that the Amended Complaint purports to be an action relating to DRL's filing of ANDA No. 211238 with the FDA pursuant to Section 505(j) of the United States Food, Drug, and Cosmetic Act. DRL denies the remaining allegations in Paragraph 12 of the Amended Complaint.

13. DRL denies the allegations in Paragraph 13 of the Amended Complaint.

14. DRL admits that Plaintiffs filed a complaint against DRL in *Bial- Portela & CA S.A., et al. v. Dr. Reddy's Laboratories Ltd., et al., C.A. No. 18-341-CFC* (the "First Suit") on March 2, 2018. DRL further admits that Plaintiffs' complaint in the First Suit included allegation of infringement of U.S. Patent Nos. 8,372,431 ("the '431 patent"), 9,206,135 ("the '135 patent"), 9,566,244 ("the '244 patent"), 9,643,929 ("the '929 patent"), 9,750,747 ("the '747 patent") and 9,763,954 ("the '954 patent"). DRL further admits that DRL's ANDA No. 211238 contains a Paragraph IV Patent Certification in accordance with Section 505(j)(2)(A)(vii)(IV) and 21 CFR § 314.94(a)(12)(i)(A)(4) that the '431 patent, the '135 patent, the '244 patent, the '929 patent, the '747 patent and the '954 patent are invalid, unenforceable, or will not be infringed by the manufacture, use or sale of DRL's ANDA Product. DRL denies the remaining allegations in Paragraph 14 of the Amended Complaint.

15. DRL admits that Plaintiffs' complaint in the First Suit did not include counts for infringement of U.S. Patent No. 5,753,646 ("the '646 patent"). DRL further admits that it maintains that the '431 patent, the '135 patent, the '244 patent, the '929 patent, the '747 patent and the '954 patent are invalid, unenforceable, or will not be infringed by the manufacture, use or sale of DRL's ANDA Product. DRL denies the remaining allegations in Paragraph 15 of the Amended Complaint.

JURISDICTION AND VENUE

16. DRL incorporates by reference each of its answers to Paragraphs 1-15 above as if fully set forth herein.

17. DRL admits that the Amended Complaint states that this is a civil action for patent infringement and declaratory judgement arising under the patent laws of the United States, 35 U.S.C. § 1, *et seq*., including 35 U.S.C. § 271, and the Declaratory Judgement Act, 28 U.S.C. §§ 2201 and 2202. DRL denies the remaining allegations in Paragraph 17 of the Amended Complaint.

18. Paragraph 18 of the Amended Complaint states a conclusion of law to which no response is required.

19. For purposes of this action only, DRL will not contest venue in this Court. DRL denies the remaining allegations in Paragraph 19 of the Amended Complaint.

20. For purposes of this action only, DRL will not contest personal jurisdiction in this Court. DRL denies the remaining allegations in Paragraph 20 of the Amended Complaint.

21. For purposes of this action only, DRL will not contest personal jurisdiction in this Court. DRL denies the remaining allegations in Paragraph 21 of the Amended Complaint.

22. For purposes of this action only, DRL will not contest personal jurisdiction in this Court. DRL denies the remaining allegations in Paragraph 22 of the Amended Complaint.

23. DRL admits that Dr. Reddy's Laboratories, Inc. filed ANDA No. 211238 with the FDA on behalf of Dr. Reddy's Laboratories, Ltd. for approval of the matters therein. DRL denies the remaining allegations in Paragraph 23 of the Amended Complaint.

24. DRL admits that Dr. Reddy's Laboratories, Inc. filed ANDA No. 211238 with the FDA on behalf of Dr. Reddy's Laboratories, Ltd. for approval of the matters therein. DRL denies the remaining allegations in Paragraph 24 of the Amended Complaint.

25. DRL admits that Dr. Reddy's Laboratories, Inc. filed ANDA No. 211238 with the FDA on behalf of Dr. Reddy's Laboratories, Ltd. for approval of the matters therein. DRL denies the remaining allegations in Paragraph 25 of the Amended Complaint.

26. For purposes of this action only, DRL will not contest personal jurisdiction in this Court. DRL denies the remaining allegations in Paragraph 26 of the Amended Complaint.

27. DRL admits that Dr. Reddy's Laboratories, Inc. filed ANDA No. 211238 with the FDA on behalf of Dr. Reddy's Laboratories, Ltd. for approval of the matters therein. DRL denies the remaining allegations in Paragraph 27 of the Amended Complaint.

28. DRL admits that the alleged website speaks for itself. For purposes of this action only, DRL will not contest personal jurisdiction in this Court. DRL denies the remaining allegations in Paragraph 28 of the Amended Complaint.

29. For purposes of this action only, DRL will not contest personal jurisdiction in this Court. DRL denies the remaining allegations in Paragraph 29 of the Amended Complaint.

30. For purposes of this action only, DRL will not contest personal jurisdiction in this Court. DRL denies the remaining allegations in Paragraph 30 of the Amended Complaint.

31. For purposes of this action only, DRL will not contest personal jurisdiction in this Court. DRL denies the remaining allegations in Paragraph 31 of the Amended Complaint.

FACTUAL BACKGROUND

The NDA

32. DRL admits that the "Approved Drug Products with Therapeutic Equivalence Evaluations" ("*Orange Book*"), published by the FDA at https://www.accessdata.fda.gov/scripts/cder/ob/results_product.cfm?Appl_Type=N&Appl_No=022416#29366, lists "Sunovion Pharmaceuticals Inc" as the holder of New Drug Application ("NDA") No. 022416 for APTIOM® (Eslicarbazepine Acetate) Tablets, in 200, 400, 600 and 800 mg dosage strengths. DRL lacks knowledge or information sufficient to admit or deny the remaining allegations in Paragraph 32 of the Amended Complaint, and therefore denies those allegations.

33. DRL lacks knowledge or information sufficient to admit or deny the allegations in Paragraph 33 of the Amended Complaint, and therefore denies those allegations.

34. DRL lacks knowledge or information sufficient to admit or deny the allegations in Paragraph 34 of the Amended Complaint, and therefore denies those allegations.

35. DRL lacks knowledge or information sufficient to admit or deny the allegations in Paragraph 35 of the Amended Complaint, and therefore denies those allegations.

36. DRL admits that the presently approved Prescribing Information for APTIOM® is a document that speaks for itself. DRL lacks knowledge or information sufficient to admit or deny the remaining allegations in Paragraph 36 of the Amended Complaint, and therefore denies those allegations.

The Patents-in-Suit

37. DRL admits that the '287 patent, on its face, is entitled "Methods of Treatment of Partial Onset Seizures Using Eslicarbazepine Acetate" and states the date of issue as June 9, 2020.

DRL further admits that Exhibit A purports to be a true and correct copy of the '287 patent. DRL denies the remaining allegations in Paragraph 37 of the Amended Complaint.

38. Paragraph 38 of the Amended Complaint states legal conclusions as to which no response is required. To the extent a response is required, DRL admits that the '287 patent, on its face, lists "BIAL – Portela & CA S.A., Sao Mamede do Coronado (PT)" as the assignee, and that according to the Orange Book published by the FDA, the '287 patent will expire on May 6, 2025. DRL lacks knowledge or information sufficient to admit or deny the remaining allegations in Paragraph 38 of the Amended Complaint, and therefore denies those allegations.

39. On information and belief DRL admits that the '287 patent is listed in the Orange Book published by the FDA for NDA No. 022416 for Eslicarbazepine Acetate (APTIOM) Tablets. DRL denies the remaining allegations of Paragraph 39 of the Amended Complaint.

40. Paragraph 40 of the Amended Complaint states legal conclusions as to which no response is required. To the extent a response is required, DRL admits that the '287 patent speaks for itself. DRL denies the remaining allegations of Paragraph 40 of the Amended Complaint.

41. DRL admits that the Prescribing Information for APTIOM® is a document that speaks for itself. DRL denies the remaining allegations of Paragraph 41 of the Amended Complaint.

42. Paragraph 42 of the Amended Complaint states legal conclusions as to which no response is required. To the extent a response is required, DRL admits that the '287 patent speaks for itself. DRL denies the remaining allegations of Paragraph 42 of the Amended Complaint.

43. DRL admits that the '354 patent, on its face, is entitled "Methods of Treatment of Partial Onset Seizures Using Eslicarbazepine Acetate" and states the date of issue as June 30, 2020.

DRL further admits that Exhibit B purports to be a true and correct copy of the '354 patent. DRL denies the remaining allegations in Paragraph 43 of the Amended Complaint.

44. Paragraph 44 of the Amended Complaint states legal conclusions as to which no response is required. To the extent a response is required, DRL admits that the '354 patent, on its face, lists "BIAL – Portela & CA S.A., Sao Mamede do Coronado (PT)" as the assignee, and that according to the Orange Book published by the FDA, the '354 patent will expire on May 6, 2025. DRL lacks knowledge or information sufficient to admit or deny the remaining allegations in Paragraph 44 of the Amended Complaint, and therefore denies those allegations.

45. On information and belief DRL admits that the '354 patent is listed in the Orange Book published by the FDA for NDA No. 022416 for Eslicarbazepine Acetate (APTIOM) Tablets. DRL denies the remaining allegations of Paragraph 45 of the Amended Complaint.

46. Paragraph 46 of the Amended Complaint states legal conclusions as to which no response is required. To the extent a response is required, DRL admits that the '354 patent speaks for itself. DRL denies the remaining allegations of Paragraph 46 of the Amended Complaint.

47. DRL admits that the Prescribing Information for APTIOM® is a document that speaks for itself. DRL denies the remaining allegations of Paragraph 47 of the Amended Complaint.

48. Paragraph 48 of the Amended Complaint states legal conclusions as to which no response is required. To the extent a response is required, DRL admits that the '354 patent speaks for itself. DRL denies the remaining allegations of Paragraph 48 of the Amended Complaint.

49. DRL admits that the '536 patent, on its face, is entitled "Methods of Treatment of Partial Onset Seizures Using Eslicarbazepine Acetate" and states the date of issue as July 7, 2020.

DRL further admits that Exhibit C purports to be a true and correct copy of the '536 patent. DRL denies the remaining allegations in Paragraph 49 of the Amended Complaint.

50. Paragraph 50 of the Amended Complaint states legal conclusions as to which no response is required. To the extent a response is required, DRL admits that the '536 patent, on its face, lists "BIAL – Portela & CA S.A., S. Mamede do Coronado (PT)" as the assignee, and that according to the Orange Book published by the FDA, the '536 patent will expire on May 6, 2020. DRL lacks knowledge or information sufficient to admit or deny the remaining allegations in Paragraph 50 of the Amended Complaint, and therefore denies those allegations.

51. On information and belief DRL admits that the '536 patent is listed in the Orange Book published by the FDA for NDA No. 022416 for Eslicarbazepine Acetate (APTIOM) Tablets. DRL lacks knowledge or information sufficient to admit or deny the remaining allegations in Paragraph 51 of the Amended Complaint, and therefore denies those allegations.

52. Paragraph 52 of the Amended Complaint states legal conclusions as to which no response is required. To the extent a response is required, DRL admits that the '536 patent speaks for itself. DRL denies the remaining allegations of Paragraph 52 of the Amended Complaint.

53. DRL admits that the Prescribing Information for APTIOM® is a document that speaks for itself. DRL denies the remaining allegations of Paragraph 53 of the Amended Complaint.

54. Paragraph 54 of the Amended Complaint states legal conclusions as to which no response is required. To the extent a response is required, DRL admits that the '536 patent speaks for itself. DRL denies the remaining allegations of Paragraph 54 of the Amended Complaint.

The ANDA

55. DRL admits that Dr. Reddy's Laboratories, Inc. filed ANDA No. 211238 with the FDA on behalf of Dr. Reddy's Laboratories, Ltd. for approval of the matters therein. DRL denies the remaining allegations in Paragraph 55 of the Amended Complaint.

56. DRL admits that DRL's ANDA contains a Paragraph IV Patent Certification in accordance with Section 505(j)(2)(A)(vii)(IV) and 21 CFR § 314.94(a)(12)(i)(A)(4) that the '431 patent, the '135 patent, the '244 patent, the '929 patent, the '747 patent and the '954 patent are invalid, unenforceable, or will not be infringed by the manufacture, use or sale of DRL's ANDA Product. DRL denies the remaining allegations in Paragraph 56 of the Amended Complaint.

57. DRL admits that according to the Orange Book published by the FDA, the '135 and '929 patents will expire on April 21, 2026 and the patents-in-suit will expire on May 6, 2025. DRL denies the remaining allegations in Paragraph 57 of the Amended Complaint.

58. DRL admits that Dr. Reddy's Laboratories, Inc. filed ANDA No. 211238 with the FDA on behalf of Dr. Reddy's Laboratories, Ltd. for approval of the matters therein before DRL sent copies of its "Notice of Paragraph IV Certification" ("DRL's Notice Letter") dated January 17, 2018 with respect to DRL's ANDA Product and the '431 patent, the '135 patent, the '244 patent, the '929 patent, the '747 patent and the '954 patent to Sunovion and Bial. DRL further admits that ANDA No. 211238 is pending before the FDA. DRL denies the remaining allegations in Paragraph 58 of the Amended Complaint.

59. DRL admits that Dr. Reddy's Laboratories, Inc. filed ANDA No. 211238 with the FDA on behalf of Dr. Reddy's Laboratories, Ltd. for approval of the matters therein. DRL denies the remaining allegations in Paragraph 59 of the Amended Complaint.

COUNT I

(ALLEGED INFRINGEMENT OF THE '287 PATENT UNDER 35 U.S.C. § 271(e)(2))

60. DRL incorporates by reference each of its answers to Paragraphs 1-59 above as if fully set forth herein.

61. DRL admits that Dr. Reddy's Laboratories, Inc. filed ANDA No. 211238 with the FDA on behalf of Dr. Reddy's Laboratories, Ltd. for approval of the matters therein. DRL denies the remaining allegations in Paragraph 61 of the Amended Complaint.

62. DRL admits that Dr. Reddy's Laboratories, Inc. filed ANDA No. 211238 with the FDA on behalf of Dr. Reddy's Laboratories, Ltd. for approval of the matters therein and that said ANDA is a document that speaks for itself. DRL denies the remaining allegations in Paragraph 62 of the Amended Complaint.

63. DRL admits that Dr. Reddy's Laboratories, Inc. filed ANDA No. 211238 with the FDA on behalf of Dr. Reddy's Laboratories, Ltd. for approval of the matters therein prior to the issuance of the '287 patent. DRL denies the remaining allegations of Paragraph 63 of the Amended Complaint.

64. DRL denies the allegations in Paragraph 64 of the Amended Complaint.

65. DRL admits that Dr. Reddy's Laboratories, Inc. filed ANDA No. 211238 with the FDA on behalf of Dr. Reddy's Laboratories, Ltd. for approval of the matters therein. DRL denies the remaining allegations in Paragraph 65 of the Amended Complaint.

66. DRL denies the allegations in Paragraph 66 of the Amended Complaint.

67. DRL denies the allegations in Paragraph 67 of the Amended Complaint.

68. DRL denies the allegations in Paragraph 68 of the Amended Complaint.

69. DRL admits that Dr. Reddy's Laboratories, Inc. filed ANDA No. 211238 with the FDA on behalf of Dr. Reddy's Laboratories, Ltd. for approval of the matters therein. DRL denies the remaining allegations in Paragraph 69 of the Amended Complaint.

70. DRL admits that Dr. Reddy's Laboratories, Inc. filed ANDA No. 211238 with the FDA on behalf of Dr. Reddy's Laboratories, Ltd. for approval of the matters therein. DRL denies the remaining allegations in Paragraph 70 of the Amended Complaint.

71. DRL denies the allegations in Paragraph 71 of the Amended Complaint.

72. DRL admits that Dr. Reddy's Laboratories, Inc. filed ANDA No. 211238 with the FDA on behalf of Dr. Reddy's Laboratories, Ltd. for approval of the matters therein. DRL denies the remaining allegations in Paragraph 72 of the Amended Complaint.

73. DRL denies the allegations in Paragraph 73 of the Amended Complaint.

COUNT II

(DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '287 PATENT)

74. DRL incorporates by reference each of its answers to Paragraphs 1-73 above as if fully set forth herein.

75. DRL admits that the Amended Complaint states that this is a civil action for patent infringement and declaratory judgement arising under the patent laws of the United States, 35 U.S.C. § 1, *et seq*., including 35 U.S.C. § 271, and the Declaratory Judgement Act, 28 U.S.C. §§ 2201 and 2202. DRL denies the remaining allegations in Paragraph 75.

76. Paragraph 76 of the Amended Complaint states legal conclusions as to which no response is required. To the extent a response is required, DRL admits that Dr. Reddy's Laboratories, Inc. filed ANDA No. 211238 with the FDA on behalf of Dr. Reddy's Laboratories,

Ltd. for approval of the matters therein. DRL denies the remaining allegations in Paragraph 76 of the Amended Complaint.

77. DRL admits that Dr. Reddy's Laboratories, Inc. filed ANDA No. 211238 with the FDA on behalf of Dr. Reddy's Laboratories, Ltd. for approval of the matters therein. DRL denies the remaining allegations in Paragraph 77 of the Amended Complaint.

78. DRL admits that Dr. Reddy's Laboratories, Inc. filed ANDA No. 211238 with the FDA on behalf of Dr. Reddy's Laboratories, Ltd. for approval of the matters therein. DRL denies the remaining allegations in Paragraph 78 of the Amended Complaint.

79. DRL lacks knowledge or information sufficient to admit or deny the allegations in Paragraph 79 of the Amended Complaint, and therefore denies those allegations.

80. DRL admits that Dr. Reddy's Laboratories, Inc. filed ANDA No. 211238 with the FDA on behalf of Dr. Reddy's Laboratories, Ltd. for approval of the matters therein. DRL denies the remaining allegations in Paragraph 80 of the Amended Complaint.

81. DRL denies the allegations in Paragraph 81 of the Amended Complaint.

82. DRL admits that Dr. Reddy's Laboratories, Inc. filed ANDA No. 211238 with the FDA on behalf of Dr. Reddy's Laboratories, Ltd. for approval of the matters therein. DRL denies the remaining allegations in Paragraph 82 of the Amended Complaint.

83. DRL admits that Dr. Reddy's Laboratories, Inc. filed ANDA No. 211238 with the FDA on behalf of Dr. Reddy's Laboratories, Ltd. for approval of the matters therein. DRL denies the remaining allegations in Paragraph 83 of the Amended Complaint.

84. DRL denies the allegations in Paragraph 84 of the Amended Complaint.

85. DRL admits that DRL is aware of the '287 patent. DRL denies the remaining allegations in Paragraph 85 of the Amended Complaint.

86. DRL admits that Dr. Reddy's Laboratories, Inc. filed ANDA No. 211238 with the FDA on behalf of Dr. Reddy's Laboratories, Ltd. for approval of the matters therein. DRL denies the remaining allegations in Paragraph 86 of the Amended Complaint.

87. DRL denies the allegations in Paragraph 87 of the Amended Complaint.

88. DRL denies the allegations in Paragraph 88 of the Amended Complaint.

89. DRL admits that Dr. Reddy's Laboratories, Inc. filed ANDA No. 211238 with the FDA on behalf of Dr. Reddy's Laboratories, Ltd. for approval of the matters therein. DRL denies the remaining allegations in Paragraph 89 of the Amended Complaint.

90. DRL denies the allegations in Paragraph 90 of the Amended Complaint.

91. DRL denies the allegations in Paragraph 91 of the Amended Complaint.

92. DRL denies the allegations in Paragraph 92 of the Amended Complaint.

COUNT III

(ALLEGED INFRINGEMENT OF THE '354 PATENT UNDER 35 U.S.C. § 271(e)(2))

93. DRL incorporates by reference each of its answers to Paragraphs 1-92 above as if fully set forth herein.

94. DRL admits that Dr. Reddy's Laboratories, Inc. filed ANDA No. 211238 with the FDA on behalf of Dr. Reddy's Laboratories, Ltd. for approval of the matters therein. DRL denies the remaining allegations in Paragraph 94 of the Amended Complaint.

95. DRL admits that Dr. Reddy's Laboratories, Inc. filed ANDA No. 211238 with the FDA on behalf of Dr. Reddy's Laboratories, Ltd. for approval of the matters therein and that said ANDA is a document that speaks for itself. DRL denies the remaining allegations in Paragraph 95 of the Amended Complaint.

96. DRL admits that Dr. Reddy's Laboratories, Inc. filed ANDA No. 211238 with the FDA on behalf of Dr. Reddy's Laboratories, Ltd. for approval of the matters therein prior to the issuance of the '354 patent. DRL denies the remaining allegations of Paragraph 96.

97. DRL denies the allegations in Paragraph 97 of the Amended Complaint.

98. DRL admits that Dr. Reddy's Laboratories, Inc. filed ANDA No. 211238 with the FDA on behalf of Dr. Reddy's Laboratories, Ltd. for approval of the matters therein. DRL denies the remaining allegations in Paragraph 98 of the Amended Complaint.

99. DRL denies the allegations in Paragraph 99 of the Amended Complaint.

100. DRL denies the allegations in Paragraph 100 of the Amended Complaint.

101. DRL admits that DRL is aware of the '354 patent. DRL denies the remaining allegations in Paragraph 101 of the Amended Complaint.

102. DRL admits that Dr. Reddy's Laboratories, Inc. filed ANDA No. 211238 with the FDA on behalf of Dr. Reddy's Laboratories, Ltd. for approval of the matters therein. DRL denies the remaining allegations in Paragraph 102 of the Amended Complaint.

103. DRL admits that Dr. Reddy's Laboratories, Inc. filed ANDA No. 211238 with the FDA on behalf of Dr. Reddy's Laboratories, Ltd. for approval of the matters therein. DRL denies the remaining allegations in Paragraph 103 of the Amended Complaint.

104. DRL denies the allegations in Paragraph 104 of the Amended Complaint.

105. DRL admits that Dr. Reddy's Laboratories, Inc. filed ANDA No. 211238 with the FDA on behalf of Dr. Reddy's Laboratories, Ltd. for approval of the matters therein. DRL denies the remaining allegations in Paragraph 105 of the Amended Complaint.

106. DRL denies the allegations in Paragraph 106 of the Amended Complaint.

COUNT IV

(DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '354 PATENT)

107. DRL incorporates by reference each of its answers to Paragraphs 1-106 above as if fully set forth herein.

108. DRL admits that the Amended Complaint states that this is a civil action for patent infringement and declaratory judgement arising under the patent laws of the United States, 35 U.S.C. § 1, *et seq*., including 35 U.S.C. § 271, and the Declaratory Judgement Act, 28 U.S.C. §§ 2201 and 2202. DRL denies the remaining allegations in Paragraph 108.

109. Paragraph 109 of the Amended Complaint states legal conclusions as to which no response is required. To the extent a response is required, DRL admits that Dr. Reddy's Laboratories, Inc. filed ANDA No. 211238 with the FDA on behalf of Dr. Reddy's Laboratories, Ltd. for approval of the matters therein. DRL denies the remaining allegations in Paragraph 109 of the Amended Complaint.

110. DRL admits that Dr. Reddy's Laboratories, Inc. filed ANDA No. 211238 with the FDA on behalf of Dr. Reddy's Laboratories, Ltd. for approval of the matters therein. DRL denies the remaining allegations in Paragraph 110 of the Amended Complaint.

111. DRL admits that Dr. Reddy's Laboratories, Inc. filed ANDA No. 211238 with the FDA on behalf of Dr. Reddy's Laboratories, Ltd. for approval of the matters therein. DRL denies the remaining allegations in Paragraph 111 of the Amended Complaint.

112. DRL lacks knowledge or information sufficient to admit or deny the allegations in Paragraph 112 of the Amended Complaint, and therefore denies those allegations.

113. DRL admits that Dr. Reddy's Laboratories, Inc. filed ANDA No. 211238 with the FDA on behalf of Dr. Reddy's Laboratories, Ltd. for approval of the matters therein. DRL denies the remaining allegations in Paragraph 113 of the Amended Complaint.

114. DRL denies the allegations in Paragraph 114 of the Amended Complaint.

115. DRL admits that Dr. Reddy's Laboratories, Inc. filed ANDA No. 211238 with the FDA on behalf of Dr. Reddy's Laboratories, Ltd. for approval of the matters therein. DRL denies the remaining allegations in Paragraph 115 of the Amended Complaint.

116. DRL admits that Dr. Reddy's Laboratories, Inc. filed ANDA No. 211238 with the FDA on behalf of Dr. Reddy's Laboratories, Ltd. for approval of the matters therein. DRL denies the remaining allegations in Paragraph 116 of the Amended Complaint.

117. DRL denies the allegations in Paragraph 117 of the Amended Complaint.

118. DRL admits that DRL is aware of the '354 patent. DRL denies the remaining allegations in Paragraph 118 of the Amended Complaint.

119. DRL admits that Dr. Reddy's Laboratories, Inc. filed ANDA No. 211238 with the FDA on behalf of Dr. Reddy's Laboratories, Ltd. for approval of the matters therein. DRL denies the remaining allegations in Paragraph 119 of the Amended Complaint.

120. DRL denies the allegations in Paragraph 120 of the Amended Complaint.

121. DRL denies the allegations in Paragraph 121 of the Amended Complaint.

122. DRL admits that Dr. Reddy's Laboratories, Inc. filed ANDA No. 211238 with the FDA on behalf of Dr. Reddy's Laboratories, Ltd. for approval of the matters therein. DRL denies the remaining allegations in Paragraph 122 of the Amended Complaint.

123. DRL denies the allegations in Paragraph 123 of the Amended Complaint.

124. DRL denies the allegations in Paragraph 124 of the Amended Complaint.

125. DRL denies the allegations in Paragraph 125 of the Amended Complaint.

COUNT V

(ALLEGED INFRINGEMENT OF THE'536 PATENT UNDER 35 U.S.C. § 271(e)(2))

126. DRL incorporates by reference each of its answers to Paragraphs 1-125 above as if fully set forth herein.

127. DRL admits that Dr. Reddy's Laboratories, Inc. filed ANDA No. 211238 with the FDA on behalf of Dr. Reddy's Laboratories, Ltd. for approval of the matters therein. DRL denies the remaining allegations in Paragraph 127 of the Amended Complaint.

128. DRL admits that Dr. Reddy's Laboratories, Inc. filed ANDA No. 211238 with the FDA on behalf of Dr. Reddy's Laboratories, Ltd. for approval of the matters therein and that said ANDA is a document that speaks for itself. DRL denies the remaining allegations in Paragraph 128 of the Amended Complaint.

129. DRL admits that Dr. Reddy's Laboratories, Inc. filed ANDA No. 211238 with the FDA on behalf of Dr. Reddy's Laboratories, Ltd. for approval of the matters therein prior to the issuance of the '536 patent. DRL denies the remaining allegations of Paragraph 129.

130. DRL denies the allegations in Paragraph 130 of the Amended Complaint.

131. DRL admits that Dr. Reddy's Laboratories, Inc. filed ANDA No. 211238 with the FDA on behalf of Dr. Reddy's Laboratories, Ltd. for approval of the matters therein. DRL denies the remaining allegations in Paragraph 131 of the Amended Complaint.

132. DRL denies the allegations in Paragraph 132 of the Amended Complaint.

133. DRL denies the allegations in Paragraph 133 of the Amended Complaint.

134. DRL admits that DRL is aware of the '536 patent. DRL denies the remaining allegations in Paragraph 134 of the Amended Complaint.

135. DRL admits that Dr. Reddy's Laboratories, Inc. filed ANDA No. 211238 with the FDA on behalf of Dr. Reddy's Laboratories, Ltd. for approval of the matters therein. DRL denies the remaining allegations in Paragraph 135 of the Amended Complaint.

136. DRL admits that Dr. Reddy's Laboratories, Inc. filed ANDA No. 211238 with the FDA on behalf of Dr. Reddy's Laboratories, Ltd. for approval of the matters therein. DRL denies the remaining allegations in Paragraph 136 of the Amended Complaint.

137. DRL denies the allegations in Paragraph 137 of the Amended Complaint.

138. DRL admits that Dr. Reddy's Laboratories, Inc. filed ANDA No. 211238 with the FDA on behalf of Dr. Reddy's Laboratories, Ltd. for approval of the matters therein. DRL denies the remaining allegations in Paragraph 138 of the Amended Complaint.

139. DRL denies the allegations in Paragraph 139 of the Amended Complaint.

COUNT VI

(DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '536 PATENT)

140. DRL incorporates by reference each of its answers to Paragraphs 1-139 above as if fully set forth herein.

141. DRL admits that the Amended Complaint states that this is a civil action for patent infringement and declaratory judgement arising under the patent laws of the United States, 35 U.S.C. § 1, *et seq*., including 35 U.S.C. § 271, and the Declaratory Judgement Act, 28 U.S.C. §§ 2201 and 2202. DRL denies the remaining allegations in Paragraph 141.

142. Paragraph 142 of the Amended Complaint states legal conclusions as to which no response is required. To the extent a response is required, DRL admits that Dr. Reddy's Laboratories, Inc. filed ANDA No. 211238 with the FDA on behalf of Dr. Reddy's Laboratories,

Ltd. for approval of the matters therein. DRL denies the remaining allegations in Paragraph 142 of the Amended Complaint.

143. DRL admits that Dr. Reddy's Laboratories, Inc. filed ANDA No. 211238 with the FDA on behalf of Dr. Reddy's Laboratories, Ltd. for approval of the matters therein. DRL denies the remaining allegations in Paragraph 143 of the Amended Complaint.

144. DRL admits that Dr. Reddy's Laboratories, Inc. filed ANDA No. 211238 with the FDA on behalf of Dr. Reddy's Laboratories, Ltd. for approval of the matters therein. DRL denies the remaining allegations in Paragraph 144 of the Amended Complaint.

145. DRL lacks knowledge or information sufficient to admit or deny the allegations in Paragraph 145 of the Amended Complaint, and therefore denies those allegations.

146. DRL admits that Dr. Reddy's Laboratories, Inc. filed ANDA No. 211238 with the FDA on behalf of Dr. Reddy's Laboratories, Ltd. for approval of the matters therein. DRL denies the remaining allegations in Paragraph 146 of the Amended Complaint.

147. DRL denies the allegations in Paragraph 147 of the Amended Complaint.

148. DRL admits that Dr. Reddy's Laboratories, Inc. filed ANDA No. 211238 with the FDA on behalf of Dr. Reddy's Laboratories, Ltd. for approval of the matters therein. DRL denies the remaining allegations in Paragraph 148 of the Amended Complaint.

149. DRL admits that Dr. Reddy's Laboratories, Inc. filed ANDA No. 211238 with the FDA on behalf of Dr. Reddy's Laboratories, Ltd. for approval of the matters therein. DRL denies the remaining allegations in Paragraph 149 of the Amended Complaint.

150. DRL denies the allegations in Paragraph 150 of the Amended Complaint.

151. DRL admits that DRL is aware of the '536 patent. DRL denies the remaining allegations in Paragraph 151 of the Amended Complaint.

152. DRL admits that Dr. Reddy's Laboratories, Inc. filed ANDA No. 211238 with the FDA on behalf of Dr. Reddy's Laboratories, Ltd. for approval of the matters therein. DRL denies the remaining allegations in Paragraph 152 of the Amended Complaint.

153. DRL denies the allegations in Paragraph 153 of the Amended Complaint.

154. DRL denies the allegations in Paragraph 154 of the Amended Complaint.

155. DRL admits that Dr. Reddy's Laboratories, Inc. filed ANDA No. 211238 with the FDA on behalf of Dr. Reddy's Laboratories, Ltd. for approval of the matters therein. DRL denies the remaining allegations in Paragraph 155 of the Amended Complaint.

156. DRL denies the allegations in Paragraph 156 of the Amended Complaint.

157. DRL denies the allegations in Paragraph 157 of the Amended Complaint.

158. DRL denies the allegations in Paragraph 158 of the Amended Complaint.

RESPONSE TO PLAINTIFFS' REQUEST FOR RELIEF

DRL denies that Plaintiffs are entitled to the relief they seek in Paragraphs (A) – (I) or any relief at all for the allegations made in the Amended Complaint.

ADDITIONAL DEFENSES

On information and belief, DRL alleges and asserts the following Additional Defenses to Plaintiffs' Amended Complaint. DRL asserts these Additional Defenses without conceding that it bears the burden of proof on them.

FIRST DEFENSE
(Failure to State a Claim Upon Which Relief Can be Granted)

Each of Plaintiffs' allegations of infringement of each of the patents-in-suit fails to state a claim upon which relief can be granted.

SECOND DEFENSE
(Non-infringement of the '287, '354 and '536 patents)

The manufacture, use, sale, offer for sale and/or importation into the United States of DRL's ANDA Product does not and will not directly or indirectly infringe, induce infringement of, or contribute to the infringement of any valid and enforceable claim of the '287, '354 and '536 patents, either literally or under the doctrine of equivalents.

THIRD DEFENSE
(Invalidity of the '287, '354 and '536 patents)

The claims of the '287, '354 and '536 patents are invalid for failing to satisfy one or more of the requirements for patentability of Title 35 of the United States Code, including 35 U.S.C. §§ 101, 102, 103 and/or 112, and/or non-statutory double patenting.

RESERVATION OF ADDITIONAL DEFENSES

DRL reserves the right to assert additional defenses in the event that discovery or other analysis indicates that additional defenses are appropriate, including, but not limited to, defenses of unenforceability, as well as any defense(s) raised by a defendant in a consolidated action.

REQUEST FOR RELIEF

WHEREFORE, DRL respectfully requests the following relief:

A. Dismissing the Amended Complaint with prejudice and denying each request for relief made by Plaintiffs;

B. Adjudging that no valid and enforceable claim of the '287, '354 and '536 patents is infringed, directly or indirectly, by the manufacture, use, sale, offer for sale in the United States and/or importation into the United States of DRL's eslicarbazepine acetate tablets, 200, 400, 600, and 800 mg, that are the subject of ANDA No. 211238, either literally or under the doctrine of equivalents;

C. Adjudging that the '287, '354 and '536 patents are invalid;

D. Adjudging that this is an exceptional case under 35 U.S.C. § 285 and awarding DRL its attorneys' fees, costs, and expenses in this action; and

E. Awarding DRL its costs and such other and further relief as the Court deems just and proper.

Dated: August 11, 2020

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