IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PFIZER INC., WARNER-LAMBERT COMPANY LLC, PF PRISM C.V., PFIZER MANUFACTURING HOLDINGS LLC and PFIZER PFE IRELAND PHARMACEUTICALS HOLDING 1 B.V.,	)	
Plaintiff,	)	
v.	)	C.A. No. 19-CV-00750-CFC
DR. REDDY'S LABORATORIES, INC. and DR. REDDY'S LABORATORIES, LTD.,	)	
Defendants.	)	

DEFENDANT'S ANSWER
TO PLAINTIFFS' COMPLAINT

Defendants Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. (individually and collectively "DRL") hereby answer the Complaint for Patent Infringement of Pfizer Inc., Warner-Lambert Company LLC, PF PRISM C.V., Pfizer Manufacturing Holdings LLC, and Pfizer PFE Ireland Pharmaceuticals Holding 1 B.V. (collectively, "Pfizer" or "Plaintiffs") as follows:

1. DRL admits that Plaintiffs purport to bring this action under the patent laws of the United States and under 28 U.S.C. §§ 2201 and 2202. DRL admits that the purported action by Pfizer relates to U.S. Patent No. 6,936,612 ("the '612 patent"), U.S. Patent No. 7,208,489 ("the '489 patent"), and U.S. Patent No. 7,456,168 ("the '168 patent") (collectively, "the patents-in-suit"). DRL denies the remaining allegations of paragraph 1.

2. DRL admits that DRL notified Pfizer by letter dated March 19, 2019 ("DRL's Notice Letter") that it had submitted to the FDA ANDA No. 213091 ("DRL's ANDA") with a Paragraph IV certification to obtain approval to engage in the commercial manufacture, use or

sale of palbociclib capsules, 75 mg, 100 mg, and 125 mg prior to the expiration of the patents-in-suit.

THE PARTIES

3. DRL admits that the Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") entry for New Drug Application ("NDA") No. 207103 for palbociclib lists Pfizer Inc. as the applicant. DRL lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations in paragraph 3 and therefore denies them.

4. DRL lacks knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 4 and therefore denies them.

5. DRL lacks knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 5 and therefore denies them.

6. DRL lacks knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 6 and therefore denies them.

7. DRL admits that Dr. Reddy's Laboratories, Ltd. is a company organized and existing under the laws of the Republic of India with its principal place of business at 8-2-337, Road No. 3, Banjara Hills, Hyderabad 50034, Telangana, India. DRL denies the remaining allegations in paragraph 7.

8. DRL admits that Dr. Reddy's Laboratories, Inc. is a New Jersey corporation having a place of business at 107 College Road East, Princeton, New Jersey 08540. DRL admits that Dr. Reddy's Laboratories, Inc. sells pharmaceutical products in the U.S. market. DRL denies the remaining allegations in paragraph 8.

9. DRL admits that Dr. Reddy's Laboratories, Inc. is a wholly owned subsidiary of Dr. Reddy's Laboratories, Ltd.

10. Paragraph 10 states legal conclusions to which no response is required. To the extent a response is required, DRL denies the allegations.

11. DRL admits that DRL Ltd. intends to engage in the manufacture of DRL's proposed ANDA Product and DRL Inc. intends to engage in marketing, selling, and distribution of DRL's proposed ANDA Product in the United States upon approval of its ANDA. DRL denies the remaining allegations in paragraph 11.

12. Paragraph 12 states legal conclusions to which no response is required. To the extent a response is required, DRL denies the allegations.

JURISDICTION

13. This paragraph contains legal conclusions to which no answer is required. To the extent that a response is required, DRL admits that Pfizer purports to base subject matter jurisdiction on 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

14. DRL admits that Dr. Reddy's Laboratories, Inc. develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs in the United States. The remainder of paragraph 14 contains legal conclusions to which no answer is required. To the extent that a response is required, DRL denies the remaining allegations in paragraph 14.

15. DRL admits that Dr. Reddy's Laboratories, Inc. develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs in the United States. The remainder of paragraph 15 contains legal conclusions to which no answer is required. To the extent that a response is required, DRL denies the remaining allegations in paragraph 15.

16. DRL admits that it has previously filed certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), has served notice letters concerning those certifications on other pharmaceutical companies, and has participated in litigation arising from the process

contemplated by the Hatch-Waxman Act. DRL denies the remaining allegations in paragraph 16.

17. DRL admits that it directed DRL's Notice Letter to Pfizer. DRL admits that DRL's Notice Letter triggered the forty-five day period for Pfizer to bring an action for patent infringement under the Hatch-Waxman Act. DRL denies the remaining allegations in paragraph 17.

18. DRL admits that it has been a litigant in connection with other infringement actions under the Hatch-Waxman Act. DRL denies the remaining allegations in paragraph 18.

19. DRL admits that DRL intends to engage in the manufacture, marketing, selling, and distribution of DRL's proposed ANDA Product upon approval of its ANDA. DRL denies the remaining allegations in paragraph 19.

20. DRL admits that it derives revenue from pharmaceutical products marketed in Delaware. DRL denies the remaining allegations in paragraph 20.

COUNT I – INFRINGEMENT OF THE '612 PATENT

21. DRL incorporates by reference each of its responses to Paragraphs 1-20 as though fully set forth herein.

22. DRL admits that the face of the '612 patent lists Mark Barvian, Richard J. Booth, John Quin, III, Joseph T. Repine, Derek J. Sheehan, Peter L. Toogood, Scott N. Vanderwel, and Hairong Zhou as inventors. DRL otherwise lacks knowledge or information regarding inventorship of the '612 patent sufficient to form a belief about the truth of any remaining allegations in paragraph 22 and therefore denies them.

23. DRL admits that the '612 patent is entitled "2-(Pyridin-2-ylamino)-pyrido[2,3-d]pyrimidin-7-ones." DRL admits that the face of the '612 patent states that it was issued on August 30, 2005. DRL avers that the allegation that the '612 patent was duly and legally issued

states a legal conclusion to which no response is required, but to the extent a response is required, DRL denies the allegation.

24. DRL admits that the face of the ’612 patent identifies Warner-Lambert Company as the assignee. DRL lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations in paragraph 24 and therefore denies them.

25. Admitted.

26. Admitted.

27. DRL admits that the ’612 patent is listed in the Orange Book with respect to IBRANCE®. DRL denies the remaining allegations in paragraph 27.

28. DRL admits that in DRL’s Notice Letter DRL notified Pfizer of the submission of DRL’s ANDA to the FDA. DRL admits that the purpose of this submission was to obtain approval under the FDCA to market DRL’s ANDA Product in the United States. DRL denies the remaining allegations in paragraph 28.

29. Admitted.

30. Denied.

31. DRL admits that DRL’s Notice Letter provided a detailed explanation regarding the invalidity of claims 1 and 2 of the ’612 patent. DRL denies the remaining allegations in paragraph 31. DRL’s Notice Letter expressly reserves the right to raise additional defenses beyond those explained in the Notice Letter.

32. Denied.

33. DRL admits that DRL intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of DRL’s proposed ANDA Product upon approval of its ANDA. DRL denies the remaining allegations in paragraph 33.

34. Denied.

35. Denied.

36. Denied.

37. Denied.

38. DRL admits that DRL intends to manufacture, offer for sale, sell, distribute, and/or import DRL's proposed ANDA Product following approval of its ANDA. DRL denies the remaining allegations in paragraph 38.

39. Denied.

40. Denied.

41. Denied.

42. Denied.

COUNT II – DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '612 PATENT

43. DRL incorporates by reference each of its responses to Paragraphs 1-42 as though fully set forth herein.

44. This paragraph contains legal conclusions to which no answer is required. To the extent that a response is required, DRL admits that Pfizer purports to base subject matter jurisdiction on 28 U.S.C. §§ 2201 and 2202.

45. Admitted.

46. Admitted.

47. DRL admits that in DRL's Notice Letter DRL notified Pfizer of the submission of DRL's ANDA to the FDA. DRL admits that the purpose of this submission was to obtain approval under the FDCA to market DRL's ANDA product in the United States. DRL denies the remaining allegations in paragraph 47.

48. Admitted.

49. Denied.

50. DRL admits that DRL's Notice Letter provided a detailed explanation regarding the invalidity of claims 1 and 2 of the '612 patent. DRL denies the remaining allegations in paragraph 50. DRL's Notice Letter expressly reserves the right to raise additional defenses beyond those explained in the Notice Letter

51. DRL admits that DRL intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of DRL's proposed ANDA Product upon approval of its ANDA. DRL denies the remaining allegations in paragraph 51.

52. Denied.

53. Denied.

54. Denied.

55. Denied.

56. DRL admits that DRL intends to manufacture, offer for sale, sell, distribute, and/or import DRL's proposed ANDA Product upon approval of its ANDA. DRL denies the remaining allegations in paragraph 56.

57. Denied.

58. Denied.

59. Denied.

60. Denied.

COUNT III – INFRINGEMENT OF THE '489 PATENT

61. DRL incorporates by reference each of its responses to Paragraphs 1-60 as though fully set forth herein.

62. DRL admits that the face of the '489 patent lists Mark Barvian, Richard J. Booth, John Quin, III, Joseph T. Repine, Derek J. Seehan, Peter L. Toogood, Scott N. Vanderwel, and

Hairong Zhou as inventors. DRL otherwise lacks knowledge or information regarding inventorship of the '489 patent sufficient to form a belief about the truth of any remaining allegations in paragraph 62 and therefore denies them.

63. DRL admits that the '489 patent is entitled "2-(pyridin-2-ylamino)-pyrido[2,3-d]pyrimidin-7-ones." DRL admits that the face of the '489 patent states that it was issued on April 24, 2007. DRL avers that the allegation that the '489 patent was duly and legally issued states a legal conclusion to which no response is required, but to the extent a response is required, DRL denies the allegation.

64. DRL admits that the face of the '489 patent identifies Warner-Lambert Company as the assignee. DRL lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations in paragraph 64 and therefore denies them.

65. DRL admits that claim 1 of the '489 patent claims, *inter alia*, a compound of the formula recited in claim 1 of the '489 patent.

66. DRL admits that the '489 patent is listed in the Orange Book with respect to IBRANCE®. DRL denies the remaining allegations in paragraph 66.

67. DRL admits that in DRL's Notice Letter DRL notified Pfizer of the submission of DRL's ANDA to the FDA. DRL admits that the purpose of this submission was to obtain approval under the FDCA to market DRL's ANDA product in the United States. DRL denies the remaining allegations in paragraph 67.

68. Admitted.

69. Denied.

70. DRL admits that DRL's Notice Letter provided a detailed explanation regarding the invalidity of claims 1-7 and 9 of the '489 patent. DRL denies the remaining allegations in

paragraph 70. DRL's Notice Letter expressly reserves the right to raise additional defenses beyond those explained in the Notice Letter.

71. Denied.

72. DRL admits that DRL intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of DRL's proposed ANDA Product upon approval of its ANDA. DRL denies the remaining allegations in paragraph 72.

73. Denied.

74. Denied.

75. Denied.

76. Denied.

77. DRL admits that DRL intends to manufacture, offer for sale, sell, distribute, and/or import DRL's proposed ANDA Product upon approval of its ANDA. DRL denies the remaining allegations in paragraph 77.

78. Denied.

79. Denied.

80. Denied.

81. Denied

COUNT IV – DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '489 PATENT

82. DRL incorporates by reference each of its responses to Paragraphs 1-81 as though fully set forth herein.

83. This paragraph contains legal conclusions to which no answer is required. To the extent that a response is required, DRL admits that Pfizer purports to base subject matter jurisdiction on 28 U.S.C. §§ 2201 and 2202.

84. DRL admits that claim 1 of the ’489 patent claims, *inter alia*, a compound of the formula recited in claim 1 of the ’489 patent.

85. DRL admits that in DRL’s Notice Letter DRL notified Pfizer of the submission of DRL’s ANDA to the FDA. DRL admits that the purpose of this submission was to obtain approval under the FDCA to market DRL’s ANDA product in the United States. DRL denies the remaining allegations in paragraph 85.

86. Admitted.

87. Denied.

88. DRL admits that DRL’s Notice Letter provided a detailed explanation regarding the invalidity of claims 1-7 and 9 of the ’489 patent. DRL denies the remaining allegations in paragraph 88. DRL’s Notice Letter expressly reserves the right to raise additional defenses beyond those explained in the Notice Letter.

89. Denied.

90. DRL admits that DRL intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of DRL’s proposed ANDA Product upon approval of its ANDA. DRL denies the remaining allegations in paragraph 90.

91. Denied

92. Denied

93. Denied

94. Denied.

95. DRL admits that DRL intends to manufacture, offer for sale, sell, distribute, and/or import DRL’s proposed ANDA Product upon approval of its ANDA. DRL denies the remaining allegations in paragraph 95.

96. Denied

97. Denied.

98. Denied.

99. Denied.

COUNT V – INFRINGEMENT OF THE '168 PATENT

100. DRL incorporates by reference each of its responses to Paragraphs 1-99 as though fully set forth herein.

101. DRL admits that the face of the '168 patent lists Mark Barvian, Richard J. Booth, John Quin, III, Joseph T. Repine, Derek J. Sheehan, Peter L. Toogood, Scott N. Vanderwel, and Hairong Zhou as inventors. DRL otherwise lacks knowledge or information regarding inventorship of the '168 patent sufficient to form a belief about the truth of any remaining allegations in paragraph 101 and therefore denies them.

102. DRL admits that the '168 patent is entitled "2-(pyridin-2-ylamino)-pyrido[2,3,d]pyrimidin-7-ones." DRL admits that the face of the '168 patent states that it was issued on November 25, 2008. DRL avers that the allegation that the '168 patent was duly and legally issued states a legal conclusion to which no response is required, but to the extent a response is required, DRL denies the allegation.

103. DRL admits that the face of the '168 patent identifies Warner-Lambert Company as the assignee. DRL lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations in paragraph 103 and therefore denies them.

104. Admitted.

105. DRL admits that the '168 patent is listed in the Orange Book with respect to IBRANCE®. DRL denies the remaining allegations in paragraph 105.

106. DRL admits that in DRL's Notice Letter DRL notified Pfizer of the submission of DRL's ANDA to the FDA. DRL admits that the purpose of this submission was to obtain

approval under the FDCA to market DRL's ANDA product in the United States. DRL denies the remaining allegations in paragraph 106.

107. Admitted.

108. Denied.

109. DRL admits that DRL's Notice Letter provided a detailed explanation regarding the invalidity of claims 1-4 of the '168 patent. DRL denies the remaining allegations in paragraph 109. DRL's Notice Letter expressly reserves the right to raise additional defenses beyond those explained in the Notice Letter.

110. Denied.

111. DRL admits that DRL intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of DRL's proposed ANDA Product upon approval of its ANDA. DRL denies the remaining allegations in paragraph 111.

112. Denied.

113. Denied.

114. Denied.

115. Denied.

116. DRL admits that DRL intends to manufacture, offer for sale, sell, distribute, and/or import DRL's proposed ANDA Product upon approval of its ANDA. DRL denies the remaining allegations in paragraph 116.

117. Denied.

118. Denied.

119. Denied.

120. Denied.

COUNT VI – DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '168 PATENT

121. DRL incorporates by reference each of its responses to Paragraphs 1-120 as though fully set forth herein.

122. This paragraph contains legal conclusions to which no answer is required. To the extent that a response is required, DRL admits that Pfizer purports to base subject matter jurisdiction on 28 U.S.C. §§ 2201, and 2202.

123. Admitted.

124. DRL admits that in DRL's Notice Letter DRL notified Pfizer of the submission of DRL's ANDA to the FDA. DRL admits that the purpose of this submission was to obtain approval under the FDCA to market DRL's ANDA product in the United States. DRL denies the remaining allegations in paragraph 124.

125. Admitted.

126. Denied.

127. DRL admits that DRL's Notice Letter provided a detailed explanation regarding the invalidity of claims 1-4 of the '168 patent. DRL denies the remaining allegations in paragraph 127. DRL's Notice Letter expressly reserves the right to raise additional defenses beyond those explained in the Notice Letter.

128. Denied.

129. DRL admits that DRL intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of DRL's proposed ANDA Product upon approval of its ANDA. DRL denies the remaining allegations in paragraph 129.

130. Denied.

131. Denied.

132. Denied.

133. Denied.

134. DRL admits that DRL intends to manufacture, offer for sale, sell, distribute, and/or import DRL's proposed ANDA Product upon approval of its ANDA. DRL denies the remaining allegations in paragraph 134.

135. Denied.

136. Denied.

137. Denied.

138. Denied.

PRAYER FOR RELIEF

DRL denies that Plaintiffs are entitled to any relief for the allegations and claims made in the Complaint, including the relief requested in subsections (a) through (g) of the Prayer for Relief.

AFFIRMATIVE DEFENSES

Without any admission as to the burden of proof, burden of persuasion, or the truth of any allegation in Plaintiffs' First Amended Complaint, and expressly reserving their right to assert additional defenses, Defendants state the following affirmative defenses:

First Affirmative Defense
(Invalidity of the '612 Patent)

The claims of the '612 Patent are invalid for failure to satisfy the statutory provisions of Title 35 of the United States Code, including without limitation, one or more of sections 101, 102, 103, 111, 112, 116, 135, 256, and 287, and/or the doctrine of obviousness-type double patenting.

Second Affirmative Defense
(Non-Infringement of the '612 Patent)

The manufacture, use, sale, offer for sale, or importation of the palbociclib products that are the subject of ANDA No. 213091 will not infringe, directly, indirectly, or by inducement, any valid or enforceable claim of the '612 Patent.

Third Affirmative Defense
(Non-Infringement of the '612 Patent)

The filing of ANDA No. 213091 has not infringed, and will not infringe, directly or indirectly, any valid or enforceable claim of the '612 Patent.

Fourth Affirmative Defense
(Invalidity of the '489 Patent)

The claims of the '489 Patent are invalid for failure to satisfy the statutory provisions of Title 35 of the United States Code, including without limitation, one or more of sections 101, 102, 103, 111, 112, 116, 135, 256, and 287, and/or the doctrine of obviousness-type double patenting.

Fifth Affirmative Defense
(Non-Infringement of the '489 Patent)

The manufacture, use, sale, offer for sale, or importation of the palbociclib products that are the subject of ANDA No. 213091 will not infringe, directly, indirectly, or by inducement, any valid or enforceable claim of the '486 Patent.

Sixth Affirmative Defense
(Non-Infringement of the '489 Patent)

The filing of ANDA No. 213091 has not infringed, and will not infringe, directly or indirectly, any valid or enforceable claim of the '489 Patent.

Seventh Affirmative Defense
(Invalidity of the '168 Patent)

The claims of the ’168 Patent are invalid for failure to satisfy the statutory provisions of Title 35 of the United States Code, including without limitation, one or more of sections 101, 102, 103, 111, 112, 116, 135, 256, and 287, and/or the doctrine of obviousness-type double patenting.

Eighth Affirmative Defense
(Non-Infringement of the ’168 Patent)

The manufacture, use, sale, offer for sale, or importation of the palbociclib products that are the subject of ANDA No. 213091 will not infringe, directly, indirectly, or by inducement, any valid or enforceable claim of the ’168 Patent.

Ninth Affirmative Defense
(Non-Infringement of the ’168 Patent)

The filing of ANDA No. 213091 has not infringed, and will not infringe, directly or indirectly, any valid or enforceable claim of the ’168 Patent.

Tenth Affirmative Defense
(No Exceptional Case)

Defendants’ actions in defending this case do not give rise to an exceptional case under 35 U.S.C. § 285.

Eleventh Affirmative Defense
(No Willful Infringement)

Defendants have not willfully infringed any claims of the patents-in-suit.

Eleventh Affirmative Defense
(No Costs)

Plaintiffs are barred by 35 U.S.C. § 288 from recovering costs associated with this suit.

Twelfth Affirmative Defense
(Reservation of Rights)

Defendant reserves the right to allege additional affirmative defenses as they become known through the course of discovery.

WHEREFORE, Defendants request that Plaintiffs' Complaint be dismissed with prejudice and that Defendants be awarded the costs of this action, its attorneys' fees, and all other relief that this Court deems just and proper.

BAYARD, P.A.

Dated: July 15, 2019

/s/ Stephen B. Brauerman

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