IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PFIZER INC., WARNER-LAMBERT COMPANY LLC and PF PRISM IMB B.V.,	)	
Plaintiffs,	)	
v.	)	C.A. No. 1:20-cv-01530-CFC
DR. REDDY'S LABORATORIES, INC. and DR. REDDY'S LABORATORIES, LTD.	)	
Defendants.	)	

DEFENDANT DRL'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; and PF PRISM IMB 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. 10,723,730 ("the '730 patent"). DRL denies the remaining allegations of paragraph 1.

2. DRL admits that DRL notified Pfizer by letter dated October 13, 2020 ("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 '730 patent.

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 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 6.

7. 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 7.

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

9. Paragraph 9 states legal conclusions to which no response is required. To the extent a response is required, DRL denies the allegations.

10. DRL denies the allegations of Paragraph 10 of the Complaint as phrased.

11. Paragraph 11 states legal conclusions to which no response is required. To the extent a response is required, DRL denies the allegations.

JURISDICTION

12. 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.

13. Paragraph 13 of the Complaint contains legal conclusions to which no response is required. To the extent that an answer is required, DRL does not contest personal jurisdiction in this Court solely for purposes of the claims asserted against DRL in this case.

14. Paragraph 14 of the Complaint contains legal conclusions to which no response is required. To the extent that an answer is required, DRL does not contest personal jurisdiction in this Court solely for purposes of the claims asserted against DRL in this case.

15. 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 15.

16. DRL admits that it directed DRL's Notice Letters 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 16.

17. 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 17.

18. DRL admits that DRL is seeking approval to engage in the manufacture, marketing, selling, and distribution of DRL's proposed ANDA Product. DRL denies the remaining allegations in paragraph 18.

19. DRL denies the allegations of Paragraph 19 of the Complaint as phrased, but does not contest subject matter jurisdiction or venue in this Court solely for purposes of the claims asserted against DRL in this case.

FACTUAL BACKGROUND

20. DRL admits that IBRANCE® contains palbociclib and has been approved for the treatment of HR-positive, HER2-negative advanced or metastatic breast cancer in combination with an aromatase inhibitor as initial endocrine based therapy in postmenopausal women; or fulvestrant in women with disease progression following endocrine therapy.

21. DRL admits that DRL's ANDA Product contains palbociclib. DRL denies the remaining allegations in paragraph 21.

22. DRL admits that the DRL Notice Letter included an Offer of Confidential Access to Pfizer to DRL's ANDA. DRL denies the remaining allegations in paragraph 22.

23. DRL admits that it received a letter from counsel for Plaintiffs on October 19, 2020 regarding access to DRL's internal documents. DRL otherwise lacks knowledge or information regarding Pfizer's intentions with respect to the October 19, 2020 letter sufficient to form a belief about the truth of any remaining allegations in paragraph 23 and therefore denies them.

24. DRL admits that it DRL and Pfizer exchanged correspondence regarding DRL's Offer of Confidential Access. DRL denies the remaining allegations in paragraph 24.

25. Admitted.

COUNT I - INFRINGEMENT OF THE '730 PATENT

26. DRL incorporates by reference each of its responses to Paragraphs 1-25 as though fully set forth herein.

27. DRL admits that the face of the '730 patent lists Brian Patrick Chekal and Nathan D. Ide as inventors. DRL otherwise lacks knowledge or information regarding inventorship of the '730 patent sufficient to form a belief about the truth of any remaining allegations in paragraph 27 and therefore denies them.

28. DRL admits that the '730 patent is entitled "Solid Forms of a Selective Cdk4/6 Inhibitor." DRL admits that the face of the '730 patent states that it was issued on July 28, 2020. The allegation that the '730 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.

29. DRL admits that the face of the '730 patent identifies Pfizer Inc. as the assignee. DRL lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations in paragraph 29 and therefore denies them.

30. DRL admits that the '730 patent is listed in the Orange Book with respect to IBRANCE®. DRL denies the remaining allegations in paragraph 30.

31. DRL admits that in DRL's Notice Letters 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 31.

32. Admitted.

33. Denied.

34. DRL admits that paragraph 34 accurately quotes claim 1 of the '730 patent. DRL denies that DRL's ANDA Product and the use of DRL's ANDA Product are covered by claim 1 of the '730 patent.

35. Denied.

36. DRL admits that paragraph 36 accurately quotes claim 7 of the '730 patent. DRL denies that DRL's ANDA Product and the use of DRL's ANDA Product are covered by claim 7 of the '730 patent.

37. Denied.

38. DRL admits that paragraph 38 accurately quotes claim 15 of the '730 patent. DRL denies that DRL's ANDA Product and the use of DRL's ANDA Product are covered by claim 15 of the '730 patent.

39. Denied.

40. Denied.

41. DRL denies the allegations of Paragraph 41 of the Complaint as phrased.

42. Denied.

43. Denied.

44. Denied.

45. Denied.

46. DRL admits that DRL is seeking approval to manufacture, offer for sale, sell, distribute, and/or import DRL's proposed ANDA Product. DRL denies the remaining allegations in paragraph 46.

47. Denied.

48. Denied.

49. Denied.

50. Denied.

COUNT II - DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '730 PATENT

51. DRL incorporates by reference each of its responses to Paragraphs 1-50 as though fully set forth herein.

52. 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.

53. 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 53.

54. Admitted.

55. Denied.

56. DRL admits that paragraph 56 accurately quotes claim 1 of the '730 patent. DRL denies that DRL's ANDA Product and the use of DRL's ANDA Product are covered by claim 1 of the '730 patent.

57. Denied.

58. DRL admits that paragraph 58 accurately quotes claim 7 of the ’730 patent. DRL denies that DRL’s ANDA Product and the use of DRL’s ANDA Product are covered by claim 7 of the ’730 patent.

59. Denied.

60. DRL admits that paragraph 60 accurately quotes claim 15 of the ’730 patent. DRL denies that DRL’s ANDA Product and the use of DRL’s ANDA Product are covered by claim 15 of the ’730 patent.

61. Denied.

62. DRL denies the allegations of Paragraph 62 of the Complaint as phrased.

63. Denied.

64. Denied.

65. Denied.

66. Denied.

67. DRL admits that DRL is seeking approval to manufacture, offer for sale, sell, distribute, and/or import DRL’s proposed ANDA Product. DRL denies the remaining allegations in paragraph 67.

68. Denied.

69. Denied.

70. Denied.

71. 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.

First Affirmative Defense
(Invalidity of the '730 Patent)

The claims of the '730 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 '730 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 '730 Patent.

Third Affirmative Defense
(Non-Infringement of the '730 Patent)

The filing of ANDA No. 213091 has not infringed, and will not infringe, directly or indirectly, any valid or enforceable claim of the '730 Patent.

Fourth 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.

Fifth Affirmative Defense
(No Willful Infringement)

Defendants have not willfully infringed any claims of the '730 patent.

Sixth Affirmative Defense
(No Costs)

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

Seventh 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' First Amended 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.

Dated: January 15, 2021

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CERTIFICATE OF SERVICE

I hereby certify that on January 15, 2021, a true and correct copy of the foregoing **Defendant DRL's Answer to Plaintiffs' Complaint** has been served upon the following parties via electronic mail.

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