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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

PFIZER INC., WARNER-LAMBERT COMPANY LLC, and PF PRISM IMB B.V. Plaintiffs, v. DR. REDDY'S LABORATORIES, INC. and DR. REDDY'S LABORATORIES, LTD. Defendants.	C.A. No. _____

COMPLAINT

Plaintiffs Pfizer Inc.; Warner-Lambert Company LLC; and PF PRISM IMB B.V. (collectively, "Pfizer") file this Complaint for patent infringement against Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. (collectively, "DRL"), and by their attorneys, hereby allege as follows:

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, and for a declaratory judgment of patent infringement under

28 U.S.C. §§ 2201 and 2202 and the patent laws of the United States, Title 35, United States Code, that arises out of DRL's submission of an Abbreviated New Drug Application ("ANDA") to the U.S. Food and Drug Administration ("FDA") seeking approval to commercially manufacture, use, offer for sale, sell, and/or import generic versions of IBRANCE® (palbociclib) capsules, 75 mg, 100 mg, and 125 mg, prior to the expiration of U.S. Patent No. 10,723,730 ("the '730 patent").

2. Dr. Reddy's Laboratories, Inc. 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"), seeking approval from the FDA to engage in the commercial manufacture, use, and/or sale of generic palbociclib capsules, 75 mg, 100 mg, and 125 mg ("DRL's ANDA Product") prior to the expiration of the '730 patent. DRL's Notice Letter purported to include an "Offer of Confidential Access" to Pfizer to DRL's ANDA.

PARTIES

3. Plaintiff Pfizer Inc. is a corporation organized and existing under the laws of the State of Delaware and having a place of business at 235 East 42nd Street, New York, New York 10017. Pfizer Inc. is the holder of New Drug Application ("NDA") No. 207103 for the manufacture and sale of palbociclib capsules, 75 mg, 100 mg, and 125 mg, which has been approved by the FDA.

4. Plaintiff Warner-Lambert Company LLC is a limited liability company organized and existing under the laws of the State of Delaware, and having a place of business at 235 East 42nd Street, New York, New York 10017.

5. Plaintiff PF PRISM IMB B.V. is a private limited company (*besloten venootschap*) organized under the law of the Netherlands, having its registered seat in

Rotterdam, the Netherlands, and having its business address at Rivium Westlaan 142, 2909 LD, Capelle aan den IJessel, the Netherlands.

6. Upon information and belief, defendant Dr. Reddy's Laboratories, Ltd. is a corporation 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. Upon information and belief, Dr. Reddy's Laboratories, Ltd. is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical products through various operating subsidiaries, including Dr. Reddy's Laboratories, Inc.

7. Upon information and belief, defendant Dr. Reddy's Laboratories, Inc. is a company organized and existing under the laws of the State of New Jersey, having a principal place of business at 107 College Road East, Princeton, New Jersey 08540. Upon information and belief, Dr. Reddy's Laboratories, Inc. is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical products for the U.S. market.

8. Upon information and belief, Dr. Reddy's Laboratories, Inc. is a wholly owned subsidiary of Dr. Reddy's Laboratories, Ltd. Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. are collectively referred to herein as "DRL."

9. Upon information and belief, Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. acted in concert to prepare and submit DRL's ANDA to the FDA.

10. Upon information and belief, Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. know and intend that upon approval of DRL's ANDA, Dr. Reddy's Laboratories, Ltd. will manufacture DRL's ANDA Product and Dr. Reddy's Laboratories, Inc. will directly or indirectly market, sell, and distribute DRL's ANDA Product throughout the

United States, including in New Jersey. Upon information and belief, Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. are agents of each other and/or operate in concert as integrated parts of the same business group, including with respect to DRL's ANDA Product, and enter into agreements with each other that are nearer than arm's length. Upon information and belief, Dr. Reddy's Laboratories, Inc. participated in, assisted, and cooperated with Dr. Reddy's Laboratories, Ltd. in the acts complained of herein.

11. Upon information and belief, following any FDA approval of DRL's ANDA, Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. will act in concert to distribute and sell DRL's ANDA Product throughout the United States, including within New Jersey.

JURISDICTION

12. Jurisdiction is proper in this Court pursuant to 28 U.S.C. §§ 1331, 1338(a), and 2201 and 2202.

13. Dr. Reddy's Laboratories, Ltd. is subject to personal jurisdiction in New Jersey because, among other things, Dr. Reddy's Laboratories, Ltd. has purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court here. Upon information and belief, Dr. Reddy's Laboratories, Ltd., itself and through its subsidiary Dr. Reddy's Laboratories, Inc., develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in the State of New Jersey, and therefore transacts business within the State of New Jersey related to Pfizer's claims, and/or has engaged in systematic and continuous business contacts within the State of New Jersey. In addition, Dr. Reddy's Laboratories, Ltd. is subject to personal jurisdiction in New Jersey because, upon information and belief, it controls Dr. Reddy's Laboratories, Inc. and

therefore the activities of Dr. Reddy's Laboratories, Inc. in this jurisdiction are attributed to Dr. Reddy's Laboratories, Ltd.

14. Dr. Reddy's Laboratories, Inc. is subject to personal jurisdiction in New Jersey because, among other things, it has purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court here. Dr. Reddy's Laboratories, Inc. is a corporation organized and existing under the laws of the State of New Jersey, is qualified to do business in New Jersey, and has appointed a registered agent for service of process in New Jersey. It therefore has consented to general jurisdiction in New Jersey. In addition, upon information and belief, Dr. Reddy's Laboratories, Inc. develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in the State of New Jersey, and therefore transacts business within the State of New Jersey related to Pfizer's claims, and/or has engaged in systematic and continuous business contacts within the State of New Jersey.

15. Upon information and belief, if DRL's ANDA is approved, DRL will directly or indirectly manufacture, market, sell, and/or distribute DRL's ANDA Product within the United States, including in New Jersey, consistent with DRL's practices for the marketing and distribution of other generic pharmaceutical products. Upon information and belief, DRL regularly does business in New Jersey, and its practices with other generic pharmaceutical products have involved placing those products into the stream of commerce for distribution throughout the United States, including in New Jersey. Upon information and belief, DRL's generic pharmaceutical products are used and/or consumed within and throughout the United States, including in New Jersey. Upon information and belief, DRL's ANDA Product will be prescribed by physicians practicing in New Jersey, dispensed by pharmacies located within New

Jersey, and used by patients in New Jersey. Each of these activities would have a substantial effect within New Jersey and would constitute infringement of Pfizer's patent in the event that DRL's ANDA Product is approved before the patent expires.

16. Upon information and belief, DRL derives substantial revenue from generic pharmaceutical products that are used and/or consumed within New Jersey, and which are manufactured by DRL and/or for which Dr. Reddy's Laboratories, Inc. or Dr. Reddy's Laboratories, Ltd. is the named applicant on approved ANDAs. Upon information and belief, various products for which Dr. Reddy's Laboratories, Ltd. or Dr. Reddy's Laboratories, Inc. is the named applicant on approved ANDAs are available at retail pharmacies in New Jersey.

FACTUAL BACKGROUND

17. IBRANCE®, which contains palbociclib, is approved for the treatment of HR-positive, HER2-negative advanced or metastatic breast cancer.

18. Upon information and belief, DRL's ANDA Product is a generic version of IBRANCE®.

19. DRL's Notice Letter purported to include an "Offer of Confidential Access" to Pfizer to DRL's ANDA. The offer, however, was subject to various unreasonably restrictive conditions.

20. On October 19, 2020, counsel for Plaintiffs sent a letter to counsel for DRL attempting to negotiate access to DRL's internal documents, data and/or samples relevant to infringement based on reasonable confidentiality terms.

21. In an exchange of correspondence, counsel for DRL and counsel for Pfizer discussed the terms of DRL's Offer of Confidential Access, though the parties were unable to

agree on terms under which Pfizer could review the internal documents, data and/or samples relevant to infringement.

22. Plaintiffs are filing this Complaint within forty-five days of receipt of DRL's Notice Letter.

COUNT I – INFRINGEMENT OF THE '730 PATENT

23. Pfizer incorporates each of the preceding paragraphs 1–22 as if fully set forth herein.

24. The inventors of the '730 patent are Brian Patrick Chekal and Nathan D. Ide.

25. The '730 patent, entitled "Solid Forms of a Selective Cdk4/6 Inhibitor" (attached as Exhibit A), was duly and legally issued on July 28, 2020.

26. Pfizer is the owner and assignee of the '730 patent.

27. IBRANCE® is covered by one or more claims of the '730 patent, which has been listed in connection with IBRANCE® in the FDA's publication *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as "the Orange Book").

28. In DRL's Notice Letter, DRL notified Pfizer of the submission of DRL's ANDA to the FDA. The purpose of this submission was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale and/or importation of DRL's ANDA Product prior to the expiration of the '730 patent.

29. In DRL's Notice Letter, DRL also notified Pfizer that, as part of its ANDA, DRL had filed a certification of the type described in Section 505(j)(2)(B)(iv) of the FDCA, 21 U.S.C. § 355(j)(2)(B)(iv), with respect to the '730 patent. Upon information and belief, DRL submitted its ANDA to the FDA containing certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV)

asserting that the '730 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of DRL's ANDA Product.

30. Upon information and belief, DRL's ANDA Product and the use of DRL's ANDA Product are covered by one or more claims of the '730 patent, either literally or under the doctrine of equivalents.

31. As an example, claim 1 of the '730 patent recites:

> A crystalline free base of 6-acetyl-8-cyclopentyl-5-methyl-2-(5-piperazin-1-yl-pyridin-2-ylamino)-8H-pyrido[2,3-d]pyrimidin-7-one, having a powder X-ray diffraction pattern comprising peaks at diffraction angles (2θ) of 8.0±0.2, 10.1±0.2 and 11.5±0.2 and a primary particle size distribution characterized by a D90 value of from about 30 µm to about 65 µm.

32. Upon information and belief, DRL's ANDA Product infringes claim 1 of the '730 patent, literally or under the doctrine of equivalents.

33. As an example, Claim 7 of the '730 patent recites:

> A crystalline free base of 6-acetyl-8-cyclopentyl-5-methyl-2-(5-piperazin-1-yl-pyridin-2-ylamino)-8H-pyrido[2,3-d]pyrimidin-7-one, having a powder X-ray diffraction pattern comprising peaks at diffraction angles (2θ) of 8.0±0.2, 10.1±0.2 and 11.5±0.2 and a volume mean diameter characterized by a D[4,3] value of from about 15 µm to about 40 µm.

34. Upon information and belief, DRL's ANDA Product infringes claim 7 of the '730 patent, literally or under the doctrine of equivalents.

35. As an example, Claim 15 of the '730 patent recites:

> A crystalline free base of 6-acetyl-8-cyclopentyl-5-methyl-2-(5-piperazin-1-yl-pyridin-2-ylamino)-8H-pyrido[2,3-d]pyrimidin-7-one, having a powder X-ray diffraction pattern comprising peaks at diffraction angles (2θ) of 8.0±0.2, 10.1±0.2 and 11.5±0.2 and a volume mean diameter characterized by a D[4,3] value of from about 15 µm to about 30 µm.

36. Upon information and belief, DRL's ANDA Product infringes claim 15 of the '730 patent, literally or under the doctrine of equivalents.

37. DRL's submission of DRL's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of DRL's ANDA Product before the expiration of the '730 patent was an act of infringement of the '730 patent under 35 U.S.C. § 271(e)(2)(A).

38. Upon information and belief, DRL will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of DRL's ANDA Product immediately and imminently upon approval of its ANDA.

39. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of DRL's ANDA Product would infringe one or more claims of the '730 patent, either literally or under the doctrine of equivalents.

40. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of DRL's ANDA Product in accordance with, and as directed by, its proposed product labeling would infringe one or more claims of the '730 patent.

41. Upon information and belief, DRL plans and intends to, and will, actively induce infringement of the '730 patent when DRL's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. DRL's activities will be done with knowledge of the '730 patent and specific intent to infringe that patent.

42. Upon information and belief, DRL knows that DRL's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '730 patent, that DRL's ANDA Product is not a staple article or commodity of commerce, and that DRL's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon

information and belief, DRL plans and intends to, and will, contribute to infringement of the '730 patent immediately and imminently upon approval of DRL's ANDA.

43. Notwithstanding DRL's knowledge of the claims of the '730 patent, DRL has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import DRL's ANDA Product with its product labeling following FDA approval of DRL's ANDA prior to the expiration of the '730 patent.

44. The foregoing actions by DRL constitute and/or will constitute infringement of the '730 patent; active inducement of infringement of the '730 patent; and contribution to the infringement by others of the '730 patent.

45. Upon information and belief, DRL has acted with full knowledge of the '730 patent and without a reasonable basis for believing that it would not be liable for infringement of the '730 patent; active inducement of infringement of the '730 patent; and/or contribution to the infringement by others of the '730 patent.

46. Pfizer will be substantially and irreparably harmed by infringement of the '730 patent.

47. Unless DRL is enjoined from infringing the '730 patent, actively inducing infringement of the '730 patent, and contributing to the infringement by others of the '730 patent, Pfizer will suffer irreparable injury. Pfizer has no adequate remedy at law.

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

48. Pfizer incorporates each of the preceding paragraphs 1–47 as if fully set forth herein.

49. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Pfizer on one

hand and DRL on the other regarding DRL's infringement, active inducement of infringement, and contribution to the infringement by others of the '730 patent, and/or the validity of the '730 patent.

50. In DRL's Notice Letter, DRL notified Pfizer of the submission of DRL's ANDA to the FDA. The purpose of this submission was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale and/or importation of DRL's ANDA Product prior to the expiration of the '730 patent.

51. In DRL's Notice Letter, DRL also notified Pfizer that, as part of its ANDA, DRL had filed certifications of the type described in Section 505(j)(2)(B)(iv) of the FDCA, 21 U.S.C. § 355(j)(2)(B)(iv), with respect to the '730 patent. Upon information and belief, DRL submitted its ANDA to the FDA containing certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that that '730 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of DRL's ANDA Product.

52. Upon information and belief, DRL's ANDA Product and the use of DRL's ANDA Product are covered by one or more claims of the '730 patent.

53. As an example, claim 1 of the '730 patent recites:

> A crystalline free base of 6-acetyl-8-cyclopentyl-5-methyl-2-(5-piperazin-1-yl-pyridin-2-ylamino)-8H-pyrido[2,3-d]pyrimidin-7-one, having a powder X-ray diffraction pattern comprising peaks at diffraction angles (2θ) of 8.0±0.2, 10.1±0.2 and 11.5±0.2 and a primary particle size distribution characterized by a D90 value of from about 30 µm to about 65 µm.

54. Upon information and belief, DRL's ANDA Product infringes claim 1 of the '730 patent, literally or under the doctrine of equivalents.

55. As an example, Claim 7 of the '730 patent recites:

> A crystalline free base of 6-acetyl-8-cyclopentyl-5-methyl-2-(5-piperazin-1-yl-pyridin-2-ylamino)-8H-pyrido[2,3-d]pyrimidin-7-

> one, having a powder X-ray diffraction pattern comprising peaks at diffraction angles (2θ) of 8.0±0.2, 10.1±0.2 and 11.5±0.2 and a volume mean diameter characterized by a D[4,3] value of from about 15 µm to about 40 µm.

56. Upon information and belief, DRL's ANDA Product infringes claim 7 of the '730 patent, literally or under the doctrine of equivalents.

57. As an example, Claim 15 of the '730 patent recites:

> A crystalline free base of 6-acetyl-8-cyclopentyl-5-methyl-2-(5-piperazin-1-yl-pyridin-2-ylamino)-8H-pyrido[2,3-d]pyrimidin-7-one, having a powder X-ray diffraction pattern comprising peaks at diffraction angles (2θ) of 8.0±0.2, 10.1±0.2 and 11.5±0.2 and a volume mean diameter characterized by a D[4,3] value of from about 15 µm to about 30 µm.

58. Upon information and belief, DRL's ANDA Product infringes claim 15 of the '730 patent, literally or under the doctrine of equivalents.

59. Upon information and belief, DRL will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of DRL's ANDA Product immediately and imminently upon approval of its ANDA.

60. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of DRL's ANDA Product would infringe one or more claims of the '730 patent.

61. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of DRL's ANDA Product in accordance with, and as directed by, its proposed labeling would infringe one or more claims of the '730 patent.

62. Upon information and belief, DRL plans and intends to, and will, actively induce infringement of the '730 patent when DRL's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. DRL's activities will be done with knowledge of the '730 patent and specific intent to infringe that patent.

63. Upon information and belief, DRL knows that DRL's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '730 patent, that DRL's ANDA Product is not a staple article or commodity of commerce, and that DRL's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, DRL plans and intends to, and will, contribute to infringement of the '730 patent immediately and imminently upon approval of DRL's ANDA.

64. Notwithstanding DRL's knowledge of the claims of the '730 patent, DRL has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import DRL's ANDA Product with its product labeling following FDA approval of DRL's ANDA prior to the expiration of the '730 patent.

65. The foregoing actions by DRL constitute and/or will constitute infringement of the '730 patent; active inducement of infringement of the '730 patent; and contribution to the infringement by others of the '730 patent.

66. Upon information and belief, DRL has acted with full knowledge of the '730 patent and without a reasonable basis for believing that it would not be liable for infringement of the '730 patent; active inducement of infringement of the '730 patent; and/or contribution to the infringement by others of the '730 patent.

67. Pfizer will be substantially and irreparably damaged by infringement of the '730 patent.

68. The Court should declare that the commercial manufacture, use, sale, offer for sale and/or importation of DRL's ANDA Product with its proposed labeling, or any other DRL drug product that is covered by or whose use is covered by the '730 patent, will infringe, induce

infringement of, and contribute to the infringement by others of the ’730 patent, and that the claims of the ’730 patent are not invalid.

PRAYER FOR RELIEF

WHEREFORE, Pfizer requests the following relief:

(a) A judgment that the ’730 patent has been infringed under 35 U.S.C. § 271(e)(2) by DRL’s submission to the FDA of DRL’s ANDA;

(b) A judgment ordering that the effective date of any FDA approval of commercial manufacture, use, or sale of DRL’s ANDA Product, or any other drug product that infringes or the use of which infringes the ’730 patent, be not earlier than the expiration date of the ’730 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(c) A preliminary and permanent injunction enjoining DRL, and all persons acting in concert with DRL, from the commercial manufacture, use, sale, offer for sale, or importation into the United States of DRL’s ANDA Products, or any other drug product covered by or whose use is covered by the ’730 patent, prior to the expiration of that patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(d) A judgment declaring that the commercial manufacture, use, sale, offer for sale or importation of DRL’s ANDA Products, or any other drug product which is covered by or whose use is covered by the ’730 patent, prior to the expiration of that patent, will infringe, induce the infringement of, and contribute to the infringement by others of, said patent;

(e) A declaration that this is an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. § 285;

(f) Costs and expenses in this action; and

(g) Such further and other relief as this Court may deem just and proper.

Dated: November 13, 2020

By: s/ Charles H. Chevalier

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