Charles H. Chevalier
GIBBONS P.C.
One Gateway Center
Newark, New Jersey 07102-5310
Phone: (973) 596-4500
cchevalier@gibbonslaw.com

OF COUNSEL
David I. Berl
Christopher J. Mandernach
Seth R. Bowers
Michael Xun Liu
Kevin Hoagland-Hanson
Andrew L. Hoffman
WILLIAMS & CONNOLLY LLP
725 Twelfth Street, NW
Washington, DC 20005
Phone: (202) 434-5000

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. AIZANT DRUG RESEARCH SOLUTIONS PVT. LTD. and MAKRO TECHNOLOGIES INC. 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 Aizant Drug Research Solutions Pvt. Ltd. and Makro Technologies Inc. (collectively, "Aizant"), 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 Aizant'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. Aizant Drug Research Solutions Pvt. Ltd. notified Pfizer by letter dated December 2, 2020 ("Aizant's Notice Letter") that it had submitted to the FDA ANDA No. 212352, 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 ("Aizant's ANDA Product") prior to the expiration of the '730 patent. Upon information and belief, Aizant's Notice Letter contains a typographical error with respect to the ANDA number for Aizant's ANDA Product. Aizant's Notice Letter recites the ANDA number for Aizant's ANDA Product as 212352; in its Answer to Pfizer's complaint describing the same ANDA, however, Aizant admitted that Aizant's ANDA Product has been assigned ANDA No. 213152. *See Pfizer Inc. v. Aizant Drug Research Solutions Pvt. Ltd.*, C.A. 19-743-CFC, D.I. 12 (D. Del. Jul. 16, 2019). Herein, the phrase "Aizant's ANDA" shall refer to the ANDA submitted by Aizant to the FDA regarding Aizant's ANDA Product.

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 Aizant Drug Research Solutions Pvt. Ltd. is a company organized and existing under the laws of the Republic of India with its principal place of business at Sy No. 172 & 173, Apparel Park Road, Dulapally Village, Quthbullapur Mandal, Hyderabad 500014, India. Upon information and belief, Aizant Drug Research Solutions Pvt. Ltd. is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical drugs.

7. Upon information and belief, defendant Makro Technologies Inc. is a corporation organized and existing under the laws of the State of New Jersey, having its principal place of business at 4 Independence Way, Suite 110, Princeton, New Jersey 08540. Upon information and belief, Makro Technologies Inc. acted as a U.S. agent for the submission of Aizant's ANDA to the FDA.

8. Upon information and belief, Aizant knows and intends that upon approval of Aizant's ANDA, Aizant will manufacture Aizant's ANDA Product, and will directly or

indirectly market, sell, and distribute Aizant's ANDA Product throughout the United States, including in New Jersey.

JURISDICTION

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

10. Aizant Drug Research Solutions Pvt. Ltd. is subject to personal jurisdiction in New Jersey because, among other things, Aizant Drug Research Solutions Pvt. 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, Aizant Drug Research Solutions Pvt. Ltd. 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.

11. Makro Technologies 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. Upon information and belief, Makro Technologies Inc., acting as an agent for Aizant Drug Research Solutions Pvt. Ltd., filed a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 355(j)(2)(A)(vii)(IV) to challenge Pfizer's patents on IBRANCE®. Makro Technologies 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.

12. Aizant has previously used the process contemplated by the Drug Price Competition and Patent Term Restoration Act of 1984, 21 U.S.C. § 355(j) (the "Hatch-Waxman Act"), to challenge branded pharmaceutical companies' patents by filing a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 355(j)(2)(A)(vii)(IV), serving a notice letter on those companies, and engaging in patent litigation arising from the process contemplated by the Hatch-Waxman Act.

13. Upon information and belief, if Aizant's ANDA is approved, Aizant will directly or indirectly manufacture, market, sell, and/or distribute Aizant's ANDA Product within the United States, including in New Jersey, consistent with Aizant's practices for the marketing and distribution of other generic pharmaceutical products. Upon information and belief, Aizant 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, Aizant's generic pharmaceutical products are used and/or consumed within and throughout the United States, including in New Jersey. Upon information and belief, Aizant'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 Aizant's ANDA Product is approved before the patent expires.

14. Upon information and belief, Aizant derives substantial revenue from generic pharmaceutical products that are used and/or consumed within New Jersey, and which are manufactured by Aizant and/or for which Aizant is the named applicant on approved ANDAs.

Upon information and belief, various products for which Aizant is the named applicant on approved ANDAs are available at retail pharmacies in New Jersey.

FACTUAL BACKGROUND

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

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

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

18. On December 15, 2020, counsel for Plaintiffs sent a letter to counsel for Aizant attempting to negotiate access to Aizant's internal documents, data and/or samples relevant to infringement based on reasonable confidentiality terms. Aizant has not responded to Plaintiffs' letter, and the parties have not agreed on terms under which Pfizer could review the internal documents, data, and/or samples relevant to infringement.

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

COUNT I – INFRINGEMENT OF THE '730 PATENT

20. Pfizer incorporates each of the preceding paragraphs 1–19 as if fully set forth herein.

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

22. 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.

23. Pfizer is the owner and assignee of the ’730 patent.

24. 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”).

25. In Aizant’s Notice Letter, Aizant notified Pfizer of the submission of Aizant’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 Aizant’s ANDA Product prior to the expiration of the ’730 patent.

26. In Aizant’s Notice Letter, Aizant also notified Pfizer that, as part of its ANDA, Aizant 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, Aizant 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 Aizant’s ANDA Product.

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

28. 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.

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

30. 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.

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

32. 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.

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

34. Aizant's submission of Aizant's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Aizant'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).

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

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

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

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

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

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

41. The foregoing actions by Aizant 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.

42. Upon information and belief, Aizant 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.

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

44. Unless Aizant 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

45. Pfizer incorporates each of the preceding paragraphs 1–44 as if fully set forth herein.

46. 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 Aizant on the other regarding Aizant'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.

47. In Aizant's Notice Letter, Aizant notified Pfizer of the submission of Aizant'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 Aizant's ANDA Product prior to the expiration of the '730 patent.

48. In Aizant's Notice Letter, Aizant also notified Pfizer that, as part of its ANDA, Aizant 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, Aizant 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 Aizant's ANDA Product.

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

50. 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.

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

52. 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.

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

54. 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.

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

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

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

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

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

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

61. Notwithstanding Aizant's knowledge of the claims of the '730 patent, Aizant has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Aizant's

ANDA Product with its product labeling following FDA approval of Aizant's ANDA prior to the expiration of the '730 patent.

62. The foregoing actions by Aizant 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.

63. Upon information and belief, Aizant 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.

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

65. The Court should declare that the commercial manufacture, use, sale, offer for sale and/or importation of Aizant's ANDA Product with its proposed labeling, or any other Aizant 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 Aizant's submission to the FDA of Aizant's ANDA;

(b) A judgment ordering that the effective date of any FDA approval of commercial manufacture, use, or sale of Aizant'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 Aizant, and all persons acting in concert with Aizant, from the commercial manufacture, use, sale, offer for sale, or importation into the United States of Aizant’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 Aizant’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: January 13, 2021

By: s/ Charles H. Chevalier
Charles H. Chevalier
GIBBONS P.C.
One Gateway Center
Newark, New Jersey 07102-5310
Phone: (973) 596-4500
cchevalier@gibbonslaw.com

OF COUNSEL:
David I. Berl
Christopher J. Mandernach
Seth R. Bowers
Michael Xun Liu
Kevin Hoagland-Hanson
Andrew L. Hoffman
WILLIAMS & CONNOLLY LLP
725 Twelfth Street, N.W.
Washington, DC 20005
(202) 434-5000

Attorneys for Plaintiffs