

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.

AIZANT DRUG RESEARCH SOLUTIONS
PVT. LTD. AND MAKRO
TECHNOLOGIES INC.,

C.A. No. 21-cv- 34 (CFC)

Defendants.

DEFENDANT AIZANT'S ANSWER TO PFIZER'S COMPLAINT

Aizant Drug Research Solutions Pvt. Ltd. ("Aizant"), by their attorneys, hereby responds to the complaint filed by Pfizer Inc., Warner-Lambert Company LLC, and PF PRISIM IMB B.V. (collectively "Pfizer"), as follows:

1. Aizant admits that Pfizer filed 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 admits that it notified Pfizer by letter dated December 2, 2020 that Aizant Drug Research Solutions Pvt. Ltd., had submitted to the FDA an ANDA ("Aizant's ANDA") seeking approval from the FDA to engage in the commercial manufacture, use and/or sale of generic palbociclib capsules, 75mg, 100 mg, and 125 mg ("Aizant's ANDA Product") prior to the expiration of the patents-in-suit. Aizant further admits that the ANDA number is 213152. Aizant further states that Aizant's Notice Letter speaks for itself.

PARTIES

3. On information and belief, Aizant admits Plaintiff Pfizer Inc.'s address is correct. Aizant further admits that 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. Aizant is without sufficient information or knowledge to admit or deny the remaining allegations contained in this paragraph and, therefore, denies them on this basis.

4. On information and belief, Aizant admits Plaintiff Warner-Lambert Company LLC's address is correct. Aizant is without sufficient information or knowledge to admit or deny the remaining allegations contained in this paragraph and, therefore, denies them on this basis.

5. On information and belief, Aizant admits Plaintiff PF PRISM IMB B.V.'s address is correct. Aizant is without sufficient information or knowledge to admit or deny the remaining allegations contained in this paragraph and, therefore, denies them on this basis.

6. Aizant admits that it is a company organized and existing under the laws of India, having a principal place of business at Sy No. 172 & 173, Apparel Park Road, Dulapally Village, Quthbullapur Mandal, Hyderabad – 500014, India. Aizant admits that it is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical drugs.

7. Aizant states that this paragraph is directed to Makro Technologies Inc., and Aizant is without sufficient information or knowledge to admit or deny the remaining allegations contained in this paragraph and, therefore, denies them on this basis.

8. Aizant denies the allegations of this paragraph.

JURISDICTION

9. This paragraph contains legal conclusions to which no answer is required. For purposes of this action only, Aizant does not contest that subject matter jurisdiction is proper.

10. Aizant admits that it develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in the State of Delaware. The remainder of the paragraph stats a legal conclusion to which no answer is required. To the extent a response is required, Aizant lacks sufficient information to admit or deny the allegations contained in this paragraph and, therefore, denies them on this basis. For purposes of this action only, Aizant does not contest jurisdiction in this matter.

11. Aizant states that this paragraph is directed to Makro Technologies Inc., and Aizant is without sufficient information or knowledge to admit or deny the remaining allegations contained in this paragraph and, therefore, denies them on this basis.

12. Aizant admits that it 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. This paragraph contains legal conclusions to which no answer is required. To the extent required, Aizant denies the allegations of this paragraph.

14. Aizant denies the allegations of this paragraph.

15. Aizant denies the allegations of this paragraph.

16. Aizant denies the allegations of this paragraph.

17. This paragraph contains legal conclusions to which no answer is required. For purposes of this action only, Aizant does not contest that venue in this litigation.

FACTUAL BACKGROUND

18. This paragraph contains legal conclusions to which no answer is required. To the extent required, Aizant denies the allegations of this paragraph.

19. This paragraph contains legal conclusions to which no answer is required. To the extent required, Aizant denies the allegations of this paragraph.

20. This paragraph contains legal conclusions to which no answer is required. To the extent required, Aizant denies the allegations of this paragraph.

21. Aizant admits receiving a communication on December 15, 2020, which speaks for itself. Aizant denies the remaining allegations of this paragraph

22. This paragraph contains legal conclusions to which no answer is required. Aizant does not contest Pfizer's assertion that it filed the Complaint within forty-five days of receipt of Aizant's Notice Letter. .

COUNT I - INFRINGEMENT OF THE '730 PATENT

23. Aizant incorporates its response to each of the preceding paragraphs 1-22 as if fully set forth here.

24. Aizant admits that the '730 patent lists, on its face, Brian Patrick Chekal and Nathan D. Ide as inventors.

25. Aizant admits that the '730 patent lists, on its face, the title "Solid Forms of a Selective Cdk4/6 Inhibitor." Aizant denies that the '730 patent was duly and legally issued on July 28, 2020.

26. Aizant lacks sufficient information to admit or deny the allegations contained in this paragraph and, therefore, denies them.

27. Aizant lacks sufficient information to admit or deny the allegations contained in this paragraph and, therefore, denies them.

28. Aizant admits that it notified Pfizer of the submission of Aizant's ANDA to the FDA. Aizant states that its notice letter speaks for itself, so no further answer is required. To the extent necessary, Aizant denies the allegations of this paragraph.

29. Aizant admits that it has 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. Aizant states that its notice letter speaks for itself, so no answer is required. To the extent necessary, Aizant denies the allegations of this paragraph.

30. Aizant denies the allegations of this paragraph.

31. Aizant admits that 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 $30\text{ }\mu\text{m}$ to about $65\text{ }\mu\text{m}.$ "

32. Aizant denies the allegations of this paragraph.

33. Aizant admits that 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 $15\text{ }\mu\text{m}$ to about $40\text{ }\mu\text{m}.$ "

34. Aizant denies the allegations of this paragraph.

35. Aizant admits that 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 $15\text{ }\mu\text{m}$ to about $30\text{ }\mu\text{m}$.

36. Aizant denies the allegations of this paragraph.
37. Aizant denies the allegations of this paragraph.
38. Aizant denies the allegations of this paragraph.
39. Aizant denies the allegations of this paragraph.
40. Aizant denies the allegations of this paragraph.
41. Aizant denies the allegations of this paragraph.
42. Aizant denies the allegations of this paragraph.
43. Aizant denies the allegations of this paragraph.
44. Aizant denies the allegations of this paragraph.
45. Aizant admits the allegations of this paragraph.
46. Aizant denies the allegations of this paragraph.
47. Aizant denies the allegations of this paragraph.

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

48. Aizant incorporates its response to each of the preceding paragraphs 1-47 as if fully set forth here.
49. This paragraph states a legal conclusion to which no answer is required.

50. Aizant admits that it notified Pfizer of the submission of Aizant's ANDA to the FDA. Aizant states that its notice letter speaks for itself, so no further answer is required. To the extent necessary, Aizant denies the allegations of this paragraph.

51. Aizant admits that it has 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. Aizant states that its notice letter speaks for itself, so no answer is required. To the extent necessary, Aizant denies the allegations of this paragraph.

52. Aizant denies the allegations of this paragraph.

53. Aizant admits that 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 $30\text{ }\mu\text{m}$ to about $65\text{ }\mu\text{m}.$ "

54. Aizant denies the allegations of this paragraph.

55. Aizant admits that 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 $15\text{ }\mu\text{m}$ to about $40\text{ }\mu\text{m}.$ "

56. Aizant denies the allegations of this paragraph.

57. Aizant admits that 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 $15\text{ }\mu\text{m}$ to about $30\text{ }\mu\text{m}$.

58. Aizant denies the allegations of this paragraph.

59. Aizant denies the allegations of this paragraph.

60. Aizant denies the allegations of this paragraph.

61. Aizant denies the allegations of this paragraph.

62. Aizant denies the allegations of this paragraph.

63. Aizant denies the allegations of this paragraph.

64. Aizant denies the allegations of this paragraph.

65. Aizant denies the allegations of this paragraph.

66. Aizant denies the allegations of this paragraph.

67. Aizant denies the allegations of this paragraph.

68. Aizant denies the allegations of this paragraph.

[PLAINTIFFS'] PRAYER FOR RELIEF

Aizant denies that Plaintiffs are entitled to any of the relief requested in its Prayer for Relief or to any relief whatsoever.

DEFENDANT'S AFFIRMATIVE DEFENSES

Aizant asserts the following defenses without prejudice to the denials in this Answer and without admitting any allegations of the Complaint not otherwise admitted. Aizant does not assume the burden of proof on any such defenses, except as required by the applicable law with respect to the particular defense asserted. Aizant

reserves the right to assert other defenses and/or to supplement or amend its Answer and Affirmative Defenses to the Complaint upon discovery of facts or evidence rendering such action appropriate.

FIRST AFFIRMATIVE DEFENSE
(No Direct Infringement)

Aizant does not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claims of the patents-in-suit and if the products that are the subject of ANDA No. 213152 were marketed, Aizant would not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claims of the patents-in-suit.

SECOND AFFIRMATIVE DEFENSE
(No Indirect Infringement)

Aizant has not induced or contributed to, and does not and will not induce or contribute to, the infringement, either literally or under the doctrine of equivalents, of any valid and enforceable claims of the patents-in-suit and if the products that are the subject of ANDA No. 213152 were marketed, Aizant would not induce or contribute to the infringement, either literally or under the doctrine of equivalents, of any valid and enforceable claims of the patents-in-suit.

THIRD AFFIRMATIVE DEFENSE
(Invalidity)

The claims of the patents-in-suit are invalid for failure to comply with one or more conditions for patentability set forth in one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation.

FOURTH AFFIRMATIVE DEFENSE
(Failure to State a Claim)

Plaintiffs have failed to state a claim upon which relief can be granted.

Dated: February 10, 2021

/s/ Stamatis Stamoulis _____
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