

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. 21-cv- 139 (CFC)

MSN PHARMACEUTICALS INC. and
MSN LABORATORIES PRIVATE LIMITED,

Defendants.

DEFENDANT MSN'S ANSWER TO PFIZER'S COMPLAINT

MSN Pharmaceuticals Inc. ("MSN Pharmaceuticals") and MSN Laboratories Private Limited ("MSN Labs") (collectively, "MSN"), by their attorneys, hereby respond to the complaint filed by Pfizer Inc., Warner-Lambert Company LLC, and PF PRISM IMB B.V. (collectively "Pfizer"), as follows:

1. MSN 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 MSN'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. MSN admits that it notified Pfizer by letter dated December 2, 2020 that MSN Drug Research Solutions Pvt. Ltd., had submitted to the FDA an ANDA ("MSN'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 ("MSN's ANDA Product") prior to the expiration of the patents-in-suit. MSN further admits that the ANDA number is 214758. MSN further states that MSN's Notice Letter speaks for itself.

PARTIES

3. On information and belief, MSN admits Plaintiff Pfizer Inc.'s address is correct. MSN 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. MSN 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, MSN admits Plaintiff Warner-Lambert Company LLC's address is correct. MSN 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, MSN admits Plaintiff PF PRISM IMB B.V.'s address is correct. MSN 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. MSN admits the allegations of this paragraph.
7. MSN admits the allegations of this paragraph.
8. MSN admits the allegations of this paragraph.
9. MSN admits the allegations of this paragraph.
10. MSN admits the allegations of this paragraph.
11. MSN admits the allegations of this paragraph.

JURISDICTION

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

13. This paragraph states a legal conclusion to which no answer is required. To the extent a response is required, MSN 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, MSN does not contest jurisdiction in this matter.

14. This paragraph states a legal conclusion to which no answer is required. To the extent a response is required, MSN 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, MSN does not contest jurisdiction in this matter.

15. MSN 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.

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

17. MSN denies the allegations of this paragraph.

18. MSN denies the allegations of this paragraph.

19. MSN denies the allegations of this paragraph.

20. MSN denies the allegations of this paragraph.

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

FACTUAL BACKGROUND

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

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

24. MSN admits the allegations of this paragraph.

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

COUNT I - INFRINGEMENT OF THE '730 PATENT

26. MSN incorporates its response to each of the preceding paragraphs 1-25 as if fully set forth here.

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

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

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

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

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

32. MSN 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. MSN states that its notice letter speaks for itself, so no answer is required. To the extent necessary, MSN denies the allegations of this paragraph.

33. MSN denies the allegations of this paragraph.

34. MSN 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 (2 \square) of 8.0 \pm 0.2, 10.1 \pm 0.2 and 11.5 \pm 0.2 and a primary particle size distribution characterized by a D90 value of from about 30 μm to about 65 μm ."

35. MSN denies the allegations of this paragraph.

36. MSN 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 (2 \square) of 8.0 \pm 0.2, 10.1 \pm 0.2 and 11.5 \pm 0.2 and a volume mean diameter characterized by a D[4,3] value of from about 15 μm to about 40 μm ."

37. MSN denies the allegations of this paragraph.

38. MSN 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 (2 \square) of 8.0 \pm 0.2, 10.1 \pm 0.2 and 11.5 \pm 0.2 and a volume mean diameter characterized by a D[4,3] value of from about 15 μm to about 30 μm .

39. MSN denies the allegations of this paragraph.

40. MSN denies the allegations of this paragraph.

41. MSN denies the allegations of this paragraph.

42. MSN denies the allegations of this paragraph.

43. MSN denies the allegations of this paragraph.
44. MSN denies the allegations of this paragraph.
45. MSN denies the allegations of this paragraph.
46. MSN denies the allegations of this paragraph.
47. MSN denies the allegations of this paragraph.
48. MSN admits the allegations of this paragraph.
49. MSN denies the allegations of this paragraph.
50. MSN denies the allegations of this paragraph.

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

51. MSN incorporates its response to each of the preceding paragraphs 1-50 as if fully set forth here.
 52. This paragraph states a legal conclusion to which no answer is required.
 53. MSN admits that it notified Pfizer of the submission of MSN's ANDA to the FDA. MSN states that its notice letter speaks for itself, so no further answer is required. To the extent necessary, MSN denies the allegations of this paragraph.
 54. MSN 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. MSN states that its notice letter speaks for itself, so no answer is required. To the extent necessary, MSN denies the allegations of this paragraph.

55. MSN denies the allegations of this paragraph.
56. MSN 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 (2 \square) 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 ."

57. MSN denies the allegations of this paragraph.

58. MSN 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 (2 \square) 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 ."

59. MSN denies the allegations of this paragraph.

60. MSN 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 (2 \square) 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 .

61. MSN denies the allegations of this paragraph.

62. MSN denies the allegations of this paragraph.

63. MSN denies the allegations of this paragraph.

64. MSN denies the allegations of this paragraph.

65. MSN denies the allegations of this paragraph.

66. MSN denies the allegations of this paragraph.

67. MSN denies the allegations of this paragraph.

68. MSN denies the allegations of this paragraph.

69. MSN denies the allegations of this paragraph.

70. MSN denies the allegations of this paragraph.

71. MSN denies the allegations of this paragraph.

[PLAINTIFFS'] PRAYER FOR RELIEF

MSN 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

MSN asserts the following defenses without prejudice to the denials in this Answer and without admitting any allegations of the Complaint not otherwise admitted. MSN 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. MSN 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)

MSN 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, MSN 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)

MSN 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, MSN 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 24, 2021

Respectfully submitted,

/s/ Stamatis Stamoulis
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