IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PFIZER INC., WARNER-LAMBERT COMPANY LLC and PF PRISM IMB B.V.,	)	
Plaintiffs,	)	C.A. No. 20-1407-CFC
v.	)	
SUN PHARMACEUTICAL INDUSTRIES, LTD., SUN PHARMA GLOBAL FZE and SUN PHARMACEUTICAL INDUSTRIES, INC.,	)	
Defendants.	)	

SUN PHARMACEUTICAL INDUSTRIES, LTD., SUN PHARMA GLOBAL FZE, AND SUN PHARMACEUTICAL INDUSTRIES, INC.'S
ANSWER TO COMPLAINT

Defendants Sun Pharmaceutical Industries, Ltd., Sun Pharma Global FZE, and Sun Pharmaceutical Industries, Inc. (collectively "Sun" or "Defendants") for their Answer in response to the Complaint of Pfizer Inc., Warner-Lambert Company LLC, and PF Prism IMB B.V. (collectively "Plaintiffs") in the above entitled action, state and allege as follows:

1. Paragraph 1 contains conclusions of law for which no response is required. To the extent a response is required, Sun admits that the Complaint purports to set forth claims of patent infringement concerning U.S. Patent No. 10,723,730 ("the '730 patent"). Sun further admits that Sun Pharmaceutical

Industries Ltd. submitted Sun's ANDA No. 213107 ("Sun's ANDA") to the FDA to obtain approval to engage in the commercial manufacture, use or sale of palbociclib capsules, 75 mg, 100 mg and 125 mg ("Sun's ANDA Product") prior to expiration of the '730 patent. Except as expressly admitted, Sun denies the allegations of Paragraph 1 of the Complaint. Sun specifically denies that Sun FZE was involved in the preparation and submission of Sun's ANDA.

2. Paragraph 2 contains conclusions of law for which no response is required. To the extent a response is required, Sun admits that Sun Pharmaceutical Industries, Ltd. sent a letter to Plaintiffs on September 22, 2020 ("Sun's Notice Letter"), notifying Plaintiffs that Sun Pharmaceutical Industries Ltd. submitted Sun's ANDA to the FDA pursuant to Section 505(j)(2)(B) of the Federal Food, Drug and Cosmetic Act. Sun further admits that Sun's Notice Letter states that Sun Pharmaceutical Industries Ltd. submitted Sun's ANDA to the FDA to obtain approval to engage in the commercial manufacture, use or sale of Sun's ANDA Product. Sun admits that Sun's Notice Letter included an Offer of Confidential Access ("OCA"), which Plaintiffs refused to execute. Sun admits that the parties discussed OCA terms but did not reach agreement. Except as expressly admitted, Sun denies the allegations of Paragraph 2 of the Complaint.

PARTIES

3. Sun admits that the FDA-approved prescribing information for IBRANCE® states that it is: "Distributed by Pfizer Labs Division of Pfizer Inc., NY, NY 10017," and that the FDA website (as of November 1, 2020) identifies Pfizer as the NDA holder of NDA No. 207103 for palbociclib capsules. Sun is without sufficient knowledge or information to form a belief as to the truth of the remaining allegations as set forth in Paragraph 3 of the Complaint and therefore denies the remaining allegations in Paragraph 3.

4. Sun is without sufficient knowledge or information to form a belief as to the truth of the allegations set forth in Paragraph 4 of the Complaint, and therefore, Sun denies the allegations in Paragraph 4.

5. Sun is without sufficient knowledge or information to form a belief as to the truth of the allegations set forth in Paragraph 5 of the Complaint, and therefore, Sun denies the allegations in Paragraph 5.

6. Sun admits that Sun Pharmaceutical Industries Ltd. is a company organized and existing under the laws of the Republic of India with its principal place of business at Sun House, CTS No. 201 B/1, Western Express Highway, Goregaon (E), Mumbai 400063, India. The remaining allegations as set forth in Paragraph 6 of the Complaint contain legal conclusions to which no answer is required. To the extent a response is required, Sun admits that certain corporate Sun

entities are in the business of manufacturing, marketing, importing, distributing and/or selling pharmaceutical drug products. To the extent a further answer is required, Sun Pharmaceutical Industries Ltd. does not contest personal jurisdiction in this Court for purposes of this action only.

7. Sun admits that Sun Pharmaceutical Industries, Inc. is a corporation organized and existing under the laws of the State of Delaware with its principal place of business at 2 Independence Way, Princeton, New Jersey 08540. The remaining allegations as set forth in Paragraph 7 of the Complaint contain legal conclusions to which no answer is required. To the extent a response is required, Sun admits that certain corporate Sun entities are in the business of manufacturing, marketing, importing, distributing and/or selling pharmaceutical drug products. To the extent a further answer is required, Sun Pharmaceutical Industries, Inc. does not contest personal jurisdiction in this Court for purposes of this action only.

8. Sun admits that Sun Pharma Global FZE is a corporation organized and existing under the laws of the United Arab Emirates, with places of business at Office #43, Block Y, SAIF Zone, P.O. Box. No. 122304, Sharjah, United Arab Emirates, and DMCC Branch, 704 Jumeirah Business Center 1, Cluster G, JLT, P.O. Box No. 643561, Dubai, United Arab Emirates. The remaining allegations as set forth in Paragraph 8 of the Complaint contain legal conclusions to which no answer is required. To the extent a response is required, Sun admits that certain corporate

Sun entities are in the business of manufacturing, marketing, importing, distributing and/or selling pharmaceutical drug products. Sun specifically denies that Sun FZE was involved in the preparation and submission of Sun's ANDA.

9. Sun admits that Sun Pharmaceutical Industries, Inc. and Sun Pharma Global FZE are either directly or indirectly wholly owned subsidiaries of Sun Pharmaceutical Industries Ltd.

10. Paragraph 10 of the Complaint contains legal conclusions to which no answer is required. To the extent a response is required, Sun denies the allegations of Paragraph 10 of the Complaint. To the extent a further answer is required, Sun specifically denies that Sun FZE was involved in the preparation and submission of Sun's ANDA.

11. Paragraph 11 of the Complaint contains legal conclusions to which no answer is required. To the extent a response is required, Sun denies the allegations of Paragraph 11 of the Complaint. To the extent a further answer is required, Sun specifically denies that Sun FZE was involved in the preparation and submission of Sun's ANDA and that Sun FZE participated, assisted, and cooperated in carrying out the acts complained of in the Complaint.

12. Paragraph 12 of the Complaint contains legal conclusions to which no answer is required. To the extent a response is required, Sun denies the allegations of Paragraph 12 of the Complaint.

JURISDICTION

13. Sun admits that this civil action of purported patent infringement arises under the patent laws of the United States, and that this Court has subject matter jurisdiction for Plaintiffs' infringement claim under 35 U.S.C. § 271(e) only. Otherwise, denied.

14. Paragraph 14 of the Complaint contains legal conclusions to which no answer is required. To the extent a response is required, Sun admits that certain corporate Sun entities are in the business of manufacturing, marketing, importing, distributing and/or selling pharmaceutical drug products, including within the United States. Except as expressly admitted, Sun denies the allegations of Paragraph 14. For the purposes of this action only, Sun does not contest personal jurisdiction in this Court.

15. Paragraph 15 of the Complaint contains legal conclusions to which no answer is required. To the extent a response is required, Sun admits that certain corporate Sun entities are in the business of manufacturing, marketing, importing, distributing and/or selling pharmaceutical drug products, including within the United States. Except as expressly admitted, Sun denies the allegations of Paragraph 15. For the purposes of this action only, Sun does not contest personal jurisdiction in this Court.

16. Paragraph 16 of the Complaint contains legal conclusions to which no answer is required. To the extent a response is required, Sun admits that certain corporate Sun entities are in the business of manufacturing, marketing, importing, distributing and/or selling pharmaceutical drug products, including within the United States. Except as expressly admitted, Sun denies the allegations of Paragraph 16. For the purposes of this action only, Sun does not contest personal jurisdiction in this Court.

17. Paragraph 17 of the Complaint contains legal conclusions to which no answer is required. To the extent a response is required, Sun admits that Sun has been involved in prior patent litigations that concerned ANDAs having certifications under Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. §355(j)(2)(A)(vii)(IV). Otherwise, denied.

18. Paragraph 18 of the Complaint contains legal conclusions to which no answer is required. To the extent a response is required, Sun admits that it has knowledge of ANDA litigation, that it properly sent a Notice Letter to Pfizer concerning Sun's ANDA, and indicated that claims of the patent-in-suit are not infringed. Sun denies the remaining allegations of Paragraph 18 of the Complaint. Sun does not contest personal jurisdiction in this Court for the purposes of this action only.

19. Paragraph 19 of the Complaint contains legal conclusions to which no answer is required. To the extent a response is required, Sun admits that it has been a litigant in connection with other ANDA cases. To the extent a further response is required, Sun denies the allegations of Paragraph 19 of the Complaint. Sun does not contest personal jurisdiction in this Court for the purposes of this action only.

20. Paragraph 20 of the Complaint contains legal conclusions to which no answer is required. To the extent a response is required, Sun admits that certain corporate Sun entities are in the business of manufacturing, marketing, importing, distributing and/or selling pharmaceutical drug products, including within the United States. To the extent a further response is required, Sun denies the allegations of Paragraph 20 of the Complaint. Sun does not contest personal jurisdiction in this Court for the purposes of this action only.

21. Paragraph 21 of the Complaint contains legal conclusions to which no answer is required. To the extent a response is required, Sun admits that certain corporate Sun entities are in the business of manufacturing, marketing, importing, distributing and/or selling pharmaceutical drug products, including within the United States. To the extent a further response is required, Sun denies (or lacks information and therefore denies) the allegations of Paragraph 21 of the Complaint. Sun does not contest personal jurisdiction in this Court for the purposes of this action only.

COUNT 1 – INFRINGEMENT OF THE '730 PATENT

22. Sun incorporates by reference each of its answers to Paragraphs 1 through 21 of the Complaint as though fully set forth herein.

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

24. Sun admits that the '730 patent, on its face, is entitled "Solid Forms of a Selective CDK4/6 Inhibitor" and states the date of issue as July 28, 2020. Sun further admits that Exhibit A to the Complaint purports to be a copy of the '730 patent. Sun denies that the '730 patent was duly and legally issued.

25. Sun is without sufficient knowledge or information to form a belief as to the truth of the allegations of Paragraph 25 and therefore denies those allegations.

26. Paragraph 26 of the Complaint contains legal conclusions to which no answer is required. To the extent a response is required, Sun admits that the '730 patent is listed in the Orange Book in connection with NDA No. 207103. To the extent a further response is required, Sun is without sufficient knowledge or information to form a belief as to the truth of the allegations of Paragraph 26 and therefore denies those allegations.

27. Sun denies that Sun FZE was involved in the submission of Sun's ANDA to FDA. Otherwise, admitted.

28. Sun admits that Sun's ANDA No. 213107 includes a Paragraph IV Certification with respect to the '730 patent. Sun further admits that Sun's Notice Letter states that the claims of the '730 patent are invalid and/or will not be infringed by Sun's ANDA Product. To the extent a further response is required, denied.

29. Denied.

30. Sun admits that claim 1 of the '730 patent states:

> 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.

Otherwise, denied.

31. Denied.

32. Sun admits that claim 7 of the '730 patent states:

> 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.

Otherwise, denied.

33. Denied.

34. Sun admits that claim 15 of the '730 patent states:

> 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.

Otherwise, denied.

35. Denied.

36. Denied.

37. Paragraph 37 of the Complaint contains legal conclusions to which no answer is required. To the extent a response is required, Sun admits that Sun submitted Sun's ANDA to the FDA pursuant to Section 505(j)(2)(B) of the Federal Food, Drug and Cosmetic Act. Sun further admits that Sun's Notice Letter states that Sun Pharmaceutical Industries Ltd. submitted Sun's ANDA to the FDA to obtain approval to engage in the commercial manufacture, use or sale of Sun's ANDA Product. Except as expressly admitted, Sun denies the allegations of Paragraph 37 of the Complaint.

38. Denied.

39. Denied.

40. Denied.

41. Denied.

42. Sun admits that Sun Pharmaceutical Industries Ltd. caused the submission of Sun's ANDA to the FDA to obtain approval to engage in the

commercial manufacture, use or sale of Sun's ANDA Product prior to expiration of the '730 patent. Otherwise, denied.

43. Denied.

44. Denied.

45. Denied.

46. Denied.

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

47. Sun incorporates by reference each of its answers to Paragraphs 1 through 46 of the Complaint as though fully set forth herein.

48. Paragraph 48 of the Complaint contains legal conclusions to which no answer is required. To the extent a response is required, Sun admits that the Court may declare the rights and legal relations of Sun and Plaintiffs pursuant to 28 U.S.C. §§ 2201 and 2202. Sun further admits that the Court has subject matter jurisdiction for claims under 35 U.S.C. § 271(e)(2) only and as to Sun Ltd. and Sun Inc. only. Otherwise, denied.

49. Sun denies that Sun FZE was involved in submission of Sun's ANDA to FDA. Otherwise, admitted.

50. Sun admits that Sun's ANDA No. 213107 includes a Paragraph IV Certification with respect to the '730 patent. Sun further admits that Sun's Notice Letter states that the claims of the '730 patent are invalid and/or will not be infringed

by Sun's ANDA Product. Sun denies that Sun FZE was involved in submission of Sun's ANDA to FDA. To the extent a further response is required, denied.

51. Denied.

52. Sun admits that claim 1 of the '730 patent states:

> 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.

Otherwise, denied.

53. Denied.

54. Sun admits that claim 7 of the '730 patent states:

> 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.

Otherwise, denied.

55. Denied.

56. Sun admits that claim 15 of the '730 patent states:

> 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.

Otherwise, denied.

57. Denied.

58. Paragraph 58 of the Complaint contains legal conclusions to which no answer is required. To the extent a response is required, Sun admits that Sun submitted Sun's ANDA to the FDA pursuant to Section 505(j)(2)(B) of the Federal Food, Drug and Cosmetic Act. Sun further admits that Sun's Notice Letter states that Sun Pharmaceutical Industries Ltd. submitted Sun's ANDA to the FDA to obtain approval to engage in the commercial manufacture, use or sale of Sun's ANDA Product. Except as expressly admitted, Sun denies the allegations of Paragraph 58 of the Complaint.

59. Denied.

60. Denied.

61. Denied.

62. Denied.

63. Sun admits that Sun Pharmaceutical Industries Ltd. caused the submission of Sun's ANDA to the FDA to obtain approval to engage in the commercial manufacture, use or sale of Sun's ANDA Product prior to expiration of the '730 patent. Otherwise, denied.

64. Denied.

65. Denied.

66. Denied.

67. Denied.

ANSWER TO PLAINTIFFS' REQUEST FOR RELIEF

Sun denies that Plaintiffs are entitled to the relief sought against Sun in Paragraphs (a)–(g) of the Complaint or any relief at all for the allegations relating to Sun made in the Complaint.

SEPARATE DEFENSES

On information and belief, Sun asserts the following Separate Defenses to Plaintiffs' Complaint.

FIRST SEPARATE DEFENSE
(*Invalidity of U.S. Patent No. 10,723,730*)

Based on information and belief, the claims of the '730 patent are invalid for failing to satisfy one or more requirements for patentability of Title 35 of the United States Code, including 35 U.S.C. §§ 101, 102, 103 and/or 112, or other judicially-created bases for invalidity or unenforceability.

SECOND SEPARATE DEFENSE
(*Non-infringement of U.S. Patent No. 10,723,730*)

The submission of ANDA No. 213107 and/or manufacture, use, sale, offer for sale and/or importation into the United States of the product covered by ANDA No. 213107 does not and will not directly infringe, indirectly infringe, induce infringement of, or contribute to the infringement of, either literally or under the

Doctrine of Equivalents, any valid and enforceable claim of U.S. Patent No. 10,723,730.

THIRD SEPARATE DEFENSE
(*Subject Matter Jurisdiction*)

The Court lacks subject matter jurisdiction over any and all claims asserted against Sun Inc. and Sun FZE and any and all claims asserted under 35 U.S.C. § 271(a), (b) or (c).

FOURTH SEPARATE DEFENSE

Plaintiffs fail to state a proper claim for exceptional case.

FIFTH SEPARATE DEFENSE

The Complaint fails to state a cause of action under 35 U.S.C. § 271(e)(2)(A) against any entity other than Sun Pharmaceutical Industries Ltd. because only this Sun entity filed Sun's ANDA with a paragraph IV certification.

SIXTH SEPARATE DEFENSE

The Complaint fails to state a cause of action under 35 U.S.C. §§ 271(a)-(c) against Sun because Plaintiffs have not pleaded with particularity facts regarding any post-ANDA-approval activities.

RESERVATION OF ADDITIONAL SEPARATE AND/OR AFFIRMATIVE DEFENSES

Sun reserves the right to assert defenses in the event that discovery or other analysis indicates that additional separate and/or affirmative defenses are appropriate, including, but not limited to, defenses of unenforceability.

PRAYER FOR RELIEF

WHEREFORE, Sun prays for the following relief:

A. An order dismissing the Complaint with prejudice and denying each request for relief made by Plaintiffs;

B. An order declaring that no valid and enforceable claim of the '730 patent is infringed by the submission of Sun's ANDA or by the making, use, sale, offer for sale, marketing or importation into the United States of the product described in Sun's ANDA No. 213107;

C. An order declaring that the claims of the '730 patent is invalid for failure to comply with one or more of the conditions set forth in Title 35 of the United States Code;

D. An order awarding Sun its attorneys' fees, costs, and expenses in this action as allowed by law or pursuant to 35 U.S.C. § 285; and

E. Awarding Sun such other and further relief as the Court deems just and proper.

/s/ Kelly E. Farnan

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