IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IN RE: PALBOCICLIB PATENT LITIGATION	)	MDL No. 19-2912 (CFC)
PFIZER INC., WARNER-LAMBERT COMPANY LLC, PF PRISM C.V., PFIZER MANUFACTURING HOLDINGS LLC, PFIZER PFE IRELAND PHARMACEUTICALS HOLDING 1 B.V., and PF PRISM IMB B.V.,	)	
Plaintiffs,	)	
v.	)	C.A. No. 19-1863 (CFC)
MYLAN PHARMACEUTICALS, INC.	)	
Defendant	)	

FIRST AMENDED COMPLAINT

Pfizer Inc., Warner-Lambert Company LLC, PF PRISM C.V., Pfizer Manufacturing Holdings LLC, Pfizer PFE Ireland Pharmaceuticals Holding 1 B.V., and PF PRISM IMB B.V. (collectively "Pfizer") file this First Amended Complaint for patent infringement against Mylan Pharmaceuticals Inc. ("Mylan"), 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 Mylan's submission of an Abbreviated New Drug Applications ("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. 6,936,612 ("the '612 patent"); U.S. Patent No. RE47,739 ("the '739 patent")[1]; and U.S. Patent No. 7,456,168 ("the '168 patent"). These three patents are referred to collectively herein as "the patents-in-suit."

2. Mylan Pharmaceuticals Inc. notified Pfizer by letters dated March 18, 2019 ("Mylan Notice Letter") and March 5, 2020 (Mylan's Supplemental Notice Letter") (collectively, "Mylan's Notice Letters") that it had submitted to the FDA ANDA No. 213141 ("Mylan'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 ("Mylan's ANDA Product") prior to the expiration of the patents-in-suit.

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 tablets, 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 C.V. is a limited partnership (*commanditaire vennootschap*) organized under the laws of the Netherlands, having its registered seat in Rotterdam, the Netherlands, that for all purposes is represented by and acting through its general partner Pfizer

[1] The '739 patent is a reissue of U.S. Patent No. 7,208,489, which was originally asserted in this litigation.

Manufacturing Holdings LLC, a limited liability company organized under the laws of the State of Delaware, and having its address at 235 East 42nd Street, New York, New York 10017.

6. Plaintiff Pfizer PFE Ireland Pharmaceuticals Holding 1 B.V. is a private limited liability company (*besloten vennootschap*) organized under the laws of the Netherlands, having its registered seat in Rotterdam, the Netherlands, having its business address at Rivium Westlaan 142, 2909 LD, Capelle aan den IJssel, the Netherlands.

7. 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.

8. Upon information and belief, defendant Mylan Pharmaceuticals Inc. is a corporation organized and existing under the laws of the State of West Virginia with its principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505. Upon information and belief, Mylan Pharmaceuticals Inc. is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical products for the U.S. market.

9. Upon information and belief, Mylan Pharmaceuticals Inc. is a wholly owned subsidiary of Mylan Inc.

10. Upon information and belief, Mylan Inc. and Mylan Pharmaceuticals Inc. acted in concert to prepare and submit Mylan's ANDA to the FDA.

11. Upon information and belief, following any FDA approval of Mylan's ANDA, Mylan Inc. and Mylan Pharmaceuticals Inc. will act in concert to distribute and sell Mylan's ANDA Product throughout the United States, including within West Virginia.

JURISDICTION

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

13. Mylan Pharmaceuticals Inc. is subject to personal jurisdiction in West Virginia because, among other things, it has purposely availed itself of the benefits and protections of West Virginia's laws such that it should reasonably anticipate being haled into court here. Mylan Pharmaceuticals Inc. is a corporation organized and existing under the laws of the State of West Virginia, is qualified to do business in West Virginia, and has appointed a registered agent for service of process in West Virginia. It therefore has consented to general jurisdiction in West Virginia. Upon information and belief, Mylan Pharmaceuticals Inc. develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in the State of West Virginia and therefore transacts business within the State of West Virginia related to Pfizer's claims, and/or has engaged in systematic and continuous business contacts within the State of West Virginia. In its Answer to Pfizer's Complaint, Mylan stated that it "does not contest personal jurisdiction or venue" in West Virginia. 1:19-cv-00097 (N.D.W. Va.), ECF No. 26, ¶¶ 11, 13, 15–16.[2]

14. Upon information and belief, if Mylan's ANDA is approved, Mylan will directly or indirectly manufacture, market, sell, and/or distribute Mylan's ANDA Product within the United States, including in West Virginia, consistently with Mylan's practices for the marketing and distribution of other generic pharmaceutical products. Upon information and belief, Mylan regularly does business in West Virginia, and its practices with other generic pharmaceutical products have involved placing those products into the stream of commerce for distribution

[2] The Joint Panel on Multidistrict Litigation has transferred the West Virginia action to this Court for "coordinated or consolidated pretrial proceedings." 1:19-md-02912, D.I. 1, at 3.

throughout the United States, including in West Virginia. Upon information and belief, Mylan's generic pharmaceutical products are used and/or consumed within and throughout the United States, including in West Virginia. Upon information and belief, Mylan's ANDA Product will be prescribed by physicians practicing in West Virginia, dispensed by pharmacies located within West Virginia, and used by patients in West Virginia. Each of these activities would have a substantial effect within West Virginia and would constitute infringement of Pfizer's patents in the event that Mylan's ANDA Product is approved before the patents expire.

15. Upon information and belief, Mylan derives substantial revenue from generic pharmaceutical products that are used and/or consumed within West Virginia, and which are manufactured by Mylan and/or for which Mylan Pharmaceuticals Inc. or Mylan Inc. is the named applicant on approved ANDAs. Upon information and belief, various products for which Mylan Pharmaceuticals Inc. or Mylan Inc. is the named applicant on approved ANDAs are available at retail pharmacies in West Virginia.

COUNT I - INFRINGEMENT OF THE '612 PATENT

16. Pfizer incorporates each of the preceding paragraphs 1–15 as if fully set forth herein.

17. The inventors named on the '612 patent are Mark Barvian, Richard J. Booth, John Quin, III, Joseph T. Repine, Derek J. Sheehan, Peter L. Toogood, Scott N. Vanderwel, and Hairong Zhou.

18. The '612 patent, entitled "2-(Pyridin-2-ylamino)-pyrido[2,3-d]pyrimidin-7-ones" (attached as Exhibit A), was duly and legally issued on August 30, 2005.

19. Pfizer is the owner and assignee of the '612 patent.

20. Claim 1 of the '612 patent recites "[a] compound which is 6-Acetyl-8-cyclopentyl-5-methyl-2-(5-piperazin-1-yl-pyridin-2-ylamino)-8H-pyrido[2,3-d]pyrimidin-7-one."

21. Claim 2 of the '612 patent recites "A pharmaceutical composition comprising a therapeutically effective amount of the compound according to claim 1 and a pharmaceutical carrier therefor."

22. IBRANCE® is covered by claims 1 and 2 of the '612 patent, and the '612 patent has been listed in connection with IBRANCE® in the FDA's Orange Book.

23. In Mylan's Notice Letter, Mylan notified Pfizer of the submission of Mylan'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 Mylan's ANDA Product prior to the expiration of the '612 patent.

24. In Mylan's Notice Letter, Mylan also notified Pfizer that, as part of its ANDA, Mylan 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 '612 patent. On information and belief, Mylan submitted its ANDA to the FDA containing certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '612 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Mylan's ANDA Product.

25. Mylan's ANDA Product and the use of Mylan's ANDA Product are covered by claims 1 and 2 of the '612 patent.

26. In Mylan's Notice Letter, Mylan did not contest the infringement of claim 1 or 2 of the '612 patent on any basis other than the alleged invalidity of those claims.

27. Mylan's submission of Mylan's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Mylan's ANDA Product before the expiration of the '612 patent was an act of infringement of the '612 patent under 35 U.S.C. § 271(e)(2)(A).

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

29. The manufacture, use, sale, offer for sale, or importation of Mylan's ANDA Product would infringe claims 1 and 2 of the '612 patent.

30. On information and belief, the manufacture, use, sale, offer for sale, or importation of Mylan's ANDA Product in accordance with, and as directed by, its proposed product labeling would infringe claims 1 and 2 of the '612 patent.

31. On information and belief, Mylan plans and intends to, and will, actively induce infringement of the '612 patent when Mylan's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Mylan's activities will be done with knowledge of the '612 patent and specific intent to infringe that patent.

32. On information and belief, Mylan knows that Mylan's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '612 patent, that Mylan's ANDA Product is not a staple article or commodity of commerce, and that Mylan's ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Mylan plans and intends to, and will, contribute to infringement of the '612 patent immediately and imminently upon approval of Mylan's ANDA.

33. Notwithstanding Mylan's knowledge of the claims of the '612 patent, Mylan has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Mylan's ANDA Product with its product labeling following FDA approval of Mylan's ANDA prior to the expiration of the '612 patent.

34. The foregoing actions by Mylan constitute and/or will constitute infringement of the '612 patent; active inducement of infringement of the '612 patent; and contribution to the infringement by others of the '612 patent.

35. On information and belief, Mylan has acted with full knowledge of the '612 patent and without a reasonable basis for believing that it would not be liable for infringement of the '612 patent; active inducement of infringement of the '612 patent; and/or contribution to the infringement by others of the '612 patent.

36. Pfizer will be substantially and irreparably damaged by infringement of the '612 patent.

37. Unless Mylan is enjoined from infringing the '612 patent, actively inducing infringement of the '612 patent, and contributing to the infringement by others of the '612 patent, Pfizer will suffer irreparable injury. Pfizer has no adequate remedy at law.

COUNT II - INFRINGEMENT OF THE '739 PATENT

38. Pfizer incorporates each of the preceding paragraphs 1–37 as if fully set forth herein.

39. The inventors named on the '739 patent are Mark Barvian, Richard J. Booth, John Quin, III, Joseph T. Repine, Derek J. Sheehan, Peter L. Toogood, Scott N. Vanderwel, and Hairong Zhou.

40. The '739 patent, entitled "2-(pyridin-2-ylamino)-pyrido [2,3-d]pyrimidin-7-ones" (attached as Exhibit B), was duly and legally issued on November 26, 2019.

41. Pfizer is the owner and assignee of the '739 patent.

42. The '739 patent claims, *inter alia*, a compound of the formula recited in claim 2 of the '739 patent.

43. IBRANCE® is covered by one or more claims of the '739 patent, including claims 2, 6, 7 and 9–12 of the '739 patent, and the '739 patent has been listed in connection with IBRANCE® in the FDA's Orange Book.

44. In Mylan's Supplemental Notice Letter, Mylan notified Pfizer of the submission of Mylan'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 Mylan's ANDA Product prior to the expiration of the '739 patent.

45. In Mylan's Supplemental Notice Letter, Mylan also notified Pfizer that, as part of its ANDA, Mylan 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 '739 patent. On information and belief, Mylan submitted its ANDA to the FDA containing certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '739 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Mylan's ANDA Product.

46. Mylan's ANDA Product and the use of Mylan's ANDA Product are covered by at least claims 2, 6, 7 and 9–12 of the '739 patent.

47. In Mylan's Supplemental Notice Letter, Mylan did not contest the infringement of claim 2, 6, 7 and 9–12 of the '739 patent on any basis other than the alleged invalidity of those claims.

48. Mylan's submission of Mylan's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Mylan's ANDA Product before the expiration of the '739 patent was an act of infringement of the '739 patent under 35 U.S.C. § 271(e)(2)(A).

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

50. The manufacture, use, sale, offer for sale, or importation of Mylan's ANDA Product would infringe one or more claims of the '739 patent, including, *inter alia*, claims 2, 6, 7 and 9–12 of the '739 patent.

51. On information and belief, the manufacture, use, sale, offer for sale, or importation of Mylan's ANDA Product in accordance with, and as directed by, its proposed product labeling would infringe one or more claims of the '739 patent, including, *inter alia*, claims 2, 6, 7 and 9–12 of the '739 patent.

52. On information and belief, Mylan plans and intends to, and will, actively induce infringement of the '739 patent when Mylan's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Mylan's activities will be done with knowledge of the '739 patent and specific intent to infringe that patent.

53. On information and belief, Mylan knows that Mylan's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '739 patent, that Mylan's ANDA Product is not a staple article or commodity of commerce, and that Mylan's ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On

information and belief, Mylan plans and intends to, and will, contribute to infringement of the '739 patent immediately and imminently upon approval of Mylan's ANDA.

54. Notwithstanding Mylan's knowledge of the claims of the '739 patent, Mylan has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Mylan's ANDA Product with its product labeling following FDA approval of Mylan's ANDA prior to the expiration of the '739 patent.

55. The foregoing actions by Mylan constitute and/or will constitute infringement of the '739 patent; active inducement of infringement of the '739 patent; and contribution to the infringement by others of the '739 patent.

56. On information and belief, Mylan has acted with full knowledge of the '739 patent and without a reasonable basis for believing that it would not be liable for infringement of the '739 patent; active inducement of infringement of the '739 patent; and/or contribution to the infringement by others of the '739 patent.

57. Pfizer will be substantially and irreparably damaged by infringement of the '739 patent.

58. Unless Mylan is enjoined from infringing the '739 patent, actively inducing infringement of the '739 patent, and contributing to the infringement by others of the '739 patent, Pfizer will suffer irreparable injury. Pfizer has no adequate remedy at law.

COUNT III - INFRINGEMENT OF THE '168 PATENT

59. Pfizer incorporates each of the preceding paragraphs 1–58 as if fully set forth herein.

60. The inventors named on the '168 patent are Mark Barvian, Richard J. Booth, John Quin, III, Joseph T. Repine, Derek J. Sheehan, Peter L. Toogood, Scott N. Vanderwel, and Hairong Zhou.

61. The ’168 patent, entitled “2-(pyridin-2-ylamino)-pyrido [2,3-d]pyrimidin-7-ones” (attached as Exhibit C), was duly and legally issued on November 25, 2008.

62. Pfizer is the owner and assignee of the ’168 patent.

63. The ’168 patent claims, *inter alia*, “[a] method of treating breast cancer in a mammal comprising administering to said mammal an amount of a compound of” the formula recited in claim 1 of the ’168 patent.

64. IBRANCE®, as well as methods of using IBRANCE®, are covered by one or more claims of the ’168 patent, including claim 1 of the ’168 patent, and the ’168 patent has been listed in connection with IBRANCE® in the FDA’s Orange Book.

65. In Mylan’s Notice Letter, Mylan notified Pfizer of the submission of Mylan’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 Mylan’s ANDA Product prior to the expiration of the ’168 patent.

66. In Mylan’s Notice Letter, Mylan also notified Pfizer that, as part of its ANDA, Mylan 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 ’168 patent. On information and belief, Mylan submitted its ANDA to the FDA containing certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the ’168 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Mylan’s ANDA Product.

67. The use of Mylan’s ANDA Product is covered by claims 1–4 of the ’168 patent.

68. Mylan’s submission of Mylan’s ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Mylan’s

ANDA Product before the expiration of the '168 patent was an act of infringement of the '168 patent under 35 U.S.C. § 271(e)(2)(A).

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

70. The manufacture, use, sale, offer for sale, or importation of Mylan's ANDA Product would directly and/or indirectly infringe claims 1–4 of the '168 patent.

71. On information and belief, the manufacture, use, sale, offer for sale, or importation of Mylan's ANDA Product in accordance with, and as directed by, its proposed product labeling would directly and/or indirectly infringe claims 1–4 of the '168 patent.

72. On information and belief, Mylan plans and intends to, and will, actively induce infringement of the '168 patent when Mylan's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Mylan's activities will be done with knowledge of the '168 patent and specific intent to infringe that patent.

73. On information and belief, Mylan knows that Mylan's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '168 patent, that Mylan's ANDA Product is not a staple article or commodity of commerce, and that Mylan's ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Mylan plans and intends to, and will, contribute to infringement of the '168 patent immediately and imminently upon approval of Mylan's ANDA.

74. Notwithstanding Mylan's knowledge of the claims of the '168 patent, Mylan has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Mylan's

ANDA Product with its product labeling following FDA approval of Mylan's ANDA prior to the expiration of the '168 patent.

75. The foregoing actions by Mylan constitute and/or will constitute infringement of the '168 patent; active inducement of infringement of the '168 patent; and contribution to the infringement by others of the '168 patent.

76. On information and belief, Mylan has acted with full knowledge of the '168 patent and without a reasonable basis for believing that it would not be liable for infringement of the '168 patent; active inducement of infringement of the '168 patent; and/or contribution to the infringement by others of the '168 patent.

77. Pfizer will be substantially and irreparably damaged by infringement of the '168 patent.

78. Unless Mylan is enjoined from infringing the '168 patent, actively inducing infringement of the '168 patent, and contributing to the infringement by others of the '168 patent, Pfizer will suffer irreparable injury. Pfizer has no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Pfizer requests the following relief:

(a) A judgment that each of the patents-in-suit has been infringed under 35 U.S.C. § 271(e)(2) by Mylan's submission to the FDA of Mylan's ANDA;

(b) A judgment ordering that the effective date of any FDA approval of commercial manufacture, use, or sale of Mylan's ANDA Product, or any other drug product that infringes or the use of which infringes one or more of the patents-in-suit, be not earlier than the latest of the expiration dates of said patents, inclusive of any extension(s) and additional period(s) of exclusivity;

(c) A preliminary and permanent injunction enjoining Mylan, and all persons acting in concert with Mylan, from the commercial manufacture, use, sale, offer for sale, or importation into the United States of Mylan's ANDA Product, or any other drug product covered by or whose use is covered by one or more of the patents-in-suit, prior to the expiration of said patents, 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 Mylan's ANDA Product, or any other drug product which is covered by or whose use is covered by one-or-more of the patents-in-suit, prior to the expiration of said patents, will infringe, induce the infringement of, and contribute to the infringement by others of, said patents;

(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.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Megan E. Dellinger

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