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. _____
APOTEX INC. and APOTEX CORP,	)	
Defendants.	)	

COMPLAINT

Pfizer Inc., Warner-Lambert Company LLC, and PF PRISM IMB B.V. (collectively "Pfizer") file this Complaint for patent infringement against Apotex Inc. and Apotex Corp. (collectively, "Apotex"), 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 Apotex'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) tablets, 75 mg, 100 mg, and 125 mg, prior to the expiration of U.S. Patent No. RE47,739 ("the '739 patent" or "the patent-in-suit")

2. Apotex Corp. notified Pfizer by letter dated May 9, 2025 ("Apotex's Notice Letter") that it had submitted to the FDA ANDA No. 220350 ("Apotex's ANDA"), seeking approval from the FDA to engage in the commercial manufacture, use and/or sale of generic Palbociclib tablets,

75 mg, 100 mg, and 125 mg ("Apotex's ANDA Products") prior to the expiration of the patent-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 66 Hudson Yards East, New York, NY 10001. Pfizer Inc. is the holder of New Drug Application ("NDA") No. 212436 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 66 Hudson Yards East, New York, NY 10001.

5. Plaintiff PF PRISM IMB B.V. is a private limited liability 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 Apotex Inc. is a company organized and existing under the laws of Canada, with a principal place of business at 150 Signet Drive, Toronto, Ontario M9L 1T9, Canada. Upon information and belief, Apotex Inc. is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical drugs through various operating subsidiaries, including Apotex Corp.

7. Upon information and belief, Apotex Corp. is a corporation organized under the laws of the State of Delaware, with a principal place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326. Upon information and belief, Apotex Corp. is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical products for the U.S. market.

8. Upon information and belief, Apotex Corp. is a wholly owned subsidiary of Apotex Inc. and is controlled and/or dominated by Apotex Inc.

9. Upon information and belief, Apotex Inc. and Apotex Corp. act in concert to file ANDAs with the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic versions of drug products that are covered by United States patents. Upon information and belief, as part of these ANDAs, Apotex Corp., acting in concert with Apotex Inc., files certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act ("Paragraph IV Certifications") to engage in the commercial manufacture, use, offer for sale, and/or importation of drug products prior to the expiration of United States patents that cover such products.

10. Upon information and belief, Apotex Inc. and Apotex Corp. acted in concert to prepare and submit Apotex's ANDA for Apotex's ANDA Products, which was done at the direction of, under the control of, and for the direct benefit of Apotex Inc.

11. Upon information and belief, Apotex Inc. and Apotex Corp. are agents of each other, and/or operate in concert as integrated parts of the same business group, and enter into agreements with each other that are nearer than arm's length, including with respect to the development, regulatory approval, marketing, sale, offer for sale, and distribution of generic pharmaceutical products throughout the United States, including into Delaware, and including with respect to Apotex's ANDA Products at issue.

12. Upon information and belief, following any FDA approval of Apotex's ANDA, Apotex Inc. and Apotex Corp. will act in concert to market, distribute, offer for sale, and sell Apotex's ANDA Products throughout the United States and within Delaware.

13. Upon information and belief, following FDA approval of Apotex's ANDA, Apotex knows and intends that Apotex's ANDA Products will be marketed, used, distributed, offered for sale, and sold in the United States and within Delaware.

JURISDICTION

14. This Court has personal jurisdiction over each of Apotex Inc. and Apotex Corp.

15. Apotex Inc. is subject to personal jurisdiction in Delaware because, among other things, Apotex Inc., itself and through its wholly owned subsidiary Apotex Corp., has purposefully availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. On information and belief, Apotex Inc., itself and through its wholly-owned subsidiary Apotex Corp., develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including the State of Delaware, and therefore transacts business within the State of Delaware, and/or has engaged in systematic and continuous business contacts within the State of Delaware. In addition, Apotex Inc. is subject to personal jurisdiction in Delaware because, on information and belief, it controls Apotex Corp. and therefore the activities of Apotex Corp. in this jurisdiction are attributed to Apotex Inc.

16. Apotex Corp. is subject to personal jurisdiction in Delaware because, among other things, it has purposely availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. Apotex Corp. is a corporation formed under the laws of the State of Delaware, is qualified to do business in Delaware, and has appointed a registered agent for service of process in Delaware. It therefore has consented to general jurisdiction in Delaware. In addition, on information and belief, Apotex Corp. develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in the State of Delaware and therefore transacts business within the State of

Delaware related to Plaintiffs' claims, and/or has engaged in systematic and continuous business contacts within the State of Delaware.

17. In addition, this Court has personal jurisdiction over Apotex Inc. and Apotex Corp. because, among other things, on information and belief: (1) Apotex Inc. and Apotex Corp. acted in concert to file an ANDA for the purpose of seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Apotex's ANDA Products in the United States, including in Delaware; and (2) Apotex Inc. and Apotex Corp., acting in concert and/or as agents of one another, will market, distribute, offer for sale, and/or sell Apotex's ANDA Products in the United States, including in Delaware, upon approval of Apotex's ANDA, and will derive substantial revenue from the use or consumption of Apotex's ANDA Products in the State of Delaware. On information and belief, if Apotex's ANDA is approved, the generic Apotex products charged with infringing the patent-in-suit would, among other things, be marketed, distributed, offered for sale, and/or sold in Delaware, prescribed by physicians practicing in Delaware, dispensed by pharmacies located within Delaware, and/or used by patients in Delaware, all of which would have a substantial effect on Delaware.

18. Further, this Court has personal jurisdiction over Apotex because Apotex Inc. and Apotex Corp. regularly engage in patent litigation concerning FDA-approved branded drug products in this district, do not contest personal jurisdiction in this district, and have purposefully availed themselves of the rights and benefits of this Court by asserting claims and/or counterclaims in this Court. *See, e.g.*, *Bayer Healthcare LLC et al. v. Apotex Inc. et al.*, Case No 21-1429-WCB, D.I. 14 (D. Del. Mar. 1, 2022); *Bial-Portela & CA S.A. v. Apotex Inc. et al.*, Case No. 21-187-CFC, D.I. 6 (D. Del. Mar. 3, 2021); *Merck Sharp & Dohme Corp. v. Apotex Inc. et al.*, Case No. 20-749-RGA, D.I. 7 (D. Del. June 26, 2020); *AstraZeneca AB v.*

Apotex Inc. et al., Case No. 18-2010-RGA, D.I. 8 (D. Del. Jan. 2, 2019); *Astellas US LLC v. Apotex Inc. et al.*, Case No. 18-1675-CFC, D.I. 84 (D. Del. July 5, 2019).

19. Alternatively, if Apotex Inc.'s connections with Delaware, including its connections with Apotex Corp., are found to be insufficient to confer personal jurisdiction, then, upon information and belief, Apotex Inc. is not subject to jurisdiction in any state's courts of general jurisdiction, and exercising jurisdiction over Apotex Inc. in Delaware is consistent with the United States Constitution and laws. *See* Fed. R. Civ. P. 4(k)(2).

VENUE

20. Venue is proper in this district for Apotex Inc. pursuant to 28 U.S.C. § 1391 because, *inter alia,* Apotex Inc. is a corporation organized and existing under the laws of Canada and is subject to personal jurisdiction in this judicial district.

21. Venue is proper in this district for Apotex Corp. pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia,* Apotex Corp. is a corporation organized and existing under the laws of the State of Delaware and is subject to personal jurisdiction in this judicial district.

FACTUAL BACKGROUND

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

23. Upon information and belief, Apotex's ANDA Products are a generic version of IBRANCE®.

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

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

COUNT I - INFRINGEMENT OF THE '739 PATENT

26. Pfizer incorporates each of the preceding paragraphs as if fully set forth herein.

27. 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.

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

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

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

31. 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 publication Approved Drug Products with Therapeutic Equivalence Evaluations (commonly known as "the Orange Book").

32. In Apotex's Notice Letter, Apotex notified Pfizer of the submission of Apotex'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 Apotex's ANDA Products prior to the expiration of the '739 patent.

33. In Apotex's Notice Letter, Apotex also notified Pfizer that, as part of its ANDA, Apotex 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, Apotex 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 Apotex's ANDA Products.

34. Apotex's ANDA Products and the use of Apotex's ANDA Products are covered by at least claims 2, 6, 7 and 9–12 of the '739 patent.

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

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

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

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

39. On information and belief, the manufacture, use, sale, offer for sale, or importation of Apotex's ANDA Products 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.

40. On information and belief, Apotex plans and intends to, and will, actively induce infringement of the '739 patent when Apotex's ANDA is approved, and plans and intends to, and

will, do so immediately and imminently upon approval. Apotex's activities will be done with knowledge of the '739 patent and specific intent to infringe that patent.

41. On information and belief, Apotex knows that Apotex's ANDA Products and their proposed labeling are especially made or adapted for use in infringing the '739 patent, that Apotex's ANDA Products are not staple articles or commodities of commerce, and that Apotex ANDA Products and their proposed labeling are not suitable for substantial noninfringing use. On information and belief, Apotex plans and intends to, and will, contribute to infringement of the '739 patent immediately and imminently upon approval of Apotex's ANDA.

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

43. The foregoing actions by Apotex 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.

44. On information and belief, Apotex 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.

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

46. Unless Apotex 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 II - DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '739 PATENT

47. Pfizer incorporates each of the preceding paragraphs as if fully set forth herein.

48. 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 the one hand and Apotex on the other regarding Apotex's infringement, active inducement of infringement, and contribution to the infringement by others of the '739 patent, and/or the validity of the '739 patent.

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

50. In Apotex's Notice Letter, Apotex notified Pfizer of the submission of Apotex'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 Apotex's ANDA Products prior to the expiration of the '739 patent.

51. In Apotex's Notice Letter, Apotex also notified Pfizer that, as part of its ANDA, Apotex 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, Apotex 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 Apotex's ANDA Products.

52. Apotex's ANDA Products and the use of Apotex's ANDA Products are covered by at least claims 2, 6, 7 and 9–12 of the '739 patent.

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

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

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

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

57. On information and belief, the manufacture, use, sale, offer for sale, or importation of Apotex's ANDA Products in accordance with, and as directed by, their 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.

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

59. On information and belief, Apotex knows that Apotex's ANDA Products and their proposed labeling are especially made or adapted for use in infringing the '739 patent, that Apotex's ANDA Products are not staple articles or commodities of commerce, and that Apotex's ANDA Products and their proposed labeling are not suitable for substantial noninfringing use. On information and belief, Apotex plans and intends to, and will, contribute to infringement of the '739 patent immediately and imminently upon approval of Apotex's ANDA.

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

61. The foregoing actions by Apotex 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.

62. On information and belief, Apotex 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.

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

64. The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of Apotex's ANDA Products with its proposed labeling, or any other Apotex drug product that is covered by or whose use is covered by the '739 patent, will infringe, induce the

infringement of, and contribute to the infringement by others of the '739 patent, and that the claims of the '739 patent are not invalid.

PRAYER FOR RELIEF

WHEREFORE, Pfizer requests the following relief:

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

(b) A judgment ordering that the effective date of any FDA approval of commercial manufacture, use, or sale of Apotex's ANDA Products, or any other drug product that infringes or the use of which infringes the patent-in-suit, be not earlier than the expiration date of the patent-in-suit, inclusive of any extension(s) and additional period(s) of exclusivity;

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

(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

Jeremy A. Tigan (#5239)
Megan E. Dellinger (#5739)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jtigan@morrisnichols.com
mdellinger@morrisnichols.com

Attorneys for Plaintiffs

OF COUNSEL:

David I. Berl
Christopher J. Mandernach
Michael Xun Liu
Kevin Hoagland-Hanson
Andrew L. Hoffman
WILLIAMS & CONNOLLY LLP
680 Maine Avenue SW
Washington, DC 20024
(202) 434-5000

June 20, 2025