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. _____
QILU PHARMACEUTICAL CO., LTD. and QILU PHARMA, INC.,	)	
Defendants.	)	

COMPLAINT

Plaintiffs Pfizer Inc.; Warner-Lambert Company LLC; and PF PRISM IMB B.V. (collectively, "Pfizer") file this Complaint for patent infringement against Qilu Pharmaceutical Co., Ltd. and Qilu Pharma, Inc. (collectively, "Qilu"), and by their attorneys, hereby alleges 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 Qilu'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. Qilu notified Pfizer by letter dated May 26, 2021 ("Qilu's Notice Letter") that it had submitted to the FDA ANDA No. 213093 ("Qilu's ANDA"), seeking approval from the FDA to engage in the commercial manufacture, use, and/or sale of generic palbociclib capsules, 75 mg, 100 mg, and 125 mg ("Qilu's ANDA Products") prior to the expiration of the '730 patent.

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 capsules, 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 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.

6. Upon information and belief, defendant Qilu Pharmaceutical Co., Ltd. is a company organized and existing under the laws of the People's Republic of China with its principal place of business at No. 243, Gong Ye Bei Road, Jinan, 250100, P.R. China. Upon information and belief, Qilu Pharmaceutical Co., Ltd. is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical drugs through various operating subsidiaries, including Qilu Pharma, Inc.

7. Upon information and belief, defendant Qilu Pharma, Inc. is a corporation organized and existing under the laws of the State of Pennsylvania with its principal place of business at 101 Lindenwood Drive, Suite 225, Malvern, Pennsylvania 19355. Upon information

and belief, Qilu Pharma, Inc. is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical drugs for the U.S. market.

8. Upon information and belief, Qilu Pharma, Inc. is a wholly owned subsidiary of Qilu Pharmaceutical Co., Ltd.

9. Upon information and belief, Qilu Pharma, Inc. is the designated U.S. agent for Qilu Pharmaceutical Co., Ltd. in connection with Qilu's ANDA.

10. Upon information and belief, Qilu Pharmaceutical Co., Ltd. and Qilu Pharma, Inc. acted in concert to prepare and submit Qilu's ANDA.

JURISDICTION

11. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338(a), and 2201 and 2202.

12. Qilu Pharmaceutical Co., Ltd. is subject to personal jurisdiction in Delaware because, among other things, Qilu Pharmaceutical Co., Ltd., itself and through its wholly-owned subsidiary Qilu Pharma, Inc., has purposefully availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. Upon information and belief, Qilu Pharmaceutical Co., Ltd., itself and through its subsidiary Qilu Pharma, Inc., 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, and/or has engaged in systematic and continuous business contacts within the State of Delaware. In addition, Qilu Pharmaceutical Co., Ltd. is subject to personal jurisdiction in Delaware because, upon information and belief, it controls Qilu Pharma, Inc. and therefore the activities of Qilu Pharma, Inc. in this jurisdiction are attributed to Qilu Pharmaceutical Co., Ltd.

13. Qilu Pharma, Inc. is subject to personal jurisdiction in Delaware because, among other things, it has purposefully availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. Upon information and belief, Qilu Pharma, Inc. 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 Pfizer's claims, and/or has engaged in systematic and continuous business contacts within the State of Delaware.

14. Qilu 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.

15. Upon information and belief, Qilu, with knowledge of the Hatch-Waxman Act process, directed Qilu's Notice Letter to, *inter alia*, Pfizer Inc., an entity incorporated in Delaware, and alleged in Qilu's Notice Letter that Pfizer's '730 patent is invalid. Upon information and belief, Qilu knowingly and deliberately challenged Pfizer's patent rights, and knew when it did so that it was triggering the forty-five day period for Pfizer to bring an action for patent infringement under the Hatch-Waxman Act.

16. Because Pfizer Inc. is incorporated in Delaware, Pfizer Inc. suffers injury and consequences from Qilu's filing of Qilu's ANDA challenging Pfizer's patent rights in Delaware. Upon information and belief, Qilu knew that it was deliberately challenging the patent rights of a Delaware entity and seeking to invalidate intellectual property held in Delaware. Qilu has been a

litigant in connection with other infringement actions under the Hatch-Waxman Act, and reasonably should have anticipated that by sending Qilu's Notice Letter to Pfizer Inc., a Delaware corporation, it would be sued in Delaware for patent infringement.

17. Upon information and belief, if Qilu's ANDA is approved, Qilu will directly or indirectly manufacture, market, sell, and/or distribute Qilu's ANDA Products within the United States, including in Delaware, consistent with Qilu's practices for the marketing and distribution of other generic pharmaceutical products. Upon information and belief, Qilu regularly does business in Delaware, and its practices with other generic pharmaceutical products have involved placing those products into the stream of commerce for distribution throughout the United States, including in Delaware. Upon information and belief, Qilu's generic pharmaceutical products are used and/or consumed within and throughout the United States, including in Delaware. Upon information and belief, Qilu's ANDA Products will be prescribed by physicians practicing in Delaware, dispensed by pharmacies located within Delaware, and used by patients in Delaware. Each of these activities would have a substantial effect within Delaware and would constitute infringement of Pfizer's patent in the event that Qilu's ANDA Products are approved before the patent expires.

18. Upon information and belief, Qilu derives substantial revenue from generic pharmaceutical products that are used and/or consumed within Delaware, and which are manufactured by Qilu and/or for which Qilu Pharmaceutical Co., Ltd. and/or Qilu Pharma, Inc. is the named applicant on approved ANDAs. Upon information and belief, various products for which Qilu Pharmaceuticals Co., Ltd. and/or Qilu Pharma, Inc. is the named applicant on approved ANDAs are available at retail pharmacies in Delaware.

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