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. _____
NATCO PHARMA, INC. and NATCO PHARMA, LTD.,	)	
Defendants.	)	

COMPLAINT

Plaintiffs Pfizer Inc.; Warner-Lambert Company LLC; and PF PRISM IMB B.V. (collectively, "Pfizer") file this Complaint for patent infringement against Natco Pharma, Inc. and Natco Pharma, Ltd. (collectively, "Natco"), 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 Natco'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. Natco Pharma, Ltd. notified Pfizer by letter dated December 15, 2020 ("Natco's Notice Letter") that it had submitted to the FDA ANDA No. 213089 ("Natco'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 ("Natco's ANDA Product") 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 Natco Pharma, Ltd. is a company organized and existing under the laws of the Republic of India with its principal place of business at Natco House, Road No-2, Banjara Hills, Hyderabad 500034, India. Upon information and belief, Natco Pharma, Ltd. is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical products through various operating subsidiaries, including Natco Pharma Inc.

7. Upon information and belief, defendant Natco Pharma, Inc. is a corporation organized and existing under the laws of the State of Delaware with its principal place of business at 241 West Roseville Road, Lancaster, PA 17601. Upon information and belief, Natco Pharma,

Inc. 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, Natco Pharma, Inc. is a wholly owned subsidiary of Natco Pharma, Ltd. Natco Pharma, Ltd. and Natco Pharma, Inc. are collectively referred to herein as "Natco."

9. Upon information and belief, Natco Pharma, Ltd. and Natco Pharma, Inc. acted in concert to prepare and submit Natco's ANDA to the FDA.

10. Upon information and belief, Natco Pharma, Ltd. and Natco Pharma, Inc. know and intend that upon approval of Natco's ANDA, Natco Pharma, Ltd. will manufacture Natco's ANDA Product and Natco Pharma, Inc. will directly or indirectly market, sell, and distribute Natco's ANDA Product throughout the United States, including in Delaware. Upon information and belief, Natco Pharma, Ltd. and Natco Pharma, Inc. are agents of each other and/or operate in concert as integrated parts of the same business group, including with respect to Natco's ANDA Product, and enter into agreements with each other that are nearer than arm's length. Upon information and belief, Natco Pharma, Inc. participated in, assisted, and cooperated with Natco Pharma, Ltd. in the acts complained of herein.

11. Upon information and belief, following any FDA approval of Natco's ANDA, Natco Pharma, Ltd. and Natco Pharma, Inc. will act in concert to distribute and sell Natco's ANDA Product throughout the United States, including within Delaware.

JURISDICTION

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

13. Natco Pharma, Ltd. is subject to personal jurisdiction in Delaware because, among other things, Natco Pharma, Ltd., itself and through its wholly-owned subsidiary Natco Pharma, Inc., has purposely 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, Natco Pharma, Ltd., itself and through its subsidiary Natco 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. In addition, Natco Pharma, Ltd. is subject to personal jurisdiction in Delaware because, upon information and belief, it controls Natco Pharma, Inc. and therefore the activities of Natco Pharma, Inc. in this jurisdiction are attributed to Natco Pharma, Ltd.

14. Natco Pharma, Inc. 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. Natco Pharma, Inc. is a corporation organized and existing 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, upon information and belief, Natco 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.

15. Natco 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. Upon information and belief, Natco, with knowledge of the Hatch-Waxman Act process, directed Natco's Notice Letter to, *inter alia*, Pfizer Inc., an entity incorporated in Delaware, and alleged in Natco's Notice Letter that Pfizer's '730 patent is invalid. Upon information and belief, Natco 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.

17. Because Pfizer Inc. is incorporated in Delaware, Pfizer Inc. suffers injury and consequences from Natco's filing of Natco's ANDA challenging Pfizer's patent rights in Delaware. Upon information and belief, Natco knew that it was deliberately challenging the patent rights of a Delaware entity and seeking to invalidate intellectual property held in Delaware. Natco has been a litigant in connection with other infringement actions under the Hatch-Waxman Act, and reasonably should have anticipated that by sending Natco's Notice Letter to Pfizer Inc., a Delaware corporation, it would be sued in Delaware for patent infringement.

18. Upon information and belief, if Natco's ANDA is approved, Natco will directly or indirectly manufacture, market, sell, and/or distribute Natco's ANDA Product within the United

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