

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. _____
)
MSN PHARMACEUTICALS INC. and)
MSN LABORATORIES PRIVATE LIMITED,)
)
Defendants.)

COMPLAINT

Plaintiffs Pfizer Inc.; Warner-Lambert Company LLC; and PF PRISM IMB B.V. (collectively, “Pfizer”) file this Complaint for patent infringement against MSN Pharmaceuticals Inc. (“MSN Pharmaceuticals”) and MSN Laboratories Private Limited (“MSN Labs”) (collectively, “MSN”), 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 MSN’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. 10,723,730 (“the ’730 patent”).

2. MSN Pharmaceuticals notified Pfizer by letter dated May 17, 2021 (“MSN’s Notice Letter”) that it had submitted to the FDA ANDA No. 216083 (“MSN’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 (“MSN’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. 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 235 East 42nd Street, New York, New York 10017.

5. Plaintiff PF PRISM IMB B.V. is a private limited company (*besloten vennootschap*) 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 IJssel, the Netherlands.

6. Upon information and belief, defendant MSN Pharmaceuticals is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 20 Duke Road, Piscataway, New Jersey 08854.

7. Upon information and belief, defendant MSN Labs is a company organized and existing under the laws of the Republic of India, having a place of business at MSN House, C-24, Sanathnagar Industrial Estate, Hyderabad, 500018, Telangana, India.

8. Upon information and belief, MSN Pharmaceuticals is in the business of, among other things, manufacturing and selling generic versions of branded versions of pharmaceutical drugs.

9. Upon information and belief, MSN Pharmaceuticals is a wholly owned subsidiary of MSN Labs.

10. Upon information and belief, MSN Pharmaceuticals is the designated U.S. agent for MSN Labs in connection with MSN's ANDA.

11. Upon information and belief, MSN Pharmaceuticals and MSN Labs acted in concert to prepare and submit MSN's ANDA.

JURISDICTION AND VENUE

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

13. MSN Pharmaceuticals is subject to personal jurisdiction in this Court 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, MSN Pharmaceuticals is organized under the laws of the State of Delaware and is registered to conduct business within the State of Delaware (File No. 5454849). Upon information and belief, MSN Pharmaceuticals maintains in the State of Delaware a registered agent for service of process—United States Corporation Agents, Inc.—with an address at 221 North Broad Street, Suite 3A, Middletown, Delaware 19709. MSN Pharmaceuticals has therefore consented to general jurisdiction in the State of Delaware. Upon information and belief, MSN Pharmaceuticals 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. MSN Labs is subject to personal jurisdiction in Delaware because, among other things, MSN Labs, itself and through its wholly owned subsidiary MSN Pharmaceuticals, 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, MSN Labs, itself and through its wholly owned subsidiary MSN Pharmaceuticals, 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 continuous and systematic business contacts with the State of Delaware. In addition, MSN Labs is subject to personal jurisdiction in Delaware because, upon information and belief, it controls MSN Pharmaceuticals, and the activities of MSN Pharmaceuticals in this jurisdiction are therefore attributed to MSN Labs.

15. MSN 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, MSN, with knowledge of the Hatch-Waxman Act process, directed MSN's Notice Letter to, *inter alia*, Pfizer Inc., an entity incorporated in Delaware, and alleged in MSN's Notice Letter that Pfizer's '730 patent is invalid. Upon information and belief, MSN 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 MSN's filing of MSN's ANDA challenging Pfizer's patent rights in Delaware. Upon information and belief, MSN knew that it was deliberately challenging the patent rights of a Delaware entity and seeking to invalidate intellectual property held in Delaware. MSN has been a litigant in connection with other infringement actions under the Hatch-Waxman Act, and reasonably should have anticipated that by sending MSN's Notice Letter to Pfizer Inc., a Delaware corporation, it would be sued in Delaware for patent infringement.

18. Upon information and belief, if MSN's ANDA is approved, MSN will directly or indirectly manufacture, market, sell, and/or distribute MSN's ANDA Products within the United States, including in Delaware, consistent with MSN's practices for the marketing and distribution of other generic pharmaceutical products. Upon information and belief, MSN 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, MSN's generic pharmaceutical products are used and/or consumed within and throughout the United States, including in Delaware. Upon information and belief, MSN'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 MSN's ANDA Products are approved before the patent expires.

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