

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA

FILED

SEP 27 2018

U.S. DISTRICT COURT-WVND
WHEELING, WV 26003

VALEANT PHARMACEUTICALS NORTH
AMERICA LLC; VALEANT
PHARMACEUTICALS IRELAND LTD.;
DOW PHARMACEUTICAL SCIENCES, INC.;
and KAKEN PHARMACEUTICAL CO., LTD.,

Civil Action No.:

1:18 cv 184

Plaintiffs,

v.

MYLAN PHARMACEUTICALS INC.;
MYLAN LABORATORIES LTD.; and
MYLAN INC.,

Defendants.

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Valeant Pharmaceuticals North America LLC (“Valeant”), Valeant Pharmaceuticals Ireland Ltd. (“Valeant Ireland”), Dow Pharmaceutical Sciences, Inc. (“Dow”), and Kaken Pharmaceutical Co., Ltd. (“Kaken”) (collectively, “Plaintiffs”) by way of this Complaint against Mylan Pharmaceuticals Inc. (“Mylan Pharmaceuticals”), Mylan Laboratories Ltd. (“Mylan Labs”), and Mylan Inc. (collectively, “Mylan”) allege as follows:

THE PARTIES

1. Plaintiff Valeant is a limited liability company organized and existing under the laws of Delaware having its principal place of business at 400 Somerset Corporate Boulevard, Bridgewater, New Jersey 08807.

2. Plaintiff Valeant Ireland is a company existing under the laws of Ireland having

an office at 3013 Lake Drive, Citywest Business Campus, Dublin 24, Ireland.

3. Plaintiff Dow is a corporation organized and existing under the laws of Delaware having its principal place of business at 1330 Redwood Way, Petaluma, California 94954.

4. Plaintiff Kaken is a corporation organized and existing under the laws of Japan having its principal place of business at 20th Floor, Bunkyo Green Court, 28-8, Honkomagome 2-chome, Bunkyo-ku, Tokyo 113-8650, Japan.

5. Upon information and belief, Mylan Pharmaceuticals is a corporation organized and existing under the laws of West Virginia, having a place of business at 781 Chestnut Ridge Road, Morgantown, WV 26505. Upon information and belief, Mylan Pharmaceuticals is a wholly-owned subsidiary of Mylan Inc. and an agent or affiliate of Mylan Labs.

6. Upon information and belief, Mylan Labs is a corporation organized and existing under the laws of India, having a place of business at Plot No. 564/A/22, Road No. 92, Jubilee Hills 500034, Hyderabad, India. Upon information and belief, Mylan Labs is a wholly-owned subsidiary of Mylan Inc. and an agent or affiliate of Mylan Pharmaceuticals.

7. Upon information and belief, Mylan Inc. is a corporation organized and existing under the laws of the Commonwealth of Pennsylvania, having a place of business at 1000 Mylan Blvd., Canonsburg, PA 15317.

NATURE OF THE ACTION

8. This is an action for infringement of United States Patent Nos. 7,214,506 (“the ’506 patent”), 8,039,494 (“the ’494 patent”), 8,486,978 (“the ’978 patent”), 9,302,009 (“the ’009 patent”), 9,566,272 (“the ’272 patent”), 9,662,394 (“the ’394 patent”), 9,861,698 (“the ’698 patent”) and 9,877,955 (“the ’955 patent”) arising under the United States patent laws, Title 35, United States Code, § 100 et seq., including 35 U.S.C. §§ 271 and 281. This action relates to

Mylan's filing of an Abbreviated New Drug Application ("ANDA") under section 505(j) of the Federal Food, Drug, and Cosmetic Act ("the Act"), 21 U.S.C. § 355(j), seeking U.S. Food and Drug Administration ("FDA") approval to market its generic efinaconazole topical solution, 10% ("Mylan's generic efinaconazole topical solution").

JURISDICTION AND VENUE

9. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1338(a), and 2201-02.

10. Upon information and belief, this Court has jurisdiction over Mylan Pharmaceuticals. Upon information and belief, Mylan Pharmaceuticals is in the business of, *inter alia*, developing, manufacturing, marketing, importing, and selling pharmaceutical products, including generic drug products. Upon information and belief, Mylan Pharmaceuticals directly, or indirectly, develops, manufactures, markets, and sells generic drug products throughout the United States and in this judicial district, and this judicial district is a likely destination for Mylan's generic efinaconazole topical solution. Upon information and belief, Mylan Pharmaceuticals purposefully has conducted and continues to conduct business in this judicial district. Upon information and belief, Mylan Pharmaceuticals is a corporation organized and existing under the laws of West Virginia, having a place of business at 781 Chestnut Ridge Road, Morgantown, WV 26505. Upon information and belief, Mylan Pharmaceuticals has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction. Mylan's notice letter invoked the jurisdiction and venue of this judicial district.

11. Mylan Pharmaceuticals has taken the costly, significant step of applying to the FDA for approval to engage in future activities—including the marketing of its generic drugs—

that will be purposefully directed at, upon information and belief, the Northern District of West Virginia and elsewhere. Mylan Pharmaceuticals' ANDA filings constitute formal acts that reliably indicate plans to engage in marketing of the proposed generic drugs. Upon information and belief, Mylan Pharmaceuticals intends to direct sales of its drugs into the Northern District of West Virginia, among other places, once it has the requested FDA approval to market them. Upon information and belief, Mylan Pharmaceuticals will engage in marketing of its proposed ANDA products in the Northern District of West Virginia upon approval of its ANDA.

12. Upon information and belief, this Court has jurisdiction over Mylan Labs. Upon information and belief, Mylan Labs is in the business of, *inter alia*, developing, manufacturing, marketing, importing, and selling pharmaceutical products, including generic drug products. Upon information and belief, Mylan Labs directly, or indirectly, develops, manufactures, markets, and sells generic drug products throughout the United States and in this judicial district, and this judicial district is a likely destination for Mylan's generic efinaconazole topical solution. Upon information and belief, Mylan Labs purposefully has conducted and continues to conduct business in this judicial district. Upon information and belief, Mylan Labs is registered to do business in this judicial district. Upon information and belief, Mylan Labs has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction.

13. Upon information and belief, this Court has jurisdiction over Mylan Inc. Upon information and belief, Mylan Inc. is in the business of, *inter alia*, developing, manufacturing, marketing, importing, and selling pharmaceutical products, including generic drug products. Upon information and belief, Mylan Inc. directly, or indirectly, develops, manufactures, markets, and sells generic drug products throughout the United States and in this judicial district, and this

judicial district is a likely destination for Mylan's generic efinaconazole topical solution. Upon information and belief, Mylan Inc. purposefully has conducted and continues to conduct business in this judicial district through at least its wholly owned subsidiary Mylan Pharmaceuticals. Upon information and belief, Mylan Inc. is registered to do business in this judicial district. Upon information and belief, Mylan Inc. has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction.

14. Mylan knows or should know that Jublia[®] is manufactured for Valeant Pharmaceuticals North America LLC in Bridgewater, NJ 08807 USA at least because that information is included in the label and prescribing information for Jublia[®].

15. Upon information and belief, venue is proper in this judicial district under 28 U.S.C. §§ 1391(c) and (d), and § 1400(b).

THE PATENTS IN SUIT

16. The United States Patent and Trademark Office ("PTO") issued the '506 patent on May 8, 2007. The '506 patent claims, generally speaking, *inter alia*, methods for treating onychomycosis by administering efinaconazole. Plaintiffs hold all substantial rights in the '506 patent and have the right to sue for infringement thereof. The '506 patent is valid and enforceable. A copy of the '506 patent is attached hereto as Exhibit A.

17. The PTO issued the '494 patent on October 18, 2011. The '494 patent claims, generally speaking, *inter alia*, methods for treatment of a disorder of the nail or nail bed by applying pharmaceutical compositions consisting essentially of a vehicle that is volatile and/or that rapidly penetrates a nail following application onto the surface of the nail, a triazole antifungal active pharmaceutical ingredient (encompassing efinaconazole) and a wetting agent.

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