United States Court of Appeals for the Federal Circuit

VALEANT PHARMACEUTICALS NORTH AMERICA LLC, VALEANT PHARMACEUTICALS IRELAND LTD., DOW PHARMACEUTICAL SCIENCES, INC., KAKEN PHARMACEUTICAL CO., LTD.,
Plaintiffs-Appellants

v.

MYLAN PHARMACEUTICALS INC., MYLAN LABORATORIES LTD., MYLAN INC.,
Defendants-Appellees

2019-2402

Appeal from the United States District Court for the District of New Jersey in No. 3:18-cv-14305-PGS-LHG, Senior Judge Peter G. Sheridan.

Decided: November 5, 2020

THOMAS P. STEINDLER, McDermott, Will & Emery LLP, Washington, DC, argued for all plaintiffs-appellants. Plaintiffs-appellants Valeant Pharmaceuticals North America LLC, Valeant Pharmaceuticals Ireland Ltd., Dow Pharmaceutical Sciences, Inc. also represented by IAN BARNETT BROOKS, CHRISTOPHER MICHAEL BRUNO, PAUL MICHAEL SCHOENHARD; CHARLES H. CHEVALIER, Gibbons P.C., Newark, NJ.

JOHN D. LIVINGSTONE, Finnegan, Henderson, Farabow, Garrett & Dunner, LLP, Atlanta, GA, for plaintiff-appellant Kaken Pharmaceutical Co., Ltd. Also represented by CORA RENAE HOLT, Washington, DC; CHARLES H. CHEVALIER, Gibbons P.C., Newark, NJ.

STEFFEN NATHANAEL JOHNSON, Wilson Sonsini Goodrich & Rosati, Washington, DC, argued for defendants-appellees. Also represented by ADAM WILLIAM BURROWBRIDGE; WENDY L. DEVINE, KRISTINA M. HANSON, TUNG ON KONG, San Francisco, CA.

Before NEWMAN, O'MALLEY, and TARANTO, *Circuit Judges*.

O'MALLEY, *Circuit Judge*.

In 2017, the Supreme Court dramatically changed the venue landscape in patent cases. *See TC Heartland LLC v. Kraft Foods Grp. Brands LLC*, 137 S. Ct. 1514 (2017). It held that the general venue provision in 28 U.S.C. § 1391—which provides that a corporation is deemed to "reside" in any judicial district in which it is subject to personal jurisdiction—does not modify the term "resides" in 28 U.S.C. § 1400, the more specific venue statute applicable to patent cases. Specifically, it held that "resides" in § 1400(b) refers only to a corporation's state of incorporation. That means that a corporation may be sued for patent infringement in only two categories of judicial districts: those in the state in which it is incorporated and those in which it has a regular and established place of business and an act of infringement has occurred. *TC Heartland* raised more questions than it answered; we and district courts around the country have been working through those questions since 2017. Today we tackle one more.

Today we answer the question of where "acts of infringement" under § 1400(b) occur with respect to

infringement claims brought pursuant to the Hatch-Waxman Act.[1] We conclude that, in cases brought under 35 U.S.C. § 271(e)(2)(A), infringement occurs for venue purposes only in districts where actions related to the submission of an Abbreviated New Drug Application ("ANDA") occur, not in all locations where future distribution of the generic products specified in the ANDA is contemplated.

Given this conclusion, we affirm the district court's order dismissing the claims against the two U.S.-based defendants pursuant to Rule 12(b)(3) of the Federal Rules of Civil Procedure for improper venue. *See Valeant Pharms. N. Am. LLC v. Zydus Pharms. (USA) Inc.*, No. 18-cv-13635-PGS-LHG, 2019 WL 4179832 (D.N.J. Aug. 14, 2019). For the reasons explained below, however, we vacate and remand the portion of the court's order dismissing the action against the foreign defendant—as to which venue was unquestionably proper—pursuant to Rule 12(b)(6), because the court failed to address the substance of that motion.

I. BACKGROUND

Because this appeal is primarily a venue dispute, the locations of the parties' places of incorporation are important. Less significantly, Valeant Pharmaceuticals North America LLC, Valeant Pharmaceuticals Ireland Ltd., Dow Pharmaceutical Sciences, Inc. ("Dow"), and Kaken Pharmaceuticals Co., Ltd. (collectively "Valeant" or "plaintiffs") reside in a range of locations, including Japan, Ireland, and Delaware. On the defendants' side, Mylan Pharmaceuticals Inc. ("MPI") is a West Virginia corporation with a principal place of business in Morgantown, West Virginia; Mylan Inc. is a Pennsylvania corporation with a principal place of business in Canonsburg,

---

[1] The Hatch-Waxman Act is the common name for the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98–417, 98 Stat. 1585.

Pennsylvania; and Mylan Laboratories Ltd. ("MLL") is an Indian corporation with a principal place of business in Hyderabad, India.

The parties are all players in the pharmaceutical industry. Dow holds New Drug Application No. 203567 for the brand name drug Jublia®, approved by the United States Food and Drug Administration ("FDA") on June 6, 2014. Jublia® is a medication used to treat fungal infections (onychomycosis) of toenails. The active ingredient in Jublia® is efinaconazole. There are nine patents listed in the Orange Book for Jublia®.

In June 2018, MPI, a generic drug company, executed an ANDA seeking approval to market a generic version of Jublia®. MPI sent the ANDA from its West Virginia corporate office to the FDA, located in White Oak, Maryland. The ANDA included a Paragraph IV certification that the Orange-Book-listed patents for Jublia® are invalid, unenforceable, or would not be infringed by the ANDA product. MPI notified Valeant of the ANDA submission in August 2018.

On September 26, 2018, Valeant filed suit against Mylan[2] in the District of New Jersey, alleging infringement of Dow's Orange Book patents pursuant to the Hatch-Waxman Act and requesting declaratory judgment of validity of the Orange Book patents.[3] The complaint contained several allegations about Mylan's connection to New Jersey:

- Each Mylan defendant "directly, or indirectly, develops, manufactures, markets, and sells generic drug products throughout the United States and in this

---

[2] We refer to appellees collectively as "Mylan."

[3] Valeant also filed complaints in the District of New Jersey against eighteen other ANDA filers. None of those filers challenged venue and the cases have been consolidated with trial scheduled for June 2, 2021.

judicial district, and this judicial district is a likely destination for Mylan's generic efinaconazole topical solution." J.A. 147, ¶ 10 (MPI), 148, ¶ 12 (MLL), 149, ¶ 13 (Mylan Inc.).

- Each Mylan defendant does business in New Jersey and is registered to do so. J.A. 147, ¶ 10 (MPI), 148 ¶ 12 (MLL), 149, ¶ 13 (Mylan Inc.).
- Each defendant has previously submitted to the jurisdiction of the court and has a place of business in New Jersey. J.A. 147–48, ¶ 10 (MPI), 148–49 ¶ 12 (MLL), 149, ¶ 13 (Mylan Inc.).
- MPI applied for FDA approval of its generic drug, which will be "purposefully directed at, upon information and belief, New Jersey and elsewhere. [MPI's] ANDA filings constitute formal acts that reliably indicate plans to engage in marketing of the proposed generic drugs." And MPI plans to market and sell its generic drug into New Jersey upon FDA approval. J.A. 148 ¶ 11.

The next day, Valeant filed an essentially identical protective suit against Mylan in the Northern District of West Virginia. *See* Complaint, *Valeant Pharms. N. Am. LLC v. Mylan Pharms. Inc.*, No. 18-cv-00184-IMK, D.I. 1 (N.D. W. Va. Sept. 27, 2018). That suit is ongoing.

In January 2019, Mylan moved to dismiss Valeant's New Jersey District Court complaint against MPI and Mylan Inc. for improper venue pursuant to Federal Rule of Civil Procedure 12(b)(3). Mylan further moved to dismiss MLL and Mylan Inc. for failure to state a claim pursuant to Rule 12(b)(6). As to venue, Mylan did not deny the majority of the venue allegations in Valeant's complaint. Instead, it argued that venue was improper under § 1400(b) because no Mylan defendant resides in New Jersey, the only alleged act of infringement—submission of the ANDA—did not occur in New Jersey, and the Mylan

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.