UNITED STATES JUDICIAL PANEL
on
MULTIDISTRICT LITIGATION

IN RE: PALBOCICLIB PATENT LITIGATION MDL No. 2912

TRANSFER ORDER

Before the Panel:[*] Pfizer plaintiffs[1] move under 28 U.S.C. § 1407 to centralize this litigation in the District of Delaware. The litigation consists of the thirteen actions listed on the attached Schedule A, twelve in the District of Delaware and one in the Northern District of West Virginia.[2] Only Mylan Pharmaceuticals Inc., which is the sole defendant in the West Virginia action, responded to the motion. Mylan supports centralization in the District of Delaware.

The Pfizer plaintiffs filed these actions after the various generic drug manufacturer defendants submitted Abbreviated New Drug Applications (ANDAs) seeking approval by the U.S. Food and Drug Administration (FDA) to make and sell generic versions of IBRANCE (Palbociclib) capsules,[3] 75 mg, 100 mg, and 125 mg. All the actions are Hatch-Waxman[4] patent infringement

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[*] Judge Ellen Segal Huvelle took no part in the decision of this matter.

[1] Pfizer Inc.; Warner-Lambert Company LLC, PF PRISM C.V.; Pfizer Manufacturing Holdings LLC; and Pfizer PFE Ireland Pharmaceuticals Holding 1 B.V.

[2] As filed, the Section 1407 motion encompassed an additional action in the District of Delaware, but that action has since been dismissed.

[3] IBRANCE is a drug used to treat metastatic breast cancer.

[4] Under the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98–417, 98 Stat. 1585 (1984) (the "Hatch-Waxman Act"), Congress established an incentive for companies to bring generic versions of branded drugs to market faster than they otherwise might by granting the first company to file an ANDA an "exclusivity period" of 180 days, during which the FDA may not approve for sale any competing generic version of the drug. *See Teva Pharm. USA, Inc. v. Sebelius*, 595 F.3d 1303, 1304-05 (D.C. Cir. 2010). Submitting an ANDA with a "paragraph IV certification"—stating that the patents listed in the FDA's Orange Book as covering the previously approved drug are invalid or will not be infringed by the generic drug—constitutes a statutory act of infringement that creates subject-matter jurisdiction for a district court to resolve any disputes regarding patent infringement or validity before the generic drug is sold. *See* 35 U.S.C. § 271(e)(2)(A); *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 676-78 (1990). If the patent-holder initiates an infringement action against the ANDA filer within 45 days of receipt of the paragraph

(continued...)

lawsuits in which the Pfizer plaintiffs allege that each defendant has infringed one or more of three U.S. Patents[5] by filing ANDAs seeking FDA approval to market generic IBRANCE in the United States.

On the basis of the papers filed and the hearing session held, we find that these actions involve common questions of fact, and that centralization in the District of Delaware will serve the convenience of the parties and witnesses and promote the just and efficient conduct of this litigation. These actions involve substantially similar claims that defendants infringed one or more of the IBRANCE patents. Centralization will eliminate duplicative discovery and other pretrial proceedings, avoid the possibility of inconsistent pretrial rulings (particularly with respect to claim construction and issues of patent validity), and conserve judicial and party resources.

We recently have centralized similar litigations, citing "the complexity of the allegations and regulatory framework governing Hatch-Waxman cases, as well as the need for swift progress in litigation involving the potential entry of generic drugs into the market." *In re Kerydin (Tavaborole) Topical Solution 5% Patent Litig.*, 366 F. Supp. 3d 1370, 1371 (J.P.M.L. 2019); *see also In re Auryxia (Ferric Citrate) Patent Litig.*, 2019 WL 4011026, at *2 (J.P.M.L. July 31, 2019) (same). We are persuaded that centralization of these cases similarly will lead to their efficient resolution.

We select the District of Delaware as the transferee district for these actions. All but one of the thirteen related actions are pending in the District of Delaware. Judge Colm F. Connolly, to whom we assign this litigation, already is presiding over those twelve actions. We are confident that he will steer this litigation on a prudent course.

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[4](...continued)
IV certification, then the FDA may not approve the ANDA until the earlier of either 30 months or the issuance of a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA. *See* 21 U.S.C. § 355(j)(5)(B)(iii).

[5] U.S. Patent Nos. 6,936,612, 7,208,489, and 7,456,168.

IT IS THEREFORE ORDERED that the action listed on Schedule A and pending outside the District of Delaware is transferred to the District of Delaware and, with the consent of that court, assigned to the Honorable Colm F. Connolly for coordinated or consolidated pretrial proceedings.

PANEL ON MULTIDISTRICT LITIGATION

Sarah S. Vance
Chair

Lewis A. Kaplan
Catherine D. Perry
Nathaniel M. Gorton

R. David Proctor
Karen K. Caldwell

IN RE: PALBOCICLIB PATENT LITIGATION MDL No. 2912

SCHEDULE A

District of Delaware

PFIZER, INC., ET AL. v. AIZANT DRUG RESEARCH SOLUTIONS PVT. LTD., C.A. No. 1:19-00743
PFIZER, INC., ET AL. v. ALEMBIC PHARMACEUTICALS, INC., ET AL., C.A. No. 1:19-00745
PFIZER, INC., ET AL. v. APOTEX INC., ET AL., C.A. No. 1:19-00747
PFIZER, INC., ET AL. v. AUROBINDO PHARMA, LTD., ET AL., C.A. No. 1:19-00748
PFIZER, INC., ET AL. v. CIPLA USA INC., ET AL., C.A. No. 1:19-00749
PFIZER, INC., ET AL. v. DR. REDDY'S LABORATORIES, INC., ET AL., C.A. No. 1:19-00750
PFIZER, INC., ET AL. v. HETERO USA, INC., ET AL., C.A. No. 1:19-00751
PFIZER, INC., ET AL. v. NATCO PHARMA, INC., ET AL., C.A. No. 1:19-00753
PFIZER, INC., ET AL. v. QILU PHARMA, INC., ET AL., C.A. No. 1:19-00754
PFIZER, INC., ET AL. v. SUN PHARMACEUTICAL INDUSTRIES, LTD., ET AL., C.A. No. 1:19-00758
PFIZER, INC., ET AL. v. TEVA PHARMACEUTICALS USA, INC., ET AL., C.A. No. 1:19-00759
PFIZER, INC., ET AL. v. ZYDUS PHARMACEUTICALS (USA) INC., ET AL., C.A. No. 1:19-00760

Northern District of West Virginia

PFIZER, INC., ET AL. v. MYLAN PHARMACEUTICALS INC., ET AL., C.A. No. 1:19-00097