UNITED STATES JUDICIAL PANEL
on
MULTIDISTRICT LITIGATION

IN RE: PALBOCICLIB ('730) PATENT LITIGATION (NO. II) MDL No. 2990

ORDER DENYING MOTION TO CENTRALIZE AND TRANSFERRING ONE ACTION TO MDL No. 2912

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 eight actions listed on the attached Schedule A, seven in the District of Delaware and one in the Northern District of West Virginia.[2] Mylan Pharmaceuticals Inc., the sole defendant in the West Virginia action, does not oppose transfer to the District of Delaware. No other party has responded to the motion.

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

[1] Pfizer Inc., Warner-Lambert Company LLC, and PF PRISM IMB B.V.

[2] Pfizer plaintiffs' motion originally sought centralization of ten actions, but two of the involved actions pending in the District of Delaware now have been voluntarily 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 IV certification, the FDA may not approve the ANDA until the earlier of either 30

in which the Pfizer plaintiffs allege that defendants have infringed U.S. Patent No. 10,723,730 ("the '730 Patent").

The Pfizer plaintiffs previously filed a series of Hatch-Waxman actions against the defendants named in seven of the present actions, alleging that their submission of ANDAs infringed one or more of three IBRANCE patents.[5] Those actions were centralized in the District of Delaware in 2019 as MDL No. 2912, and assigned to Judge Colm F. Connolly. *See In re Palbociclib Patent Litig.*, 396 F. Supp. 3d 1360 (J.P.M.L. 2019).

Pfizer argues that the actions on the motion involve common questions of fact and that centralization before Judge Connolly, as the judge presiding over MDL No. 2912, would best serve the convenience of the parties and witnesses. There are substantial similarities between the actions now before us and those in the existing MDL. In fact, seven of the eight actions are pending in the District of Delaware and have been related to MDL No. 2912. During briefing of this matter, the Clerk of the Panel directed the parties to submit supplemental briefs on whether the single action pending in the Northern District of West Virginia should be transferred to the District of Delaware for inclusion in MDL No. 2912. Among the defendants, only Mylan in the Northern District of West Virginia action responded to the order, stating that it does not oppose transfer to MDL No. 2912. The Pfizer plaintiffs are opposed. They argue that the '730 Patent cases differ substantially in both substance and procedural posture from the MDL No. 2912 actions and therefore should be centralized in a separate MDL.

On the basis of the papers filed and the hearing session held,[6] we conclude that the actions on the motion involve common questions of fact with the actions centralized in MDL No. 2912, and that creation of a separate MDL involving only the '730 Patent cases is not necessary to serve the convenience of the parties and witnesses or to further the just and efficient conduct of this litigation. These eight actions, like those in MDL No. 2912, involve claims that defendants infringed one or more IBRANCE patents by seeking FDA approval to market generic Palbociclib drugs in the United States. Nearly all defendants and ANDAs in the litigation also are involved in MDL No. 2912. Seven of the actions on the motion are pending in the District of Delaware, where they have been assigned to Judge Connolly and related to the actions in MDL No. 2912. In these circumstances, pretrial proceedings in the '730 Patent actions can proceed most efficiently in the existing MDL. The Pfizer plaintiffs' concerns about any differences between the '730 Patent actions and earlier-filed actions may be raised with Judge Connolly, who is free to establish separate tracks for discovery and motion practice, as he deems appropriate.

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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] The '730 Patent was not issued until July 2020, and thus was not involved in these earlier actions, which were filed in April 2019.

[6] In light of the concerns about the spread of the COVID-19 virus (coronavirus), the Panel heard oral argument by videoconference at its hearing session of January 28, 2021. *See* Suppl. Notice of Hearing Session, MDL No. 2990 (J.P.M.L. May 10, 2021), ECF No. 26.

IT IS THEREFORE ORDERED that the motion for centralization of these actions is denied.

IT IS FURTHER 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 inclusion in the coordinated or consolidated pretrial proceedings occurring there in MDL No. 2912.

IT IS FURTHER ORDERED that the Clerk of the Panel shall enter a copy of this order in the docket for MDL No. 2912.

PANEL ON MULTIDISTRICT LITIGATION

Karen K. Caldwell
Chair

Catherine D. Perry
Matthew F. Kennelly
Roger T. Benitez
Nathaniel M. Gorton
David C. Norton
Dale A. Kimball

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SCHEDULE A

District of Delaware

PFIZER INC., ET AL. v. ZYDUS PHARMACEUTICALS (USA) INC., ET AL., C.A. No. 1:20−01396
PFIZER INC., ET AL. v. SUN PHARMACEUTICAL INDUSTRIES, LTD., ET AL., C.A. No. 1:20−01407
PFIZER INC., ET AL. v. AUROBINDO PHARMA, LTD., ET AL., C.A. No. 1:20−01528
PFIZER INC., ET AL. v. DR. REDDY'S LABORATORIES, INC., ET AL., C.A. No. 1:20−01530
PFIZER INC., ET AL. v. AIZANT DRUG RESEARCH SOLUTIONS PVT. LTD., ET AL., C.A. No. 1:21−00034
PFIZER INC., ET AL. v. NATCO PHARMA, INC., ET AL., C.A. No. 1:21−00078
PFIZER INC., ET AL. v. MSN PHARMACEUTICALS INC., ET AL., C.A. No. 1:21−00139

Northern District of West Virginia

PFIZER INC., ET AL. v. MYLAN PHARMACEUTICALS INC., ET AL., C.A. No. 1:20−00244