UNITED STATES JUDICIAL PANEL
on
MULTIDISTRICT LITIGATION

IN RE: PALBOCICLIB PATENT LITIGATION MDL No. 2912

TRANSFER ORDER

Before the Panel: Defendants[1] in the Middle District of North Carolina action (*Synthon*) listed on the attached Schedule A move under Panel Rule 7.1 to vacate the Panel's order conditionally transferring the action to MDL No. 2912. Plaintiffs[2] oppose the motion.

After considering the argument of counsel, we find that this action involves common questions of fact with the actions previously transferred to MDL No. 2912, and that transfer under 28 U.S.C. § 1407 will serve the convenience of the parties and witnesses and promote the just and efficient conduct of the litigation. Thus, transfer is warranted for the reasons set out in our order directing centralization. The Hatch-Waxman actions[3] in the MDL share factual questions arising from allegations that "each defendant has infringed one or more of three U.S. Patents by filing ANDAs seeking FDA approval to market generic IBRANCE in the United States." *See In re*

[1] Synthon Pharmaceuticals, Inc., Synthon B.V., and Synthon International Holding B.V. (collectively, Synthon).

[2] Pfizer Inc., Warner-Lambert Company LLC, PF PRISM C.V., Pfizer Manufacturing Holdings LLC, and PF PRISM IMB B.V.

[3] 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 Abbreviated New Drug Application (ANDA) an "exclusivity period" of 180 days, during which the U.S. Food and Drug Administration (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 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).

Palbociclib Patent Litig., 396 F. Supp. 3d 1360 (J.P.M.L. 2019) (footnote omitted).[4] Actions later transferred or related to the litigation allege infringement of a fourth IBRANCE patent—U.S. Patent No. 10,723,730 (the '730 Patent). This action, which alleges that defendant has infringed the original three Palbociclib patents and the '730 Patent, implicates the same questions.

Defendants move to vacate the conditional transfer order by arguing that the action brought against it involves questions of fact and law not shared by other actions in the MDL because its ANDA product is a Palbociclib tablet rather than a capsule and because Synthon will raise a unique invalidity defense. We are not persuaded by these arguments. The record shows that the MDL already includes a number of actions involving Palbociclib tablets. In any event, the presence of some factual differences among products, the patents at issue, and noninfringement defenses are not sufficient to outweigh the efficiencies of centralization when actions involve overlapping discovery, claim construction issues, and noninfringement defenses as to related families of products and patents. *See In re BRCA1- & BRCA2-Based Hereditary Cancer Test Patent Litig.*, 999 F. Supp. 2d 1377, 1379 (J.P.M.L. 2014) ("While there is some difference in the asserted patents and claims between the actions, and some difference in the accused products, the core factual and legal inquiries in each action will be similar, if not identical, and centralization will allow a single judge to preside over the discovery relating to these patents and to consistently rule on challenges to the validity thereof.").

Defendants further contend that transfer would be neither efficient nor fair because the actions involving the original set of Palbociclib patents have been resolved and the actions involving the '730 Patent are more advanced than the *Synthon* action. Again, however, the record contradicts these claims. The MDL includes several recently filed actions involving the '730 Patent, one of which also asserts infringement of one of the original three patents. We have transferred related patent actions before under similar circumstances, observing that "[w]hile transfer may require the parties to acquaint themselves with pretrial proceedings and orders in this litigation, significant efficiencies can be gained by having all actions proceed before a judge who is already familiar with the nuances of this patent litigation." *See In re Method of Processing Ethanol Byproducts & Related Subsystems '858 Patent Litig.*, MDL No. 2181, 2013 U.S. Dist. LEXIS 177090, at *2 (J.P.M.L. Dec. 13, 2013). The same is true here.

[4] IBRANCE (Palbociclib) is a drug used to treat metastatic breast cancer. The three patents at issue were U.S. Patent Nos. 6,936,612; 7,208,489 (since reissued as Patent No. RE47,739); and 7,456,168.

IT IS THEREFORE ORDERED that this action 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.

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

IN RE: PALBOCICLIB PATENT LITIGATION MDL No. 2912

SCHEDULE A

Middle District of North Carolina

PFIZER INC., ET AL. v. SYNTHON PHARMACEUTICALS, INC., ET AL.,
C.A. No. 1:21−00157