UNITED STATES JUDICIAL PANEL
on
MULTIDISTRICT LITIGATION

IN RE: DENOSUMAB
PATENT LITIGATION MDL No. 3138

TRANSFER ORDER

Before the Panel:[*] Common plaintiffs Amgen Inc. and Amgen Manufacturing Limited LLC (together Amgen) move under 28 U.S.C. § 1407 to centralize this litigation in the District of New Jersey. This litigation consists of four actions, two in the District of New Jersey, one in the Northern District of Illinois, and one in the Eastern District of North Carolina, as listed on Schedule A. All responding defendants[1] oppose centralization.

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 New Jersey will serve the convenience of the parties and witnesses and promote the just and efficient conduct of this litigation. All actions were brought under the Biologics Price Competition and Innovation Act (BPCIA).[2] In each action, Amgen alleges that the defendant infringed various U.S. patents

[*] Judge Matthew F. Kennelly and Judge David C. Norton did not participate in the decision of this matter.

[1] In the Eastern District of North Carolina action, Accord Biopharma, Inc., Accord Healthcare, Inc., and Intas Pharmaceuticals Ltd. In the Northern District of Illinois action, Fresenius Kabi USA, LLC, Fresenius Kabi SwissBioSim GmbH, Fresenius Kabi Deutschland GmbH, and Fresenius Kabi Austria GmbH. Defendants in the District of New Jersey *Celltrion* action (Celltrion, Inc., and Celltrion USA, Inc.) filed a brief in opposition to centralization. But after the conclusion of briefing and before oral argument was held in this matter, the parties to *Celltrion* reached a consent judgment and injunction. The case remains pending at this time. Defendants in the District of New Jersey *Samsung Bioepis* action did not respond to the motion.

[2] The Biologics Price Competition and Innovation Act of 2009, Pub. L. No. 111-148, §§ 7001-7003, 124 Stat. 119, 804-21 (2010), was enacted to expedite the entry of follow-on biologic drugs into the market. Biologic drugs are larger-molecule drugs or vaccines that are produced by manipulating a living tissue or microorganism, such as a virus or protein. *See, e.g.*, Kate S. Gaudry, *Exclusivity Strategies and Opportunities in View of the Biologics Price Competition and Innovation Act*, 66 FOOD & DRUG L.J. 587, 587 & n.1 (2011). Submitting an abbreviated Biologics License Application (aBLA) constitutes a statutory act of infringement that creates subject-matter jurisdiction for a district court to resolve any disputes regarding patent infringement or validity prior to the biosimilar drug's being sold. *See, e.g.*, *Sandoz Inc. v. Amgen Inc.*, 582 U.S. 1, 8 (2017). Under 42 U.S.C. § 262(l)(2)(A), an aBLA applicant must provide its application and

covering its drugs Prolia® and XGEVA®, used in the treatment of certain types of bone disease, by submitting aBLAs and seeking to market their follow-on biologic products. Common factual questions will include whether the proposed biosimilar products infringe the patents, the evidence related to claim construction, and patent validity considerations such as the level of ordinary skill in the art, the scope and content of the prior art, and obviousness. Centralization will avoid the risk of duplicative discovery and prevent inconsistent rulings as to claim construction, patent validity, and other issues.

All responding defendants oppose the motion. They argue that each action involves dozens of patents—when the motion was filed, a total of 47 across all actions—and that many non-overlapping patents are asserted against each defendant. In addition, some of the common patents relate to manufacturing methods that defendants contend are unique to each defendant; thus, they argue, they may have different invalidity and non-infringement defenses even as to the same patents. Defendants also contend that centralization will require special discovery protections because defendants are competitors with confidential manufacturing methods. Defendants maintain that these complexities make this BPCIA litigation significantly different from litigation under the Hatch-Waxman Act[3] that the Panel typically centralizes and would result in an unmanageable MDL. Given the relatively small number of involved actions, they argue, centralization is not appropriate.

We recently rejected similar arguments. *See In re Aflibercept Pat. Litig.*, 730 F. Supp. 3d 1374 (J.P.M.L. 2024). Now that the District of New Jersey *Celltrion* action has reached a settlement, Amgen states that it asserts a common set of 24 patents in the three remaining actions here, three of which (the Dillon '205 patent, the Boyle '736 patent, and the Huang '514 patent) were the subject of a six-day preliminary injunction hearing in a previously-pending action in the District of New Jersey. *See Amgen Inc. et al. v. Sandoz Inc. et al.*, No. 1:23-cv-02406-CPO-EAP (D.N.J.). Certain defendants concede that the Boyle '736 patent is directed to the denosumab antibody itself.[4] "Even if there is some variation among defendants' defenses to certain patents, it

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manufacturing information to the branded drug sponsor within 20 days of the date the U.S. Federal Drug Administration notifies the applicant that it has accepted the aBLA for review. This commences an exchange between the applicant and the branded drug sponsor of lists of potentially relevant patents and the companies' respective arguments regarding those patents. *Id.* § 262(l)(3). The BPCIA provides two paths for patent litigation. First, the parties may negotiate to identify patents on the lists for immediate litigation or, if agreement is not reached, the branded drug sponsor may bring an action alleging infringement of all patents on the lists. *Id.* § 262(l)(6). Second, when a biosimilar applicant gives the branded drug sponsor 180-days' notice that it intends to begin commercially marketing the biosimilar product, as required under § 262(l)(8)(A), the branded drug sponsor may seek a preliminary injunction to prevent the marketing of the biosimilar product. *Id.* § 262(l)(8)(B).

[3] The Drug Price Competition and Patent Term Restoration Act of 1984 ("Hatch-Waxman Act"), Pub. L. No. 98-417, 98 Stat. 1585 (1984).

[4] These defendants argue that certain overlapping patents are expired or soon will expire, but Amgen argues it may seek damages for past infringement after the patents' expirations.

seems far more efficient to allow a single court to construe the patents at issue and to decide whether injunctive relief is warranted." *In re Aflibercept*, 730 F. Supp. 3d at 1376. Defendants argue that Amgen will narrow the patents asserted in each action, and there may be even fewer overlapping patents. But each defendant's product is asserted to be "highly similar" to Amgen's Prolia® and XGEVA® products, and it seems unlikely that ultimately no patents will overlap. These are highly complex patent disputes and, contrary to the argument that defendants' status as competitors weighs against centralization, Amgen argues that there already is a demonstrated need for a single judge to coordinate disclosures of requested confidential information across the different actions. Allowing these actions to proceed before a judge who already has familiarity with the products at issue, relevant manufacturing processes and technologies, and previous litigation that already has involved overlapping discovery is likely to streamline resolution of the litigation. It may be, on further refinement of the issues and close scrutiny by the transferee judge, that some actions can be remanded in advance of the other actions in the transferee district. If the transferee judge deems Section 1407 remand of any claims or actions appropriate, this can be accomplished with minimal delay. *See* Panel Rules 10.1-10.3.

In opposing centralization, certain defendants also argued that the District of New Jersey *Celltrion* action is in a different procedural posture than the other three actions, and transfer might delay progress in *Celltrion*. That action has reached a consent judgment and injunction. While it currently remains open, its resolution appears imminent. Given that we are assigning this litigation to the district where *Celltrion* is pending, we leave to the discretion of the transferee judge whether it is necessary to coordinate any remaining proceedings in *Celltrion* with the three other actions on the motion, each of which are in a similar early procedural posture.

The District of New Jersey is the most appropriate transferee district for this litigation. The Honorable Christine P. O'Hearn presides over the *Samsung Bioepis* action, as well as *Celltrion*, and previously presided over the *Sandoz* action. In *Sandoz*, she held a technical tutorial on denosumab and the manufacturing processes and technologies involved in producing Prolia® and XGEVA®, and she presided over a preliminary injunction motion. She therefore has substantial familiarity with the drugs at issue and at least some of the asserted patents.

IT IS THEREFORE ORDERED that the actions listed on Schedule A and pending outside the District of New Jersey are transferred to the District of New Jersey and, with the consent of that court, assigned to the Honorable Christine P. O'Hearn for coordinated or consolidated pretrial proceedings.

PANEL ON MULTIDISTRICT LITIGATION

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Chair

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SCHEDULE A

Northern District of Illinois

AMGEN, INC., ET AL. v. FRESENIUS KABI USA, LLC, ET AL., C.A. No. 1:24−09555

District of New Jersey

AMGEN, INC., ET AL. v. CELLTRION, INC., ET AL., C.A. No. 1:24−06497
AMGEN, INC., ET AL. v. SAMSUNG BIOEPIS CO., LTD., ET AL., C.A. No. 1:24−08417

Eastern District of North Carolina

AMGEN, INC., ET AL. v. ACCORD BIOPHARMA, INC., ET AL., C.A. No. 5:24−00642