

**UNITED STATES JUDICIAL PANEL  
on  
MULTIDISTRICT LITIGATION**

**IN RE: AVYCAZ (CEFTAZIDIME AND  
AVIBACTAM) PATENT LITIGATION**

MDL No. 3134

**TRANSFER ORDER**

**Before the Panel:**\* Common plaintiffs AbbVie Inc. and Allergan Pharmaceuticals International Limited (together, AbbVie) move under 28 U.S.C. § 1407 to centralize this litigation in the District of New Jersey. This litigation consists of two actions, one in the District of New Jersey and one in the Northern District of Illinois, as listed on Schedule A. Defendants Fresenius Kabi USA, LLC, and Fresenius Kabi Ipsum SRL (together, Fresenius), named in both actions, oppose centralization. The remaining defendants,<sup>1</sup> named in the District of New Jersey action, did not respond to the motion.

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 AVYCAZ, which is an antibacterial medicine indicated for the treatment of intra-abdominal infections, complicated urinary tract infections, and bacterial pneumonia. The actions on the motion are two Hatch-Waxman<sup>2</sup> patent infringement lawsuits, in which the plaintiff alleges that each defendant group

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\* Judge Matthew F. Kennelly did not participate in the decision of this matter.

<sup>1</sup> Qilu Pharma, Inc.; Qilu Antibiotics Pharmaceutical Co., Ltd.; and Apotex Inc.

<sup>2</sup> 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 Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1063–65 (D.C. Cir. 1998). Submitting an ANDA with a “paragraph IV certification”—stating that the patents listed in the FDA publication “Approved Drug Products with Therapeutic Equivalence Evaluations” (the 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 patentholder initiates an infringement action against the ANDA filer within 45 days of receipt of

has infringed one or more claims of five patents<sup>3</sup> by filing an ANDA seeking FDA approval to market generic versions of AVYCAZ in the United States.

After considering the arguments of counsel, we find that the actions listed on Schedule A 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. These actions involve substantially similar claims that defendants infringed the same five patents. Centralization is warranted to eliminate duplicative discovery; prevent inconsistent pretrial rulings (particularly with respect to claim construction and issues of patent validity); and conserve the resources of the parties, their counsel, and the judiciary.

Fresenius argues that the involved common factual questions are not “unusually complex.” We disagree and find these actions involve sufficiently complex factual questions concerning these five pharmaceutical patents that involve the complex technologies of polymorphism, synthetic chemistry, and pharmaceutical formulation. We have centralized similar patent 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.” *See In re Kerydin (Tavaborole) Topical Solution 5% Patent Litig.*, 366 F. Supp. 3d 1370, 1371 (J.P.M.L. 2019). Fresenius argues that defendant-specific discovery will be required. But that is often true in litigation involving claims that various defendants have infringed the same patents. “Discovery with respect to any case-specific issues can also proceed concurrently with discovery on common issues.” *In re Rosuvastatin Calcium Patent Litig.*, 560 F. Supp. 2d 1381, 1383 (J.P.M.L. 2008).

Fresenius also argues that it is too early in the litigation to tell whether common factual issues will predominate. First, Section 1407 does not contain a predominance requirement. Second, both defendant groups filed ANDAs seeking approval to market generic versions of the same drug, and the overlap in factual questions between the actions is substantial. It seems far more efficient to allow a single court to construe the common patents at issue and to decide whether injunctive relief is warranted, particularly with regard to Fresenius, which is named in both actions. Fresenius argues that centralization is not warranted because defendants are direct competitors. But centralization does not introduce any further complication to the litigation in that regard, because both defendant groups already are named in a single action, pending in the District of New Jersey.

Fresenius has not persuaded us that informal coordination of the actions is preferable. Requiring two courts to adjudicate the same complex claims against the same parties would not be efficient. Even if Fresenius were cooperative in coordination efforts, it adds an element of unnecessary delay, duplication, and uncertainty to the progress of these cases.

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the paragraph 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).

<sup>3</sup> U.S. Patent Nos. 8,471,025; 8,835,455; 8,969,566; 9,284,314; and 9,695,122.

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The District of New Jersey is an appropriate transferee district for this litigation. All parties involved in the litigation already are presiding in the action in that district before Judge Zahid N. Quraishi. Judge Quraishi is an experienced transferee judge, and we are confident that he will steer this litigation on a prudent and expeditious course.

IT IS THEREFORE ORDERED that the action listed on Schedule A and pending outside the District of New Jersey is transferred to the District of New Jersey and, with the consent of that court, assigned to the Honorable Zahid N. Quraishi for coordinated or consolidated pretrial proceedings.

PANEL ON MULTIDISTRICT LITIGATION

A handwritten signature in black ink, reading "Karen K. Caldwell", is positioned above a horizontal line.

Karen K. Caldwell  
Chair

Nathaniel M. Gorton  
Roger T. Benitez  
Madeline Cox Arleo

David C. Norton  
Dale A. Kimball

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**SCHEDULE A**

Northern District of Illinois

ABBVIE, INC., ET AL. v. FRESENIUS KABI USA, LLC, ET AL.,  
C.A. No. 1:24-04914

District of New Jersey

ABBVIE, INC., ET AL. v. QILU PHARMA, INC., ET AL., C.A. No. 3:24-06759