BEFORE THE UNITED STATES
JUDICIAL PANEL ON MULTIDISTRICT LITIGATION

In re AVYCAZ® (ceftazidime and avibactam) Patent Litigation	)	MDL No._____

CORRECTED BRIEF IN SUPPORT OF PLAINTIFFS' MOTION FOR TRANSFER OF ACTION TO THE DISTRICT OF NEW JERSEY PURSUANT TO 28 U.S.C. § 1407 FOR COORDINATED AND CONSOLIDATED PRETRIAL PROCEEDINGS

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Pursuant to 28 U.S.C. § 1407 and Rule 6.2 of the Rules of Procedure of the Judicial Panel on Multidistrict Litigation, plaintiffs AbbVie Inc. and Allergan Pharmaceuticals International Limited ("AbbVie" of "Plaintiffs") hereby move to transfer *AbbVie Inc. et al v. Fresenius Kabi USA, LLC et al.*, Case No. 1-24-cv-04914, pending before Judge John Robert Blakey in the Northern District of Illinois, to Judge Zahid N. Quraishi in the District of New Jersey for coordinated and consolidated pretrial proceedings with an earlier filed related action pending before Judge Quraishi in the District of New Jersey involving the same patents and defendants.

I. BACKGROUND

AVYCAZ® (ceftazidime and avibactam) is AbbVie's antibacterial medicine indicated for the treatment of intra-abdominal infections, complicated urinary tract infections, and bacterial pneumonia. After receiving priority review, AVYCAZ® was approved by the U.S. Food & Drug Administration ("FDA") in 2015 as a novel antibiotic treatment for serious infections in patients with limited or no alternative treatment options. The FDA designated AVYCAZ® as a qualified infectious disease product under the Generating Antibiotic Incentives Now ("GAIN") Act, conveying a 5-year extension to its new chemical entity regulatory exclusivity.

Fresenius USA and Qilu Pharma, Inc. ("Qilu") have submitted Abbreviated New Drug Applications ("ANDAs") to the U.S. Food & Drug Administration ("FDA") seeking approval of generic versions of AVYCAZ® ("ANDA Products"). In April 2024, Qilu and Fresenius USA provided AbbVie with letters containing notice of their ANDA submissions, which included "Paragraph IV certifications" against five patents listed as covering AVYCAZ® in the FDA publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*, known as the "Orange Book." By submitting an ANDA to FDA containing a Paragraph IV certification, Qilu and Fresenius USA have represented that those patents are invalid, unenforceable and/or will not be infringed by their proposed generic versions of AVYCAZ® and are seeking approval to market

their generic products before those patents expire. The Hatch-Waxman Act makes the submission of an ANDA containing a Paragraph IV certification an act of patent infringement. *See* 35 U.S.C. § 271(e)(2).

AbbVie sued Qilu, Qilu's related entities Qilu Antibiotics Pharmaceutical Co., Ltd. and Apotex Inc. (the "Qilu Defendants"), and the Fresenius Defendants for infringement of the five patents that were the subject of the Paragraph IV Certifications[1] in the District of New Jersey on June 6, 2024 (the "New Jersey Action"). Prior to filing the New Jersey Action, AbbVie asked the Qilu Defendants and the Fresenius Defendants to consent to venue in the District of New Jersey, where both parties had previously litigated a number of Hatch-Waxman patent litigations.[2] The Qilu Defendants agreed but the Fresenius Defendants refused. The Fresenius Defendants, however, did not foreclose the possibility that they would answer the Complaint after it was filed and proceed with the case in New Jersey. Because the Fresenius Defendants did not agree to venue in the District of New Jersey, on June 13, 2024, AbbVie also filed a protective suit against just the Fresenius Defendants for infringement of the same five Patents-in-Suit in the Northern District of Illinois, where Fresenius USA is headquartered (the "Illinois Action").

[1] U.S. Patent Nos. 8,471,025; 8,835,455; 8,969,566; 9,284,314; and 9,695,122 Action (together, the "Patents-in-Suit") have been asserted against the Fresenius Defendants in both the Illinois Action and New Jersey.

[2] The Fresenius Defendants have previously consented to at least 10 Hatch-Waxman litigations and affirmatively filed at least 18 patent litigation actions in the District of New Jersey. *See, e.g.*, *Merck Sharp & Dohme BV, et al. v. Fresenius Kabi USA, LLC, et al.*, No. 2:20-CV-02892 (D.N.J.); *Boehringer Ingelheim Pharms., Inc., et al., v. Fresenius Kabi USA, LLC, et al.*, No. 3:18-CV-03244 (D.N.J.); *Helsinn Healthcare SA et al. v. Fresenius Kabi USA, LLC et al.*, No. 3:15-CV-07378 (D.N.J); *Novartis Pharms. Corp. v. Fresenius Kabi USA, LLC*, No. 2:13-CV-07914 (D.N.J.); *Fresenius Kabi USA, LLC v. Accord Healthcare, Inc.*, No. 1:24-cv-05674 (D.N.J.); *Fresenius Kabi USA LLC v. Amneal Pharms. LLC, et al.*, 2:23-CV-04343 (D.N.J.); *Fresenius Kabi USA, LLC v. Zydus Pharms. (USA) Inc.*, No. 3:22-CV-01702 (D.N.J.).

Instead of answering the Complaint in the New Jersey Action, on October 7, 2024, the Fresenius Defendants filed a letter with the Court requesting a pre-motion conference. *See AbbVie Inc. et al v. Qilu Pharma, Inc. et al.*, Case No. 3:24-cv-06759, ECF No. 31 (D.N.J. Oct. 7, 2024). The Fresenius Defendants' letter sought leave to file a motion to dismiss under Fed. R. Civ. P. 12(b)(3) challenging venue with respect to Fresenius USA, and a motion to transfer under 28 U.S.C. § 1404(a) with respect to Fresenius iPSUM. AbbVie's response stated that it did not oppose leave but would oppose Fresenius's proposed motions because they lacked merit. *Id.,* ECF No. 32. The Court has not yet ruled on the Fresenius Defendants' request for leave in the New Jersey Action. The Qilu Defendants have consented to jurisdiction and venue in the District of New Jersey and have answered the Complaint in the New Jersey Action. The parties are scheduled to appear for their Rule 16 conference in the New Jersey Action on November 7, 2024. In the Illinois Action, the Fresenius Defendants filed their Answer and Affirmative Defenses, and Fresenius USA filed Counterclaims on October 7, 2024. The Fresenius Defendants have not contested personal jurisdiction or venue in the Illinois Action. *See AbbVie Inc. et al v. Fresenius Kabi USA, LLC et al.*, Case No. 1-24-cv-04914, ECF No. 16 (N.D. Ill. Oct. 7, 2024). AbbVie provided its Answer to Fresenius USA's counterclaims on October 28, 2024.

As explained further below, AbbVie respectfully requests transfer of the Illinois Action and consolidation with the New Jersey Action. Both the New Jersey Action and the Illinois Action are in the very early stages of litigation. Both actions will involve the same Patents-in-Suit and common questions of fact with regards to their claim construction, infringement, and validity. Transfer will ensure efficient and consistent conduct of the actions; will lessen the burden on the courts, the parties, and the witnesses; and will guard against the risk of inconsistent decisions on

very similar (if not identical) legal and factual issues resulting from parallel proceedings in different courts.

II. ARGUMENT

A. The Panel Should Transfer the Illinois Action and Consolidate the AVYCAZ® Patent Litigations

The Panel may centralize actions pursuant to 28 U.S.C. § 1407 if the movant establishes: (1) that there are "common questions of fact" between or among the actions; (2) that centralization will "be for the convenience of [the] parties and witnesses;" and (3) that centralization "will promote the just and efficient conduct of [the] actions."

As discussed below, transferring the Illinois Action to the District of New Jersey satisfies all three statutory prongs. Specifically, centralization is warranted because (1) there will be common questions of fact between the two actions relating to claim construction, infringement, and validity of the Patents-in-Suit; (2) transfer will be convenient for and reduce the discovery burden on the parties; and (3) the District of New Jersey is an experienced patent forum with local Hatch-Waxman rules. The "complexity of . . . the regulatory framework governing Hatch-Waxman cases," and "the need for swift progress in litigation involving the potential entry of generic drugs into the market," support the transfer of such cases. *In re: Kerydin (Tavaborole) Topical Sol. 5% Pat. Litig.*, 366 F. Supp. 3d 1370, 1371 (J.P.M.L. 2019). The transfer of the Illinois Action to Judge Quraishi in the District of New Jersey would conform to this Panel's routine practice of consolidating Hatch-Waxman proceedings where multiple infringement actions are pending in different districts. *Id.*; *see also, In re: Ozempic (Semaglutide) Pat. Litig.*, 621 F. Supp. 3d 1354, 1356 (J.P.M.L. 2022); *In re: Xarelto (rivaroxaban) ('310) Pat. Litig.*, 577 F. Supp. 3d 1377, 1378-79 (J.P.M.L. 2021); *In re: Entresto (Sacubitril/Valsartan) Patent Litig.*, 437 F. Supp. 3d 1372, 1373-74 (J.P.M.L. 2020); *In re: Palbociclib Patent Litig.*, 396 F. Supp. 3d 1360,

1361-62 (J.P.M.L. 2019); *In re: Armodafinil Pat. Litig.*, 755 F. Supp. 2d 1359, 1360 (J.P.M.L. 2010); *In re: Brimonidine Pat. Litig.*, 507 F. Supp. 2d 1381, 1382 (J.P.M.L. 2007); *In re Metoprolol Succinate Pat. Litig.*, 329 F. Supp. 2d 1368, 1369-70 (J.P.M.L. 2004).

a. The Illinois Action Shares Common Questions of Fact with the New Jersey Action

Both the Illinois Action and the New Jersey Action are Hatch-Waxman patent infringement cases involving the same Patents-in-Suit that will inevitably raise common questions of fact. The Patents-in-Suit claim polymorphic forms of the active pharmaceutical ingredients ("APIs") in AVYCAZ®, synthetic processes for making the APIs, and pharmaceutical compositions containing the APIs. AbbVie has made nearly identical infringement allegations with regards to Fresenius's ANDA product in both the Illinois Action and New Jersey Action. *See AbbVie Inc. et al v. Fresenius Kabi USA, LLC et al.*, Case No. 1-24-cv-04914, ECF No. 1 (N.D. Ill. Jun. 13, 2024); *AbbVie Inc. et al v. Qilu Pharma, Inc. et al*., Case No. 3-24-cv-06759, ECF No. 1 (D.N.J. Jun. 6, 2024).

This Panel has recognized that patent infringement cases where the same patents are asserted will necessarily "share factual and legal questions concerning such matters as the technology underlying the patents, prior art, claim construction and issues of infringement involving the patents." *In re PharmaStem Therapeutics, Inc., Pat. Litig.*, 360 F. Supp. 2d 1362, 1364 (J.P.M.L. 2005). That is true in this case. Common questions of fact exist between the Illinois Action and New Jersey Action relating to (1) claim construction of terms in the asserted Patents-in-Suit; (2) infringement by the Fresenius Defendants' and the Qilu Defendants' ANDA Products; and (3) the validity of the Patents-in-Suit.

Claim construction is a necessary prerequisite to deciding questions of validity and infringement of the Patents-in-Suit. Because both Actions involve the same Patents-in-Suit, it is

likely that the same claim construction issues will arise in both proceedings. For instance, it is conceivable that the same claim terms will be proposed by the parties for construction, and therefore the actions will share common issues of fact in determining the meaning of those claim terms. Permitting each action to construe the claims of the Patents-in-Suit could result in the same claim terms being interpreted differently. Different rulings on claim construction would only serve to further complicate issues relating to the infringement and validity of the Patents-in-Suit. This Panel has repeatedly taken the position that centralization is necessary to avoid inconsistent pretrial rules "particularly on claim construction issues." *See, e.g.*, *In re: RAH Color Techs. LLC Patent Litig.*, 347 F. Supp. 3d 1359, 1360 (J.P.M.L. 2018); *In re: Nebivolol ('040) Patent Litig.*, 867 F. Supp. 2d 1354, 1355 (J.P.M.L. 2012). A consolidated approach would avoid inconsistent claim constructions, which could lead to conflicting outcomes with respect to the infringement and validity of the Patents-in-Suit.

Because both the Qilu Defendants and the Fresenius Defendants have submitted ANDAs to FDA and intend to market generic versions of AVYCAZ®, common questions as to whether their respective ANDA Products infringe the Patents-in-Suit will arise. While each defendant may raise unique non-infringement arguments, the determination of whether an accused product infringes each claim, either literally, or under the doctrine of equivalents, will involve common questions of fact. *See, e.g., In re: Nebivolol*, 867 F. Supp. 2d at 1355 ("While there may be some variances in the proposed formulations of defendants' respective drugs, this does not weigh strongly against centralization because all defendants are anticipated to raise similar arguments concerning non-infringement defenses . . . ."). The Qilu Defendants and the Fresenius Defendants have raised similar non-infringement defenses in their pleadings to date.

Both the New Jersey Action and the Illinois Action will involve common factual issues related to the validity of the Patents-in-Suit. Again, AbbVie has asserted that the Qilu Defendants and the Fresenius Defendants infringe the same five Patents-in-Suit. All of the Defendants have asserted that the Patents-in-Suit are invalid, including because they are obvious under 35 U.S.C. § 103.[3] For instance, in each of their respective notice letters, the Qilu Defendants and the Fresenius Defendants have identified many of the same references they contend render certain claims invalid as obvious. Determination of whether a patent is invalid as obvious requires a factual investigation into the scope and content of the prior art, the level of ordinary skill in the art, the differences between the claimed invention and the prior art, whether the person of ordinary skill would have been motivated to combine prior art references, whether the person of ordinary skill would have had a reasonable expectation of success in achieving the claimed invention, and evidence of objective indicia of non-obviousness. *Eli Lilly & Co. v. Zenith Goldline Pharms., Inc.*, 471 F.3d 1369, 1377 (Fed. Cir. 2006). These factual inquiries will be common to both the Illinois Action and the New Jersey Action.

B. Transfer Will Serve the Convenience of the Parties and Witnesses

Transfer of the Illinois Action for consolidation before Judge Quraishi in the District of New Jersey will serve the convenience of the parties and witnesses through a common pretrial schedule, common fact and expert discovery, and will provide a "streamlined" approach to scheduling, motions practice, claim construction, and summary judgment. *In re: Fenofibrate Patent Litig.*, 787 F. Supp. 2d 1352, 1354 (J.P.M.L. 2011).

[3] The Fresenius Defendants have alleged in their Answer in the Illinois Action that the Patents-in-Suit are invalid as obvious under 35 U.S.C. § 103. *See AbbVie Inc. et al v. Fresenius Kabi USA, LLC et al.*, Case No. 1-24-cv-04914, ECF No. 16 (N.D. Ill. Oct. 7, 2024).

Transfer and consolidation will simplify and streamline fact discovery. For instance, transfer and consolidation will eliminate the need for multiple document productions, conducted on different schedules, and according to different search and review parameters. This approach will also reduce the financial burden on the parties as it relates to document collection and production. Transfer and consolidation will also allow for joint resolution of discovery disputes, sparing the courts the burden of deciding the same disputes in different jurisdictions. It will also eliminate the need for fact witnesses to appear for and participate in depositions in more than one proceeding. This factor is of particular importance as several witnesses listed as inventors of the Patents-in-Suit—who may be noticed for deposition—reside in Europe and are not employed by AbbVie (but rather are third parties). *See PharmaStem,* 360 F. Supp. 2d at 1364 ("[T]ransfer under Section 1407 has the benefit of placing all actions . . . before a single judge who can structure pretrial proceedings to consider all parties' legitimate discovery needs while ensuring that common parties and witnesses are not subjected to discovery demands which duplicate activity that has already occurred or is occurring in other actions."); *see also In re: Nebivolol,* 867 F. Supp. 2d at 1355 (noting the value of eliminating "duplicative discovery" that "will likely be international in scope").

Transfer and consolidation will also reduce the burden on the parties throughout expert discovery. For instance, consolidation will eliminate the need for expert witnesses to submit expert reports on different schedules in two different jurisdictions, which will likely set forth the same opinions. Transfer and consolidation will also eliminate the need for multiple depositions of the same expert witnesses.

C. Transfer and Consolidation of the Illinois Action to the District of New Jersey Will Promote the Just and Efficient Conduct of the Actions

Transferring the Illinois Action to the District of New Jersey and consolidating the AVYCAZ® litigation will also promote justice and efficiency by eliminating duplicative discovery, preventing inconsistent pretrial rulings, and conserving resources of the judiciary and the parties. The drafters of the Hatch-Waxman Act expressly appreciated the need for consolidation of Hatch-Waxman litigation:

> In the event of multiple ANDA's certifying patent invalidity or noninfringement, the courts should employ the existing rules for multi-district litigation, when appropriate, to avoid hardship on the parties and witnesses and to promote the just and efficient conduct of the patent infringement actions.

See H.R. Rep. No. 98-857, pt. 1, at 28 & n.14 (1984). Likewise, the Panel has recognized that "actions involving the validity of complex pharmaceutical patents and the entry of generic versions of the patentholder's drugs are particularly well-suited for transfer under Section 1407." *In re: Nebivolol*, 867 F. Supp. 2d at 1355 (quoting *In re Alfuozosin Hydrochloride Patent Litig.*, 560 F. Supp. 2d 1372, 1372 (J.P.M.L. 2008)). Indeed, the Panel has frequently centralized litigation consisting of just two Hatch-Waxman actions. *See e.g., In re Nebivolol*, 867 F. Supp. 2d at 1355 & n.4.

The alternative would result in unnecessary and inefficient parallel litigations in the District of New Jersey and the Northern District of Illinois. Proceeding with parallel litigations may result in inconsistent rulings related to discovery disputes, claim construction, infringement, and validity. Moreover, duplicative proceedings would also weigh heavily on the parties and their witnesses with competing case schedules, multiple depositions and hearings, and the added inconvenience and expense that comes with this redundancy. On the other hand, centralization in New Jersey will promote fair and efficient resolution of the disputes by minimizing these burdens.

The District of New Jersey makes for a particularly strong venue for transfer given the strong body of case law that has developed over the years thanks to its frequent use as a venue for resolving Hatch-Waxman disputes. One reason is that the District of New Jersey has adopted local rules specific to the conduct of Hatch-Waxman litigation. *See* D.N.J. Loc. Pat. R. 3.6. The local rules streamline the discovery process and case schedule in an effort to resolve Hatch-Waxman disputes efficiently and expeditiously. For instance, the District of New Jersey local rules regarding Hatch-Waxman disputes calls for the early disclosure of asserted claims, non-infringement contentions, infringement contentions, invalidity contentions, alleged prior art that the ANDA filers intend to rely upon, and supporting document productions. These disclosures provide the parties with ample notice of infringement and invalidity positions and allow the parties to efficiently focus on issues for fact discovery. As previously noted, the Fresenius Defendants have availed themselves to these local patent rules and body of case law on multiple occasions. *See supra n.* 2.

III. CONCLUSION

For the foregoing reasons, AbbVie respectfully requests that the Panel transfer *AbbVie Inc. et al v. Fresenius Kabi USA, LLC et al.*, Case No. 1-24-cv-04914, pending before Judge John Robert Blakey in the Northern District of Illinois, to Judge Zahid N. Quraishi in the District of New Jersey for coordinated pretrial proceedings.

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