IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF VIRGINIA
NORFOLK DIVISION

ALVOTECH USA INC. and
ALVOTECH HF.,

Plaintiffs,

v.

ABBVIE INC. and
ABBVIE BIOTECHNOLOGY LTD.,

Defendants.

C. A. No. 2:21-cv-265-RAJ-DEM

MEMORANDUM OPINION AND ORDER

Before the Court is Defendants', AbbVie Inc. and AbbVie Biotechnology Ltd. (collectively "Defendants"), Motion to Dismiss or, in the Alternative, to Transfer Venue ("Motion"), pursuant to the first-to-file rule, Federal Rule of Civil Procedure 12(b)(2), and 28 U.S.C. § 1404(a). For the reasons set forth below, Defendants' Motion is **GRANTED IN PART**. Defendants' Motion to Transfer Venue is **GRANTED**, and it is **ORDERED** that this case be transferred to the Northern District of Illinois. Accordingly, the Court **FINDS** Defendants' Motion to Dismiss **MOOT**.

I. FACTUAL AND PROCEDURAL HISTORY

AbbVie Inc. ("AbbVie") is a pharmaceutical company that is incorporated in Delaware and headquartered in North Chicago, Illinois. Defs.' Am. Mem. in Supp. of Mot. to Dismiss or Transfer ("Defs.' Mem. in Supp."), ECF No. 43 at 3; Decl. of Sowmyan Ranganathan ("Ranganathan Decl."), ECF No. 34 ¶ 7. AbbVie employs over 10,000 people in Illinois, nearly all of whom work at AbbVie's main campus and two additional locations in the North Chicago area. Defs.' Mem. in Supp. at 3; Ranganathan Decl. ¶ 8. AbbVie Biotechnology Ltd. ("ABL") is a wholly-owned subsidiary of AbbVie, organized and existing under the laws of Bermuda. Defs.' Mem. in Supp.

at 3; Ranganathan Decl. ¶ 12. ABL manufactures and owns the patents for adalimumab, the active ingredient in HUMIRA®, which is used to treat autoimmune disorders. Pls.' Mem. in Opp. to Defs.' Mot. to Dismiss or Transfer ("Pls.' Mem. in Opp."), ECF No. 44 at 4; Defs.' Mem. in Supp. at 3; Ranganathan Decl. ¶¶ 10, 13. AbbVie's predecessor invented adalimumab in 1996. Defs.' Mem. in Supp. at 3; Ranganathan Decl. ¶ 10. Since then, Defendants have continued to develop and improve the drug, while licensing the patents for adalimumab to AbbVie exclusively for final packaging in North Chicago before HUMIRA® is shipped to customers. Defs.' Mem. in Supp. at 3; Ranganathan Decl. ¶¶ 10, 13–14.

Alvotech hf. is an Icelandic pharmaceutical company with headquarters and manufacturing operations in Reykjavik, Iceland. Compl., ECF No. 1 at 6. In Iceland, Alvotech hf. houses a "multi-product, 140,000 square foot biopharmaceutical facility, with personnel specializing in [the] process and product development and commercial manufacturing" of pharmaceutical biosimilars. *Id.*; Pls.' Mem. in Opp. at 3. Alvotech USA is a wholly owned subsidiary of Alvotech hf. that is incorporated and headquartered in Arlington, Virginia. *Id.* Alvotech USA is responsible for the legal, governmental policy, and regulatory affairs of the Alvotech "family of companies." *Id.* In addition to employing the Head of Regulatory Affairs, Chief Intellectual Property Counsel, and Chief Scientific Officer out of its sole office in Virginia, "the core of [Alvotech USA's] business is interactions with the FDA, Capitol Hill, and the Patent and Trademark Office." Compl. at 7; Pls.' Mem. in Opp. at 3.

In November 2020, Alvotech USA Inc. and Alvotech Hf. (collectively "Plaintiffs") engaged Defendants in "the patent dance" under the Biosimilar Price Competition and Innovation Act of 2009 ("BPCIA"), seeking FDA approval to commercialize AVT02, an adalimumab biosimilar. Pls.' Mem. in Opp. at 5; Defs.' Mem. in Supp. at 5–6. Alvotech hf. manufactured and

produced AVT02, while Alvotech USA filed the biologies license application ("BLA") with the FDA. Compl. at 7. During the patent dance, Plaintiffs identified four out of 62 potential patents for litigation under the BPCIA: U.S. Patent Nos. 8,420,081; 9,085,619; 8,926,975; and 8,961,973. Compl. at 4; Defs.' Mem. in Supp. at 6–7. Two of the patents at issue relate to the high-concentration formulas of adalimumab used in HUMIRA®, while the other two patents relate to treatment methods for the autoimmune diseases that HUMIRA® is employed to improve. *Id.*

On April 27, 2021, in accordance with the BPCIA's framework for FDA approval of biosimilars, Defendants filed a patent infringement action against Alvotech hf. in the Northern District of Illinois under 35 U.S.C. § 271(e)(2), alleging that Alvotech hf. infringed on the four patents identified during the patent dance. Plaintiffs then filed the present declaratory judgment action in the Eastern District of Virginia on May 11, 2021. In the present action, Plaintiffs are seeking declaratory judgement for multiple noninfringement, invalidity, and unenforceability claims regarding the same four patents at issue in Defendants' first suit in the Northern District of Illinois. Compl. at 4; Defs.' Notice Re: Defs.' Mot. to Dismiss or Transfer ("Defs.' Notice"), ECF No. 48 at Ex. 1. Subsequently, on May 28, 2021, Defendants filed a second suit against Alvotech hf. in the Northern District of Illinois, alleging infringement of the remaining 58 patents identified during the patent dance.

In June 2021, Defendants moved to dismiss or, in the alternative, transfer the present action to the Northern District of Illinois. On August 23, 2021, the court in Defendants' first action against Alvotech hf. in the Northern District of Illinois denied Alvotech hf.'s motion to dismiss Defendants' infringement claims, rejecting many of the same arguments Plaintiffs filed in opposition to Defendants' Motion here. Defs.' Notice at Ex. 1.

II. LEGAL STANDARD

The decision of whether to transfer an action under 28 U.S.C. § 1404(a) is committed to the sound discretion of the district court. *Stewart Org., Inc. v. Ricoh Corp.*, 487 U.S. 22, 24 (1988); *JTH Tax, Inc. v. Lee*, 482 F. Supp. 2d 731, 732 (E.D. Va. 2007). The moving party bears the burden of showing that transfer is proper and must demonstrate that transfer does more than merely shift the inconvenience to the other party. *JTH Tax*, 482 F. Supp. 2d at 736 (internal citations omitted). Courts must make two overarching inquiries in deciding whether transfer is proper: (1) whether the claims could have been brought in the transferee forum; and (2) whether the interest of justice and convenience of the parties and witnesses justify transfer to that forum. 28 U.S.C. § 1404(a); *id.* at 732 (citing *In re Ralston Purina Co.*, 726 F.2d 1002, 1005 (4th Cir. 1984); *Verosol B.V. v. Hunter Douglas, Inc.*, 806 F. Supp. 582, 592 (E.D. Va. 1992)).

III. DISCUSSION

(A) Venue in Transferee Forum

Venue for this suit would be proper in the Northern District of Illinois. Where jurisdiction is not founded solely on diversity of citizenship, venue is proper in "a judicial district in which any defendant resides, if all defendants are residents of the State in which the district is located . . . ." 28 U.S.C. § 1391(b)(1); *JTH Tax*, 482 F. Supp. 2d at 736. An entity, if a defendant, shall be deemed to reside in any judicial district in which such defendant is "subject to the court's personal jurisdiction with respect to the civil action in question." 28 U.S.C. § 1391(c)(2).

In this case, venue would be proper in the Northern District of Illinois. Since Plaintiffs are seeking declaratory judgement in a patent dispute, the Northern District of Illinois would have subject matter jurisdiction over this case under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2022. Compl. at 7; Defs.' Mem. in Supp. at 20. In addition, Defendants contend—and Plaintiffs do not

dispute—that Defendants are subject to personal jurisdiction in the Northern District of Illinois. Defs.' Mem. in Supp. at 20–21. At minimum, Defendants have headquarters in the Northern District of Illinois and sued Plaintiffs there regarding the same patents at issue in this matter, establishing personal jurisdiction in the district. For these reasons, the jurisdiction inquiry weighs in favor of transfer.

(B) Convenience of the Parties and Witnesses and the Interest of Justice

Next, this Court must consider the following factors: (1) the plaintiff's initial choice of venue; (2) the convenience of the parties and witnesses; and (3) the interest of justice. *Bluestone Innovations, LLC v. LG Elecs., Inc.*, 940 F. Supp. 2d 310, 313 (E.D. Va. 2013); *Heinz Kettler GmbH & Co. v. Razor USA, LLC*, 750 F. Supp. 2d 660, 667 (E.D. Va. 2010); *JTH Tax*, 482 F. Supp. 2d at 736. The Court will address each factor in turn.

(1) Plaintiffs' Initial Choice of Venue

Plaintiffs' choice of venue is not entitled to deference under the first factor because the Eastern District of Virginia has little connection to the underlying cause of action. Under 28 U.S.C. § 1404(a),"[t]he party seeking transfer bears the burden of proving that the circumstances of the case are strongly in favor of transfer." *Heinz*, 750 F. Supp. 2d at 667. "The plaintiff's choice of forum is typically entitled to substantial weight, especially where the chosen forum is the plaintiff's home or bears a substantial relation to the cause of action." *Bluestone Innovations*, 940 F. Supp. 2d at 314. The amount of deference given to a plaintiff's forum choice, however, varies with the significance of the contacts between the selected venue and the underlying cause of action. *Id.* Ultimately, "a plaintiff's choice of forum is not entitled to substantial weight if the . . . cause of action bears little or no relation to that forum." *Noetic Specialty Ins. Co. v. N.C. Mut. Wholesale Drug Co.*, 453 F. Supp. 3d 842, 846 (E.D. Va. 2020). *See also Koh v. Microtek Int'l, Inc.*, 250 F.

Supp. 2d 627, 635 (E.D. Va. 2003) ("[I]f there is little connection between the claims and this judicial district, that would militate against a plaintiff's chosen forum and weigh in favor of transfer to a venue with more substantial contacts."); *Ion Beam Applications S.A. v. Titan Corp.*, 156 F. Supp. 2d 552, 563 (E.D. Va. 2000) ("[W]here the plaintiff's choice of forum is a place where neither the plaintiff nor the defendant resides and where few or none of the events giving rise to the cause of action accrued, that plaintiff's choice loses its place status in the court's consideration."); *Automated Tracking, Sols., LLC v. Validfill, LLC*, No. 3:15CV142-HEH, 2015 WL 9025703, at *2 (E.D. Va. Dec. 15, 2015) ("Even when a plaintiff sues in its home forum, that fact alone is not controlling and the weight of that factor depends on the nexus between the case and forum.") (citing *Global Tel Link Corp. v. Securus Tech. Inc.*, 2014 WL 860609, at *4 (E.D. Va. Mar. 5, 2014) (internal quotations omitted)).

In this matter, the parties agree that the Eastern District of Virginia is Alvotech USA's home forum, while Alvotech hf. is an Icelandic corporation. Compl. at 6; Defs.' Mem. in Supp. at 21. Alvotech hf.'s status as a foreign party neutralizes its' forum preference in the analysis. *Piper Aircraft Co. v. Reyno*, 454 U.S. 235, 255 (1981) (holding that the strong presumption in favor of the plaintiff's choice of forum "applies with less force when the plaintiff or real parties in interest are foreign"). Plaintiffs contend that their choice of the Eastern District of Virginia should be given substantial weight because Alvotech USA is incorporated and headquartered in the district, employs key employees in the district, and interacts with the FDA regarding Plaintiffs' BLA filings in the district. Pls.' Mem. in Opp. at 28.

These few points of information alone, however, do little to establish a substantial connection between the Eastern District of Virginia and Plaintiffs' noninfringement, invalidity, and unenforceability claims. *See Automated Tracking, Sols., LLC*, No. 3:15CV142-HEH, 2015

WL 9025703, at *2 (holding that a plaintiff's choice of forum should not be given significant weight in a patent infringement action where the plaintiff does not allege that it designs, develops, manufactures, or sells any products within that forum). It is clear from Plaintiffs' pleadings that its business in Virginia is limited to fulfilling legal, governmental policy, and regulatory obligations in the United States, while all of Plaintiffs' product development and manufacturing takes place at a biopharmaceutical facility in Iceland. Pls.' Mem. in Opp. at 3–4, 12. Moreover, Defendants contend—and Plaintiffs do not dispute—that Plaintiffs' invalidity and unenforceability claims stem from events occurring outside of Virginia. Defs.' Mem. in Supp. at 22. For these reasons, the minimal connection between Plaintiffs' claims and the Eastern District of Virginia militate the weight ordinarily afforded to a plaintiff's choice of their home forum. *See Acterna, L.L.C. v. Adtech, Inc.*, 129 F. Supp. 2d 936, 939 (E.D. Va. 2001) (holding that the preferred forum in a patent infringement action is that which is "the center of the accused activity"); *GTE Wireless, Inc. v. Qualcomm, Inc.*, 71 F. Supp. 2d 517, 519 (E.D. Va. 1999) (granting transfer because "[t]he trier of fact ought to be as close as possible to the milieu of the infringing device and the hub of activity centered around its production").

(2) Convenience of the Parties and Witnesses

The second factor weighs in favor of transfer as well because while the patents underlying Plaintiffs' claims have some connection to Illinois, Defendants' do not have any relevant documents or witnesses in Virginia. Courts are required to consider the "ease of access to sources of proof, the costs of obtaining witnesses, and the availability of compulsory process" in evaluating the convenience of the parties. *Lycos, Inc. v. TiVo, Inc.*, 499 F.Supp.2d 685, 693 (E.D.Va.2007) (quoting *Samsung Elecs. Co. v. Rambus, Inc.*, 386 F.Supp.2d 708, 717 n.13 (E.D.Va.2005)). "[T]ransfer is not appropriate where it will only serve to shift the balance of inconvenience from

one party to the other." *Heinz*, 750 F. Supp. 2d at 668. Moreover, the party asserting witness inconvenience "has the burden to proffer, by affidavit or otherwise, sufficient details respecting the witnesses and their potential testimony to enable the court to assess the materiality of evidence and the degree of inconvenience." *Id.* (citing *Koh*, 250 F.Supp.2d at 636) (internal quotations omitted). Courts give "greater weight . . . to the potential inconvenience of witnesses whose testimony is central to a claim and whose credibility is also likely to be an important issue." *Lycos*, 499 F.Supp.2d at 693. Courts give less weight, however, to this factor "when the appearance of witnesses can be secured without the necessity of compulsory process." *Id.*

Defendants have met their burden of proving that transfer is strongly preferred for the convenience of the parties and witnesses. First, Defendants establish via declaration that while the active ingredient for HUMIRA® is manufactured by ABL, AbbVie's facilities in Illinois play an active role in the development and final production of HUMIRA®. Defs.' Mem. in Supp. at 3; Ranganathan Decl. ¶¶ 14, 16. Second, Defendants demonstrate via declarations and other documentary evidence that at least 13 of its witnesses with relevant knowledge do not reside in Virginia, including four of the inventors and an undetermined number of Rule 30(b)(6) witnesses who all reside in Illinois. Defs.' Mem. in Supp. at 23; Decl. of Herman H. Yue ("Yue Decl."), ECF No. 35 ¶¶ 31–34, Ex. 21–24; Ranganathan Decl. ¶¶ 8, 9, 15, 21–23. Defendants also provide some indication that the compulsory process may be necessary for at least two key witnesses who are not employed by Defendants and do not reside in Virginia. Defs.' Mem. in Supp. at 23. And finally, Defendants establish that the "documents relating to the development of the inventions, including documentation relating to the relevant clinical trials and lab notebooks, are primarily located at or near AbbVie's facilities in the North Chicago area; its research facility in Worcester, Massachusetts; or in Germany . . . ," not Virginia. *Id.* at 23; Ranganathan Decl. ¶ 19.

Plaintiffs, on the other hand, acknowledge that all aspects of development, manufacturing, and production of their biosimilar product, ABL, did not take place in Virginia. Pls.' Mem. in Opp. at 3 (stating that Alvotech hf. oversees "product development and manufacturing" for AVT02 in Reykjavik, Iceland). Plaintiffs also state, however, that Alvotech USA "holds relevant documents" in Virginia and "sent the BLA and other information required by 42 U.S.C. § 262(*l*)(2) from its headquarters in Arlington, Virginia." Pls.' Mem. in Opp. at 24; Compl. at 12. Without more information, it is hard for this Court to determine that all or at least most of Plaintiffs' relevant documents are in Virginia, especially since the activity centered around the production of AVT02 occurs in Iceland.

It is important to note that Plaintiffs cite *Heinz* to argue that the convenience of the parties rarely, if ever, operates to justify transfer when a plaintiff files suit in their home forum. Pls.' Mem. in Opp. at 28. In *Heinz*, however, the court deferred to the plaintiffs' choice of their home forum in part because "*all* of [plaintiffs'] employees, including the directors and employees with information relevant to the patent infringement suit, [we]re located in Virginia." *Heinz*, 750 F. Supp. 2d at 667 (emphasis added). As discussed above, in this case, Plaintiffs' choice of their home forum is not given substantial weight because Plaintiffs' Virginia office is limited to performing administrative and regulatory functions, while all research, development, and production for AVT02 occurred outside of Virginia. Pls.' Mem. in Opp. at 3–4, 12; Yue Decl. at Ex. 15.

Additionally, Plaintiffs do not allege that all or even most of their witnesses with relevant knowledge are in Virginia, nor do Plaintiffs comment on the necessity of the compulsory process. Plaintiffs only provide quick reference to three officers who are employed in Virginia: the Head of Regulatory Affairs, the Chief IP Counsel, and the Chief Scientific Officer. Pls.' Mem. in Opp. at 3. Plaintiffs also do not allege the extent to which these individuals are knowledgeable about

Plaintiffs' non-infringement, unenforceability, and invalidity claims. The Court can only assume that the Chief IP Counsel and Chief Scientific Officer will have knowledge relevant to this suit, but the Court cannot assume the same regarding the Head of Regulatory Affairs. Plaintiffs then acknowledge in their pleadings that they have witnesses in Iceland. Pls.' Mem. in Opp. at 28. Therefore, unlike *Heintz*, the extent to which Plaintiffs' witnesses reside in this district is unclear at best, with a maximum of only three witnesses residing in Virginia.[1] And regardless of venue in the United States, the parties are likely to accrue significant travel costs for witnesses residing outside the United States, while those same witnesses can travel to Illinois just as easily as they can travel to Virginia. For these reasons, the second factor—the convenience of the parties and witnesses—weighs in favor of transfer.

(3) Interest of Justice

And finally, in the interest of justice, this case should be transferred to avoid unnecessary conflicts of law, forum shopping, and docket congestion. 28 U.S.C. 1401(a) requires courts to consider "the interest of justice," which "encompasses public interest factors aimed at systemic integrity and fairness," such as "docket congestion, interest in having local controversies decided at home, knowledge of applicable law, unfairness in burdening forum citizens with jury duty, and interest in avoiding unnecessary conflicts of law." *Jaffé v. LSI Corp.*, 874 F. Supp. 2d 499, 505 (E.D. Va. 2012) (internal quotations omitted).

Systemic integrity and fairness, like the previous factors, support transfer to the Northern District of Illinois. As discussed above, this suit has little to no significant connection to the Eastern District of Virginia, eliminating the need for the controversy to be decided within the district.

[1] The Court also notes the evidence presented by Defendants in their Reply to Plaintiffs' Opposition to Defendants' Motion, indicating that the Chief Scientific Officer may reside in Florida. Defs.' Reply to Pls.' Opp. to Defs.' Mot. to Dismiss or Transfer, ECF No. 46 at 10 n.3; Decl. of Herman H. Yue in Supp. of Defs.' Reply, ECF No. 47 at Ex. 31, 32.

Moreover, this Court has an interest in avoiding unnecessary conflicts of law, forum shopping, and docket congestion in this district. Plaintiffs acknowledge that their preference for the Eastern District of Virginia stems, at least in part, from their belief that "this district will generally provide a faster trial than AbbVie's requested forum." Pls.' Mem. in Opp. at 29. And most notably, there are already two pending suits between the parties regarding the same patents at issue here in the Northern District of Illinois, one of which has advanced beyond the motion to dismiss stage. Allowing this matter to progress in this district would surely foster unnecessary conflicts of law and require the parties to simultaneously litigate the same patents in multiple districts, which would be the ultimate inconvenience to the parties and witnesses. Therefore, in the interest of justice, this matter should be transferred to the Northern District of Illinois.

IV. CONCLUSION

For the reasons stated above, Defendants' Motion to Transfer is **GRANTED**. Accordingly, the Court **FINDS** Defendants' Motion to Dismiss **MOOT**.

It is **ORDERED** that this case be **TRANSFERRED** to the United States District Court for the Northern District of Illinois.

IT IS SO ORDERED.

Norfolk, Virginia
October 21, 2021

UNITED STATES DISTRICT JUDGE