UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

GENENTECH, INC. and HOFFMAN-LA ROCHE INC.,

Plaintiffs,

v.

SANDOZ, INC. and LEK PHARMACEUTICALS d.d.,

Defendants.

Civ. No. 23-4085 (JXN) (LDW)

OPINION AND ORDER DENYING TRANSFER

LEDA DUNN WETTRE, United States Magistrate Judge

Before the Court is a Motion to Transfer Venue to the United States District Court for the District of Delaware pursuant to 28 U.S.C. § 1404(a), filed by defendants Sandoz, Inc. ("Sandoz") and Lek Pharmaceuticals d.d.'s ("Lek") (collectively, "Sandoz"). (ECF Nos. 47, 51). Plaintiffs Genentech, Inc. ("Genentech") and Hoffman-La Roche Inc. ("HLR") (collectively, "Genentech") oppose the motion. (ECF No. 49). The Court held oral argument on January 12, 2024 and reserved decision. For the reasons set forth below, the motion is **DENIED**.

I. BACKGROUND

A. This Action

Plaintiffs bring this action under 35 U.S.C. § 271 for alleged infringement of United States Patent No. 10,188,637 (the "'637 Patent" or the "Patent"). (ECF No. 1 ("Compl.") ¶ 1). HLR owns the Patent, and Genentech exclusively licenses it. (*Id.* ¶ 16). The Patent claims a novel tablet formulation of pirfenidone, a drug used to treat idiopathic pulmonary fibrosis ("IPF"), a lung disease. (*Id.* ¶ 1 & Exh. 1). The Patent is one of twenty-one patents listed in the Food and Drug Administration's ("FDA") *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") for Genentech's product Esbriet®, a treatment for IPF. (*See id.* ¶ 1; Defs. Initial Moving Brief ("Def. Br."), ECF No. 47-25 at 6¹).

Genentech is the holder of approved New Drug Applications ("NDAs") for Esbriet® pirfenidone tablets of various strengths. (*See* Compl. ¶¶ 3, 13). Defendants filed and eventually obtained approval from the FDA of an Abbreviated New Drug Application ("ANDA") to sell generic pirfenidone tablets of strengths covered by Genentech's NDAs. In May 2022, after a Hatch Waxman Act trial between Genentech and Sandoz in the United States District Court for the District of Delaware, defendants began to sell their generic pirfenidone product. (*Id.* ¶ 20). Plaintiffs now claim that defendants' generic pirfenidone tablets infringe the '637 Patent, which does not expire until March 28, 2037, by using a formulation claimed by the Patent. (*Id.* ¶¶ 15, 44-56). They seek monetary damages for the alleged infringement under 35 U.S.C. §§ 284 and 285.

B. The Prior Delaware Action

The primary basis for the instant motion is the prior Hatch Waxman Act trial between these parties concerning defendants' ANDA, in which Sandoz prevailed in both the United States District Court for the District of Delaware and on appeal to the Federal Circuit. *See Genentech, Inc. v. Sandoz, Inc.*, 592 F. Supp. 3d 355 (D. Del.), *aff'd*, 55 F.4th 1368 (Fed Cir. 2022). In the Delaware action before the Honorable Richard J. Andrews, U.S.D.J., Genentech claimed Sandoz infringed the *other* twenty patents listed in the Orange Book for Esbriet®, omitting the '637 Patent at issue here from the action. Although both Genentech and Sandoz had the ability to bring the

¹ References to page numbers in the motion briefs are to the page number affixed by the filing party rather than the ECF pagination number in the header of the filed document.

'637 Patent into that suit in Delaware, neither opted to do so. (See ECF No. 55 (Oral Arg. Tr.) at 9:7 - 9:21, 10:5 - 10:14, 11:25 - 12:6).²

Of the twenty patents that were asserted in the action, only claims from six of the patents were actually presented at trial as a result of a pretrial claims-narrowing process. (*See* ECF No. 49 at 12). Those six patents fell into two groups: four Liver Function Test ("LFT") patents and two Drug Drug Interaction ("DDI") patents. *See Genentech, Inc.*, 592 F. Supp. 3d at 359-60. Both the LFT and DDI patent groups were method-of-treatment patents; none was a formulation patent like the '637 Patent. *See id*. No formulation patent was tried in the Delaware case, nor did Judge Andrews perform any claim construction on any formulation patent. Only a single term from three of the LFT Patents proceeded to a *Markman* decision. *See Genentech, Inc.*, *v. Aurobindo Pharma Ltd.*, No. 19-0078 (RGA), 2020 WL 6144696 (D. Del. Oct. 20, 2020).³

All parties acknowledged at oral argument that Genentech could have sued Sandoz on the '637 Patent before Sandoz provided its Paragraph IV certification asserting that the Patent was invalid or not infringed. (See id.). And Sandoz does not dispute Genentech's contention that it could have induced suit on the Patent earlier in the Delaware litigation by issuing its Paragraph IV certification shortly after the Patent was added to the Orange Book for Esbriet® in February 2019, nor that Sandoz itself could have filed a declaratory judgment claim of non-infringement or invalidity of the Patent. But Genentech did not assert the Patent in its case, and Sandoz waited almost two years after the Patent's inclusion in the Orange Book to provide a Paragraph IV certification as to it, asserting in December 2020 that it did not infringe the claims of the Patent because they were invalid. (Compl. ¶ 18-19). By that time, deadlines to amend pleadings in the case had passed, and claim construction and fact discovery had concluded. (ECF No. 49 at 14). Thus, bringing the Patent into the existing suit, if permitted, would likely have delayed trial, something neither side may have wanted. For these reasons, and in view of the sophistication of these parties and the high stakes of ANDA litigation, the Court infers the parties' decision not to put the '637 Patent in suit in the prior Delaware proceedings was a strategic decision on each side and no oversight.

³ The only apparent mention of the '637 Patent in the prior Delaware ANDA litigation was a reference to it in a stipulation and order of dismissal between Genentech and certain other defendants. (*See* ECF No. 47-25 at 8-9). Though Sandoz describes this Stipulation and Order as Genentech's having "brought the '637 patent into [the Delaware action]" (*id.* at 8), a more accurate description would be that the '637 Patent was mentioned in the stipulation as a patent that had not been part of the lawsuit but that was included in the dismissal order because it was an Orange Book-listed patent for Esbriet[®]. (*See* ECF No. 47-8 (Exh. 7 to Abraham Decl.)).

After a three-day bench trial before Judge Andrews, the District Court found that the LFT Patents were not infringed by Sandoz and that they were "invalid for obviousness over the Azuma Article, the Pirespa Label, and standard practice generally disclosed in the prior art." *Genentech, Inc.*, 592 F. Supp. 3d at 364-75. The District Court further held that the DDI patents were not infringed by Sandoz but rejected Sandoz's claims that those patents were invalid as obvious. *Id.* at 375-80. After trial, the District Court, over Genentech's objection, dismissed with prejudice Genentech's claims in the fourteen other patents in suit that had not been selected for trial. (ECF No. 47-16 (Exh. 15 to Abraham Decl.)).

Sandoz launched its generic pirfenidone tablets about two months after the District Court's March 2022 decision in its favor. (Compl. ¶ 20). In December 2022, the Federal Circuit affirmed the District Court's finding that the LFT patents were invalid as obvious (not reaching infringement) and that the DDI patents were not infringed. *See Genentech, Inc.*, 55 F.4th at 1368.

II. DISCUSSION

Defendants seek transfer of this action to Delaware, primarily on the grounds that judicial efficiency would be furthered by having Judge Andrews, who presided over the Delaware ANDA action, adjudicate this purportedly related action as well. While Judge Andrews certainly gained relevant background knowledge to this action by presiding over the prior case, a comparison of the two actions beyond the most superficial level reveals that the overlap between them is not sufficiently significant to warrant transfer under 28 U.S.C. § 1404, particularly where the other transfer factors are largely neutral.

A. Legal Standard

Pursuant to 28 U.S.C. § 1404(a), "[f]or the convenience of parties and witnesses, in the interest of justice, a district court may transfer any civil action to any other district or division where it might have been brought." 28 U.S.C. § 1404(a). "The ultimate decision of whether to

transfer a case lies within the sound discretion of the trial court." *Teva Pharms. USA, Inc. v. Sandoz Inc.,* No. 17-275 (FLW), 2017 WL 2269979, at *4 (D.N.J. May 23, 2017) (internal quotations omitted). As transfer is considered non-dispositive, it is within a Magistrate Judge's authority to decide. *See Azurity Pharmaceuticals, Inc. v. Novitium Pharma, LLC*, No. 22-5860 (ES) (ESK), 2023 WL 358538, at *3 (D.N.J. Jan. 20, 2023); *Lifecell Corp. v. Lifenet Health*, No. 15-6701 (CCC), 2016 WL 3545752, at *1 (D.N.J. June 28, 2016).

The Court must perform a two-part analysis to determine whether a transfer of venue is appropriate. *See Vanda Pharms. Inc. v. Teva Pharms. USA, Inc.*, No. 22-7528 (CCC), 2023 WL 1883357, at *2 (D.N.J. Feb. 10, 2023). First, the Court must analyze whether venue would be proper in the transferee district. *See Clark v. Burger King Corp.*, 255 F. Supp. 2d 334, 337 (D.N.J. 2003). If this first step is satisfied, then the Court "should determine whether a transfer would be in the interests of justice." *Id.* (citing *Jumara v. State Farm*, 55 F.3d 873, 879 (3d Cir. 1995)). Such an analysis requires the Court to engage in an "individualized, case-by-case consideration of convenience and fairness regarding which forum is most appropriate to consider the case." *Telebrands Corp. v. Mopnado*, No. 14-7969 (JAD), 2016 WL 368166, at *10 (D.N.J. Jan. 12, 2016) (internal quotations omitted).

Although this is a patent case subject to the exclusive appellate jurisdiction of the Federal Circuit, Third Circuit law applies to transfer issues that are not unique to patent law. *See Arendi S.A.R.L. v. LG Elecs. Inc.*, 47 F.4th 1380, 1384 (Fed. Cir. 2022). In *Jumara v. State Farm*, the Third Circuit explained that "while there is no definitive formula or list of the factors to consider" in adjudicating a transfer motion, courts should weigh certain private and public interests. 55 F.3d at 879. The private interests generally include: (1) "plaintiff's forum preference as manifested in the original choice"; (2) "the defendant's preference"; (3) "whether the claim arose elsewhere";

(4) "the convenience of the parties as indicated by their relative physical and financial condition"; (5) "the convenience of the witnesses—but only to the extent that the witnesses may actually be unavailable for trial in one of the fora"; and (6) "the location of books and records (similarly limited to the extent that the files could not be produced in the alternative forum)." *Id.* (citations omitted). As for the public factors, courts typically consider: (1) "the enforceability of the judgment"; (2) "practical considerations that could make the trial easy, expeditious, or inexpensive"; (3) "the relative administrative difficulty in the two fora resulting from court congestion"; (4) "the local interest in deciding local controversies at home"; (5) "the public policies of the fora"; and (6) "the familiarity of the trial judge with the applicable state law in diversity cases." *Id.* at 879-80 (citations omitted). This extensive list of factors, however, "is merely a guide, and not all the factors may be relevant or determinative in each case." *LG Elecs., Inc. v. First Int'l. Computer, Inc.*, 138 F. Supp. 2d 574, 587 (D.N.J. 2001).

It is the moving party's burden to show that that the proposed forum is "not only adequate, but also more convenient than the present forum." *Lawrence v. Xerox Corp.*, 56 F. Supp. 2d 442, 451 (D.N.J. 1999). "The burden to 'sho[w] that the balance of convenience factors and interests of justice weigh strongly in favor of transfer' lies with the Defendant. Thus, '[i]t follows that transfer will be denied if the factors are evenly balanced or weigh only slightly in favor of the transfer." *Eagle View Techs., Inc. v. GAF Materials, LLC*, 594 F. Supp. 3d 613, 619 (D.N.J. 2022) (internal quotations and citations omitted). *See also Deibler v. Basic Rsch., LLC*, No. 19-CV-20155 (NLH) (MJS), 2023 WL 6058866, at *4 (D.N.J. Sept. 18, 2023) ("The burden is on the movant to demonstrate that the balance of factors strongly favors transfer such that an even break or slight tilt toward transfer is insufficient."); *Armotek Indus., Inc. v. Emps. Ins. of Wausau*, No. 88-3110 (CSF), 1989 WL 21771, at *2 (D.N.J. Mar. 7, 1989) (same).

B. Application of the Transfer Factors

1. Whether Venue Is Proper in the Transferee Court

The Court first must make a threshold determination as to whether venue is proper in the proposed transferee court, the United States District Court for the District of Delaware. *See Anthony's LLC v. Babcock*, No. 11-6362 (MF), 2012 WL 5465376, at *3 (D.N.J. Nov. 8, 2012). In addition to being a proper venue, the transferee district must be "capable of asserting subject matter jurisdiction over the claims and in personam jurisdiction over the defendants." *Id.* at *4. *See also In re Genentech, Inc.*, 566 F.3d 1338, 1346 (Fed Cir. 2009) (transfer requires that "transferee court have jurisdiction over the defendants in the transferred complaint").

Genentech does not contest Sandoz's assertion that Delaware would have venue, subject matter jurisdiction, and personal jurisdiction to entertain this action. First, venue would be proper in this patent infringement suit because it is a "judicial district where the defendant resides, or where the defendant has committed acts of infringement and has a regular and established place of business." 28 U.S.C. § 1400(b). Sandoz is considered to reside in Delaware because it was incorporated there (ECF No. 47-25 (Def. Br.) at 15; *see T.C. Heartland LLC v. Kraft Foods Grp. Brands LLC*, 581 U.S. 258, 261-62 (2017)), and Lek is a foreign corporation that may be sued in any judicial district. (Compl. ¶¶ 28, 43; 28 U.S.C. § 1391(c)(3)). Second, the District of Delaware has federal question subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338. Finally, defendants concede there is personal jurisdiction over them in Delaware. (ECF 47-25 (Def. Br.) at 15-16). Therefore, the Court finds that venue is proper in the District of Delaware within the meaning of § 1404(a).

2. Private Interest Factors

Turning next to *Jumara*'s private interest factors, defendants concede that many of them are neutral. *See* ECF No. 47-25 (Def. Br.) at 26-35. However, the Court addresses each of the factors addressed in the parties' briefing for the sake of completeness. As none of the private interest factors below strongly favors transfer, and rather most are either neutral or disfavor transfer, the balance of the private interest factors does not weigh in favor of granting defendants' motion.

a. Plaintiffs' Forum Preference

"In the Third Circuit, a plaintiff's choice of forum is a 'paramount concern' in deciding a motion to transfer." *Wm. H. McGee & Co. v. United Arab Shipping Co.*, 6 F. Supp. 2d 283, 289 (D.N.J. 1997). This deference is enhanced when "a plaintiff chooses its home forum" but may be diminished when a "plaintiff has chosen a foreign forum." *Id.* at 290.

Sandoz argues plaintiffs' preference for this District is entitled to little weight. Sandoz bases this contention principally on Genentech's being a non-New Jersey plaintiff, as it is a Delaware corporation with a principal place of business in California, and its New Jersey-based co-plaintiff HLR purportedly having little stake in this case given that it has licensed the Patent to Genentech. Sandoz further maintains that Genentech's choice of forum is not entitled to deference because its choice of this District is a result of "forum shopping" to avoid the District of Delaware, where Genentech lost the prior ANDA litigation. The Court does not find these arguments persuasive.

First, HLR is a New Jersey plaintiff that filed in its home forum, and that choice is entitled to deference even if its co-plaintiff Genentech is not a New Jersey resident. To the extent that Sandoz portrays HLR as not being a "true plaintiff," this assertion is based on HLR's having exclusively licensed the Patent to Genentech and the further speculation that "HLR may have *assigned* the patents to Genentech for all intents and purposes, which would mean that its presence in the litigation is not necessary at all." (ECF No. 47-25 (Def. Br.) at 27 (emphasis in original)). But the facts of record at this stage of the action are that HLR is the owner of the Patent, that it has exclusively licensed the Patent to Genentech, and that it has sued in its home forum. Sandoz cites nothing to demonstrate that the licensing of the Patent to Genentech renders HLR an improper party plaintiff, and it provides no further information on the precise terms of the license to support its conjecture that HLR relinquished all rights to the Patent. Sandoz therefore fails to establish that HLR is not a necessary or proper plaintiff. *Cf. Lone Star Silicon Innovations LLC v. Nanya Tech. Corp.*, 925 F.3d 1225 (Fed Cir. 2019) (demonstrating nuanced analysis of terms of transfer of patent rights necessary to determine proper plaintiffs).

Second, Sandoz's argument that the choice of this District is a result of forum shopping, and thus should be discounted, is overstated. To be sure, Genentech fared poorly in the prior litigation in Delaware and likely would not relish a second round before Judge Andrews. But the prior Delaware lawsuit was fully concluded before this one was filed, such that Genentech was under no practical or legal imperative to file in Delaware to join an ongoing, related suit.

Nor in this Court's considered view can Genentech's decision to bring suit in this District rather than Delaware fairly be portrayed as anything more than a permissible strategic decision in high-stakes litigation, as opposed to the type of forum shopping section 1404(a) is designed to prevent. Sandoz posits that Genentech forum-shopped by holding back the Patent in the prior Delaware litigation in the hopes of trying its luck on it elsewhere if the results of the Delaware action were adverse, calling this action "a blatant second bite at the apple" after Genentech failed to assert it in the prior action, which it could have done "from its inception." (ECF No. 47-25

(Def. Br.) at 22-23; *see also id.* at 4-5, 10-11). But if Genentech did in fact pursue such a strategy, it was with Sandoz's acquiescence. Genentech did not put the Patent in suit in Delaware, as it could have. But neither did Sandoz take available steps to force Genentech's hand in that regard. (*See* n.2 *supra*). Sandoz did not file a Paragraph IV certification as to the '637 Patent until nearly two years after the Patent was listed in the Orange Book for Esbriet®, and by the time it did so, there was little incentive for Genentech to add it to the suit. The ongoing ANDA case was past fact discovery and well on its way toward trial, so adding the Patent to the suit would likely have delayed trial, something neither side likely wanted.⁴ Perhaps for the same reason, Sandoz did not avail itself of the right to file a separate declaratory judgment action on the '637 Patent in Delaware while the other ANDA litigation was still pending, something Genentech notes could have been done without contradiction from Sandoz. (ECF No. 49 at 2-3). Therefore, any alleged "holding back" of the Patent from suit in Delaware seems to have been the strategic choice of Sandoz and Genentech alike. This is not the type of unilateral forum manipulation that might diminish the deference due to plaintiffs' choice of forum.

The Court therefore concludes that this "paramount" factor of the plaintiffs' choice of forum weighs against transfer.

b. Defendants' Forum Preference

The private interest factors also consider a defendant's forum preference. *See Jumara*, 55 F. 3d at 879. However, "a defendant's bare preference for a particular forum does not usually get

⁴ While the FDA is stayed from approving an ANDA for 30 months during Hatch Waxman Act litigation, once the stay period elapses, the FDA may approve the ANDA, and the ANDA holder potentially may launch its product "at risk" (of an adverse infringement decision). *See In Re Niaspan Antitrust Litigation*, No. 13-MD-2460, 2018 WL 2363577, at *1 n.1 (E.D. Pa. May 24, 2018) (citing *FTC v. Actavis, Inc.*, 570 U.S. 136, 143 (2013)). This prospect incentivizes both NDA and ANDA holders to strive to obtain a final court decision well within the 30-month period, in order to avoid a preliminary injunction motion or prejudgment generic launch.

much weight in a transfer analysis." *Beychok v. Baffert*, No. 21-14112 (MEF) (CLW), 2024 WL 685551, at *9 (D.N.J. Feb. 20, 2024). Indeed, a defendant's choice of forum is typically "entitled to 'considerably less' weight than plaintiff's." *Conroy v. Pennsylvania Tpk. Comm'n*, No. 10-1234 (TFM) (RCM), 2011 WL 578779, at *2 (W.D. Pa. Jan. 19, 2011), *R&R adopted*, 2011 WL 549858 (W.D. Pa. Feb. 9, 2011). Instead, a Court is to weigh the reasons underlying a defendant's preference "to determine if they tip the 'balance' strongly in favor of transfer." *Affymetrix, Inc. v. Synteni, Inc.*, 28 F. Supp. 2d 192, 201 (D. Del. 1998). Accordingly, the analysis of the defendant's forum preference often "collapses into other portions of the *Jumara* analysis." *Id.* at 201.

Defendants, as evidenced by the instant motion, prefer to litigate in Delaware. In support of this position, they point out that Sandoz is a Delaware corporation. But it is also true that Sandoz is a New Jersey resident, as its principal place of business is in the Garden State. Given that there is little difference in convenience for Sandoz between Delaware and New Jersey, this factor tips only slightly in favor of transfer.

c. Where the Claims Arose

Defendants admit that this factor is either neutral or disfavors transfer. (ECF No. 47-25 (Def. Br.) at 29). This District employs the "center of gravity" test to determine where the operative facts arose in patent infringement suits. *See Teva*, 2017 WL 2269979, at *6. This inquiry "looks to the location of the product's development, testing, research and production, as well as where marketing decisions are made." *Id.* at *6 (internal quotations omitted). The center of gravity test is particularly apt for ANDA litigation when the accused product has typically not come to market; however, here, Sandoz's generic product has entered the market and thus the "sales approach" is also applicable. *See id.* at *6-*7. The sales approach instructs courts to consider patent claims to arise wherever the allegedly infringing products are sold. *See id.* at *6.

The Court finds that this factor disfavors transfer. Sandoz, because its principal place of business is in New Jersey, likely made at least some marketing and sales decisions regarding their generic pirfenidone product in this District. Moreover, even if the product was developed by Lek in Slovenia as defendants claim (ECF No. 47-25 (Def. Br.) at 30), it seems unlikely that this was done without any input from Sandoz, Lek's parent company. (*See* Compl. ¶ 28). Therefore, the Court concludes that while under the sales theory this factor is largely neutral, the center of gravity test instructs that this factor should weigh at least minimally against transfer.

d. Convenience of the Parties and Witnesses and the Location of Books and Records

The Court assesses these factors together. First, the Court finds that the convenience of the parties is largely neutral. As defendants correctly note, the two fora are close geographically, and neither party—both large pharmaceutical companies—will have difficulty litigating in either forum. (ECF No. 47-25 (Def. Br.) at 32). Moreover, Sandoz is at home in New Jersey and thus the forum is "at least as convenient as Delaware if not more convenient for the Defendants because the original venue is their home forum." *Indivior Inc. v. Dr. Reddy's Labs. S.A.*, No. 17-7106 (KM)(CLW), 2018 WL 4089031, at *7 (D.N.J. July 12, 2018), *R & R adopted*, 2018 WL 4089031 (D.N.J. Aug. 27, 2018). As plaintiffs chose New Jersey as their preferred forum, they can have no complaint as to its convenience.

Next, the Court finds that the convenience of potential witnesses is also neutral. This factor is only relevant "to the extent that the witnesses may actually be unavailable for trial in one of the fora." *Jumara*, 55 F.3d at 879-80. Movants identify no anticipated witness who will be unavailable in New Jersey but available in Delaware.

Finally, the location of books and records is also neutral. Sandoz admits that the parties will be able to produce all relevant records to this case in both fora. (ECF No. 47-25 (Def. Br.) at 33-34).

3. Public Interest Factors

Turning next to the *Jumara* public interest factors, defendants rely on the following factors in seeking transfer: (1) practical considerations that could make the trial more expeditious; (2) court congestion; and (3) New Jersey's lack of a local interest in deciding the dispute. Because the balance of the private interests do not tip in favor of transfer, transfer depends on whether at least one of these public interest factors, or a combination of them, strongly favors transfer. The Court finds that none of the factors does, as set forth below.

a. Practical Considerations

Both parties acknowledge, and the Court agrees, that the instant motion principally hinges on the second public interest factor: "practical considerations that could make the trial easy, expeditious, or inexpensive." *Jumara*, 55 F.3d at 879. This factor focuses on whether transfer would promote judicial economy. *See, e.g., In re Eli Lilly & Co.*, 541 F. App'x 993, 994 (Fed Cir. 2013); *Vanda Pharms. Inc. v. Teva Pharms. USA, Inc.*, No. 22-7528 (CCC), 2023 WL 1883357, at *6 (D.N.J. Feb. 10, 2023); *Bayer Pharma AG v. Watson Labs., Inc.*, No. 14-1804 (JLL) (JAD), 2014 WL 2516412, at *8-*9 (D.N.J. June 2, 2014).

Because there is no pending, related litigation in Delaware, there is no efficiency to be gained by transfer with respect to consolidating or coordinating this case with another action. *Cf. Bayer Pharma AG*, 2014 WL 2516412 (granting transfer where claims could be joined to ongoing ANDA case in transferee district); *Azurity Pharms., Inc.*, 2023 WL 358538 (same). Therefore, whether practical considerations favor transfer turns largely upon the knowledge gained by Judge

Andrews in the prior Delaware action that would make his learning curve significantly less steep in this action than that of the assigned District Judge here, rendering litigation of this case in Delaware more expeditious, more efficient, and less expensive.⁵ *See Vanda Pharms.*, 2023 WL 1883357, at *6 ("[T]he Federal Circuit has made clear that a court's familiarity with related patents and facts from prior litigation – separate and apart from efficiencies gained by consolidation with pending litigation – is a valid factor for purposes of a motion to transfer."). A comparison of the issues to be adjudicated in this action to those of the prior Delaware action indicates, however, that there would be no significant judicial efficiency gained by transfer.

The Court recognizes that Judge Andrews would have acquired general knowledge at the previous trial on certain subjects that may arise in this case. He would have learned, for instance, about Genentech's Esbriet® product and Sandoz's proposed generic pirfenidone product as described in its ANDA. And he did hear Genentech, in arguing against dismissal with prejudice of the twenty other Orange Book patents asserted in the Delaware case, downplay as "far-fetched" that it would revive those patents in a second action (ECF No. 47-15 (Exh. 14 to Abraham Decl., Exh. C, at 35-36)) and make other statements regarding damages that Sandoz will portray as inconsistent with Genentech's damages contentions here.

While this general knowledge would give Judge Andrews a head-start that would result in some judicial economy if this case were transferred to him, there are important differences between

⁵ Defendants' arguments depend entirely on the presumption that this action, if transferred, would be assigned to Judge Andrews as "related" to the prior ANDA litigation. But the District of Delaware's Local Rule concerning assignment of related cases, D. Del. LR 3.1(b), make this merely a possibility, not a *fait accompli*, because whether the two actions are related within the meaning of the Local Rule will depend on the Delaware court's application in its discretion of the prescribed multi-factor test. Moreover, the Court takes judicial notice that Judge Andrews recently assumed senior status and thus presumably would have greater discretion to determine which cases to accept as part of his docket.

this case and the prior action that would render that lead insubstantial. As shown by his published trial opinion, the focus of Judge Andrews' bench trial was the particular six patents that were tried before him, the prior art related to those patents, and the secondary considerations of non-obviousness with an alleged nexus to those patents. *See Genentech, Inc.*, 592 F. Supp. 3d 355. That focus contrasts starkly with what is at issue in this case.

As an initial matter, the Patent here is completely unrelated to the patents tried by Judge Andrews. While the Patent in this action is a formulation patent, the patents on which Judge Andrews held a *Markman* hearing and that he considered at trial were all method-of-treatment patents. The Patent in this case claims the use of glidants that "improve[] the flow properties of the granulate formulation during the manufacturing process and allows for the preparation of more patient friendly pirfenidone tablets." (ECF No. 49 at 4). In contrast, the LFT patents at issue in the Delaware trial "are directed to methods for administering pirfenidone to a patient who has exhibited abnormal biomarkers of liver function in response to pirfenidone administration." *Genentech, Inc.*, 55 F.4th at 1371. And the DDI patents tried in Delaware "are directed to methods for avoiding adverse interactions between pirfenidone and fluvoxamine" in a patient. *Id.* at 1374. Sandoz admits that none of the patents tried in Delaware are in the same "family" as the Patent here or even related. (ECF No. 55 (Oral Arg. Tr.) at 23, 24).

Instead, Sandoz asserts that the Patent is similar to a formulation patent that was initially asserted in Delaware, the '150 Patent. (ECF No. 51 (Def. Reply Br.) at 3-5). The '150 Patent was one of four formulation patents that Genentech asserted in the Delaware litigation, but as part of the pretrial claims-narrowing process in that action, they were dropped from active litigation early in fact discovery and prior to claim construction, and thus neither was construed by nor proceeded to trial before Judge Andrews. (ECF No. 49 at 12; ECF No. 55 (Oral Arg. Tr.) at 25). Thus, Judge

Andrews would have had no reason to learn about any of the formulation patents initially asserted in the prior case, including the '150 Patent. He would therefore not have begun to ascend the learning curve in understanding the formulation patent at issue in this case.

Moreover, in analyzing at trial whether the LFT and DDI Patents were invalid as obvious, Judge Andrews was presented with prior art that would seem to be irrelevant to the '637 Patent. That prior art, as described in Judge Andrews' bench opinion, had nothing to do with formulation. Instead, the prior art on the LFT patents and DDI patents concerned methods-of-treatment with pirfenidone. *See Genentech, Inc.*, 592 F. Supp. 3d at 368-75, 378-81. Therefore, as argued by Genentech (ECF No. 49 at 13), there is no indication – or even assertion – that this action may present any of the same prior art in the likely event Sandoz asserts that the Patent is invalid as obvious over the prior art.

Sandoz further argues that Judge Andrews heard evidence concerning secondary considerations of non-obviousness (pirfenidone's arduous road to approval, the long felt need for treatments for IPF, and continued skepticism about pirfenidone's safety and efficacy) that would contribute to judicial efficiency upon transfer. (ECF No. 51 (Def. Reply Br.) at 5). The Court views as unlikely, however, that evidence of secondary considerations will necessarily be the same here as that presented in Delaware. This is because secondary considerations require a nexus to the claims in the patent at issue, "*i.e.*, there must be a 'legally and factually sufficient connection' between the evidence and the patented invention." *Henny Penny Corp. v. Frymaster LLC*, 938 F.3d 1324, 1332 (Fed Cir. 2019) (citation omitted). But as set forth above, the patents tried in Delaware are unrelated to the Patent in suit here, making it unlikely the relevant secondary considerations evidence would be the same as the evidence presented in the prior action.

A further distinction between the present and prior case is that this action has a claim for monetary damages, whereas no actual damages – just the prospect of damages, as related to an application for injunctive relief - were at issue in Judge Andrews' case. While defendants argue that Genentech's representations in the motion papers seeking an injunction pending appeal in Delaware about threats to its loss of market share from approval of Sandoz's ANDA will undercut damages arguments Genentech makes here, any prior, inconsistent representations to the Delaware court are of record and as such can be used here. (See, e.g., ECF No. 47-2 (Exh. 1 to Abraham Decl., at 12); ECF 47-18, (Exh. 17 to Abraham Decl, at 7)). In any event, the damages case here plainly will go far beyond the arguments about prospective loss that Judge Andrews considered in the injunction motion. For example, Genentech claims that the market for its branded product, which Sandoz asserts sold for \$100,000 per patient per year (ECF No. 47-25 (Def. Br.) at 1), has been "eviscerated" by generic competition as a result of Sandoz's alleged infringement. (Compl. ¶ 21). Accordingly, adjudication of the quantum and cause of those alleged damages will present a much broader and deeper examination of harm than the Delaware court was required to assess on the injunction motion. Thus, Judge Andrews will not have much of a leg up on the damages phase of this case by virtue of deciding that injunction motion.

To the extent that Sandoz further argues that claim preclusion issues in this case will invoke Judge Andrews' existing knowledge, the Court disagrees. Sandoz argues that Genentech's claims of infringement of the Patent are *res judicata* because substantially similar claims in the '150 Patent were dismissed with prejudice by the Delaware court. (ECF No. 51 (Def. Reply Br.) at 3-5; ECF No. 48). To determine whether there is claim preclusion, the Court will need to ascertain whether the scope of the Patent's claims is substantially similar to that of the claims in the dismissed '150 Patent. *See XY, LLC v. Trans Ova Genetics, LC*, 968 F.3d 1323, 1333 (Fed. Cir.

2020). But as set forth above, Judge Andrews gained no knowledge of the '150 Patent in the prior action because it was not the subject of claim construction nor one of the patents that proceeded to trial. Therefore, there is no apparent judicial economy in having the Delaware court adjudicate the claim preclusion issue. Both courts would need to start from scratch in deciding it.

For all of these reasons, the Court views any judicial economy to be gained by transfer as minimal. To the extent both sides cite extensively to other transfer cases as supporting their respective positions, none is exactly on point given each transfer motion turns on its own unique facts. However, a common thread runs through this practical considerations factor in other patent cases, which is that courts tend to grant transfer where there are closely related patents that have been or will be tried in the transferee forum, and they tend to deny transfer where the patents are distinct. Compare cases finding transfer warranted: In re Eli Lilly & Co., 541 F. App'x at 994; Vanda Pharms. Inc., 2023 WL 1883357, at *1, *3, *6; Azurity Pharmaceuticals, Inc., 2023 WL 358538, at *1-*5; Lifecell Corp. v. Lifenet Health, No. 15-6701 (CCC)(MF), 2016 WL 544489 (D.N.J. Feb. 9, 2016), aff'd, 2016 WL 3545752 (D.N.J. June 28, 2016); with cases finding transfer unwarranted: Indivior Inc., 2018 WL 4089031, at *3, *6; Teva Pharmaceutical Ind. Ltd. v. AstraZeneca Pharmaceuticals LP, No. 08-4786, 2009 WL 2616816, at *6-*7 (E.D. Pa. Aug. 24, 2009). But see Bayer Pharma AG, 2014 WL 2516412 (granting transfer despite different patents at issue in transferor and transferee courts because claims on additional patents could be consolidated into ongoing ANDA case in transferee court).

The Court thus finds that practical considerations, on balance, weigh only slightly in favor of transfer.

b. Court Congestion

With respect to "the relative administrative difficulty in the two fora resulting from court congestion," *Jumara*, 55 F.3d at 879-80, the Court finds that this factor is neutral. "The Third Circuit considers whether there is an 'appreciable difference in docket congestion' between the two fora and whether there is a disparity in the qualifications of federal judges sitting in the two dockets." *Indivior*, *Inc.*, 2018 WL 4921541, at *6. Both parties cite statistics that they purport weigh in favor of or against transfer. Defendants claim that trial will likely occur sooner in Delaware because it takes a case, on average, 36.7 months from filing to trial, compared to New Jersey where it takes 56.5 months from filing to trial. (ECF No. 47-25 (Def. Br.) at 25). Plaintiffs rebuff this argument by recounting the time it takes for *patent* actions to reach trial in each District, which are nearly equivalent: 45 months in Delaware compared to 41 months in New Jersey. (ECF No. 49 at 28). As these more on-point statistics do not indicate an "appreciable difference" in court congestion, and given that judges in both Districts are well-versed in pharmaceutical patent litigation given the prevalence of these cases in both Delaware and New Jersey, the Court finds this factor to be neutral.

c. New Jersey's Interest in Deciding the Dispute

Pharmaceutical patent cases are "matters of national concern that are not local controversies, nor do they implicate the public policies of any one forum." *Azurity*, 2023 WL 358538, at *4 (internal quotations and citations omitted). Accordingly, this District does not have a particular local interest in deciding this dispute but neither does the District of Delaware. *See Teva Pharms. USA, Inc.*, 2017 WL 2269979, at *8. The Court, therefore, finds that this factor is neutral.

III. CONCLUSION

The Court concludes that defendants have not met their burden to demonstrate that the *Jumara* factors weigh in favor of transfer. Accordingly, defendants' Motion to Transfer (ECF No. 47) is **DENIED**. The Clerk of the Court is directed to terminate the motion at ECF No. 47. **It is SO ORDERED**.

Dated: March 5, 2024

<u>s/Leda Dunn Wettre</u> Hon. Leda Dunn Wettre United States Magistrate Judge