IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVARTIS PHARMACEUTICALS CORPORATION,	:	
Plaintiff,	:	
v.	:	C.A. No. 21-645-LPS
HANDA NEUROSCIENCE, LLC, HANDA PHARMACEUTICALS, INC., HANDA PHARMA, INC., and HANDA PHARMACEUTICALS, LLC,	:	
Defendants.	:	

Daniel M. Silver and Alexandra M. Joyce, McCARTER & ENGLISH, LLP, Wilmington, Delaware

Jane M. Love, Ph.D. and Robert W. Trenchard, GIBSON, DUNN & CRUTCHER LLP, New York, New York

Andrew P. Blythe, GIBSON, DUNN & CRUTCHER LLP, Los Angeles, California

Christine L. Ranney, GIBSON, DUNN & CRUTCHER LLP, Denver, Colorado

Attorneys for Plaintiff

John C. Phillips, Jr. and David A. Bilson, PHILLIPS McLAUGHLIN & HALL, P.A., Wilmington, Delaware

Don J. Mizerk, HUSCH BLACKWELL LLP, Chicago, Illinois

Dustin L. Taylor, HUSCH BLACKWELL LLP, Denver, Colorado

Attorneys for Defendants

MEMORANDUM OPINION

March 1, 2022
Wilmington, Delaware

STARK, U.S. District Judge:

Pending before the Court is a motion to dismiss and/or transfer filed by Defendants Handa Pharmaceuticals, Inc. ("Pharmaceuticals, Inc."), Handa Pharma, Inc. ("Pharma, Inc."), Handa Pharmaceuticals, LLC ("Pharmaceuticals, LLC"), and Handa Neuroscience, LLC ("Neuroscience" and, together with Pharmaceuticals, Inc., Pharma, Inc., and Pharmaceuticals, LLC "Defendants") (D.I. 9). Defendants move to dismiss the claims brought by Plaintiff Novartis Pharmaceuticals Corporation ("Novartis" or "Plaintiff") against Pharmaceuticals, Inc., Pharma, Inc., and Pharmaceuticals, LLC pursuant to Federal Rule of Civil Procedure 12(b)(6), and to dismiss the claims against Neuroscience under Federal Rule of Civil Procedure 12(b)(3). (*Id.*) Alternatively, Defendants request that the Court transfer this matter in full to the Northern District of California under 28 U.S.C. §§ 1404(a) and 1406(a). (*Id.*)

The parties submitted briefing (*see* D.I. 10, 16, 27) and accompanying exhibits, as well as letters regarding supplemental authority and subsequent developments (*see* D.I. 35-37, 39-40, 42-43, 45-46). The Court held a teleconference on January 24, 2022 to hear argument from the parties. (D.I. 44) ("Tr.")

Having considered the parties' filings and arguments, and for the reasons stated below, the Court will deny with prejudice Defendants' motion as it pertains to the claims against Pharmaceuticals, Inc., Pharma, Inc., and Pharmaceuticals, LLC, as well as Defendants' request to transfer this case. It will deny Defendants' motion as it pertains to the claims against Neuroscience ***without*** prejudice to renew upon completion of venue-related discovery.

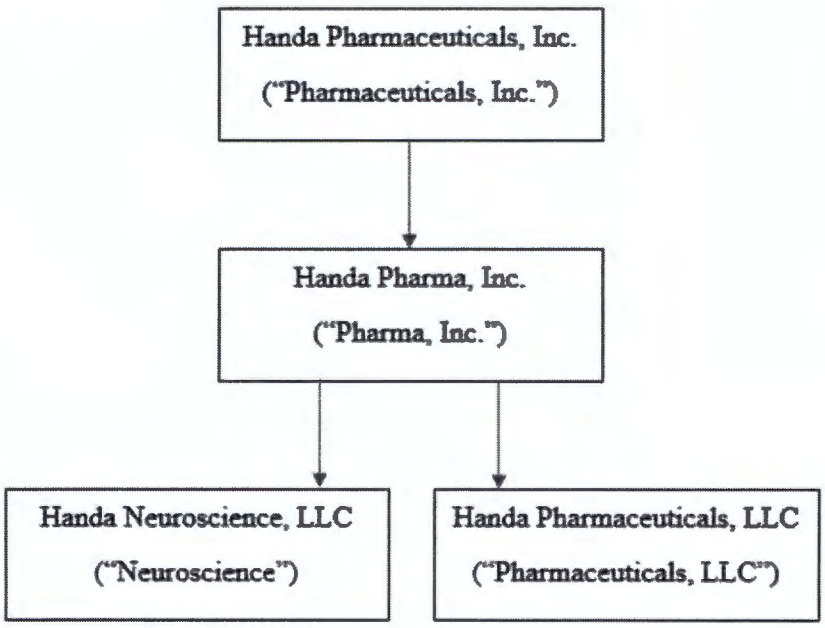
I. BACKGROUND

This case arises out of Neuroscience's submission to the U.S. Food and Drug Administration ("FDA") of NDA No. 214962 ("NDA"), which seeks to market a version of

GILENYA®, Novartis' medicine for treating relapsing forms of multiple sclerosis. (D.I. 1 ¶¶ 1, 7, 37) On May 4, 2021, Novartis filed suit under the Hatch-Waxman and Declaratory Judgment Acts to enforce two patents covering GILENYA®: U.S. Patent Nos. 9,187,405 (the "'405 patent") and 10,543,179 (the "'179 patent"). (*Id.* ¶ 1) Two days later, Plaintiff filed a "safety suit" in the Northern District of California, asserting the same two patents against the same four Defendants, purportedly to protect the Hatch-Waxman automatic 30-month stay of FDA approval of Defendants' proposed drug product, regardless of the resolution of any venue dispute here in Delaware, which is Novartis' preferred District. *See Novartis Pharms. Corp. v. Handa Neuroscience, LLC*, C.A. No. 5:21-03397 (N.D. Cal.).

Novartis is a Delaware corporation with its principal place of business in East Hanover, New Jersey. (D.I. 1 ¶ 2)

To understand the relationships among the Defendants, the various Handa entities, the following diagram, recreated from Defendants' opening brief (*see* D.I. 10 at 3; *see also* D.I. 20-1 Ex. 33 at 84), is helpful:



Pharmaceuticals, Inc., the parent company of the other three Defendants, is a Taiwanese corporation with its principal place of business in Taiwan. (*Id.* ¶ 3) Pharma, Inc. and Pharmaceuticals, LLC are Delaware companies, while Neuroscience is a California company. (*Id.* ¶¶ 4-6) All three subsidiaries have their principal place of business in San Jose, California, where they share an office. (*Id.* ¶¶ 4-6, 13)

Pharmaceuticals, LLC was founded in 2005 by Dr. Fangyu Liu. (*See* D.I. 16 at 3) In 2016, Pharmaceuticals, LLC joined with a Taiwanese company to bring Handa public. (*See id.*) That parent company is Pharmaceuticals, Inc.; at the time, Pharmaceuticals, LLC became a U.S. subsidiary. (*See id.*) Today, Pharmaceuticals, Inc. is Handa's headquarters and global research and development center, and Pharmaceuticals, LLC leads Handa's generics business. (D.I. 1 ¶ 12)

Both Neuroscience and Pharma, Inc. were created in July 2020. (*Id.* ¶ 19; D.I. 16 at 5) Defendants assert that Neuroscience is responsible for Handa's new central nervous system drug products (*see* D.I. 10 at 3), but Novartis alleges Neuroscience is "an empty shell with no approved products, no revenue, no employees, and no money" (D.I. 16 at 5). Defendants contend that Pharma, Inc. is a "mere holding company for the U.S. subsidiaries" (D.I. 10 at 2), but Plaintiff alleges "Pharma, Inc. is responsible for business development, intellectual property, and regulatory affairs" of Handa (D.I. 1 ¶ 12).

In August 2020, Pharmaceuticals, LLC transferred the NDA and related rights to Neuroscience. (*See* D.I. 16 at 5; D.I. 10 at 3) A securities filing from the same month, however, states that the parent company (Pharmaceuticals, Inc.) "still has substantial control over the product development progress and future benefits." (D.I. 20-1 Ex. 34) While Defendants contend that Neuroscience bought the NDA from Pharmaceuticals, LLC for fair market value

(D.I. 10-1 Ex. 1 ("Cary Decl.") ¶ 7), Novartis argues the transfer involved no money (*see* D.I. 16 at 5). On December 18, 2020, Neuroscience submitted the NDA to FDA, where it remains under review. (D.I. 1 ¶ 21; Cary Decl. ¶¶ 11-12)

Novartis alleges that all four Defendants "acted collaboratively in the preparation and submission of" Handa's application, and further that all four "will work in concert with one another to make, use, offer to sell, and/or sell" Handa's proposed product. (D.I. 1 ¶ 10) Novartis notes, for example, that Pharmaceuticals, LLC corresponded with FDA in advance of submitting the application and contracted with third parties to prepare test batches of the product and to conduct stability and other tests to be included as part of the application. (*See* D.I. 16 at 3) Additionally, Pharmaceuticals, LLC is listed at various points in the NDA as the "applicant." (*Id.* at 6) Novartis also contends that Defendants are under common control, noting that Dr. Liu serves the Handa constituent companies in all the following capacities: "President" and "Chairman of the Board of Directors" of Pharmaceuticals, Inc.; "the President" of Pharma, Inc.; "the Manager" of Pharmaceuticals, LLC; "the CEO and agent for the service of process" for Neuroscience; and the named inventor on patents purportedly covering Handa's product. (D.I. 1 ¶¶ 14-16)

Defendants seek dismissal of the claims against Pharmaceuticals, Inc., Pharma, Inc., and Pharmaceuticals, LLC, arguing none of these entities is a "submitter" of the NDA at issue. They also seek to dismiss the claims against Neuroscience on the ground that venue is improper in this District with respect to Neuroscience. Alternatively, Defendants urge the Court to transfer this case to the Northern District of California, where the parties have agreed venue is proper.

II. LEGAL STANDARDS

A. Motion To Dismiss Pursuant To Rule 12(b)(6)

Evaluating a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6) requires the Court to accept as true all material allegations of the complaint. *See Spruill v. Gillis*, 372 F.3d 218, 223 (3d Cir. 2004). "The issue is not whether a plaintiff will ultimately prevail but whether the claimant is entitled to offer evidence to support the claims." *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1420 (3d Cir. 1997) (internal quotation marks omitted). Thus, the Court may grant such a motion to dismiss only if, after "accepting all well-pleaded allegations in the complaint as true, and viewing them in the light most favorable to plaintiff, plaintiff is not entitled to relief." *Maio v. Aetna, Inc.*, 221 F.3d 472, 481-82 (3d Cir. 2000) (internal quotation marks omitted).

The Court, however, is not obligated to accept as true "bald assertions," *Morse v. Lower Merion Sch. Dist.*, 132 F.3d 902, 906 (3d Cir. 1997) (internal quotation marks omitted), "unsupported conclusions and unwarranted inferences," *Schuylkill Energy Res., Inc. v. Pa. Power & Light Co.*, 113 F.3d 405, 417 (3d Cir. 1997), or allegations that are "self-evidently false," *Nami v. Fauver*, 82 F.3d 63, 69 (3d Cir. 1996).

B. Motion To Dismiss Pursuant To Rule 12(b)(3)

Generally, "venue provisions are designed, not to keep suits out of the federal courts, but merely to allocate suits to the most appropriate or convenient federal forum." *Brunette Mach. Works, Ltd. v. Kockum Indus., Inc.*, 406 U.S. 706, 710 (1972). A party believing it has been sued in an improper federal venue may move to dismiss or transfer venue under Rule 12(b)(3). *See also* 28 U.S.C. § 1406(a) (stating that court granting Rule 12(b)(3) motion based on improper venue "shall dismiss, or if it be in the interest of justice, transfer such case to any district or

division in which it could have been brought"). When such a motion is filed, the Court must determine whether venue is proper in accordance with the applicable statutes. *See Albright v. W.L. Gore & Assocs., Inc.*, 2002 WL 1765340, at *3 (D. Del. July 31, 2002).

In a patent infringement action, venue is governed solely and exclusively by the patent venue statute, 28 U.S.C. § 1400(b). *See TC Heartland LLC v. Kraft Foods Grp. Brands LLC*, 137 S. Ct. 1514, 1516 (2017). Section 1400(b) provides that a patent infringement action may be brought only "in the judicial district where the defendant resides, or where the defendant has committed acts of infringement and has a regular and established place of business."

Generally, "it is not necessary for the plaintiff to include allegations in his complaint showing that venue is proper." *Great W. Mining & Min. Co. v. ADR Options, Inc.*, 434 F. App'x 83, 86-87 (3d Cir. 2011). However, "upon motion by the Defendant challenging venue in a patent case, the Plaintiff bears the burden of establishing proper venue." *In re ZTE (USA) Inc.*, 890 F.3d 1008, 1013 (Fed. Cir. 2018). The Court will accept any venue-related allegations in the complaint as true unless they are contradicted by the defendant's evidence. *See Bockman v. First Am. Mktg. Corp.*, 459 F. App'x 157, 158 n.1 (3d Cir. 2012); *In re First Solar, Inc. Derivative Litig.*, 2013 WL 817132, at *2 (D. Del. Mar. 4, 2013). In addition, the Court may consider affidavits submitted by the plaintiff. *See Bockman*, 459 F. App'x at 161.

C. Motion To Transfer

Pursuant to 28 U.S.C. § 1404(a), a district court may transfer any civil action to any other district where the action might have been brought, for the convenience of the parties and witnesses and in the interests of justice. Congress intended through Section 1404 to place discretion in the district court to adjudicate motions to transfer according to an individualized, case-by-case consideration of convenience and the interests of justice. *See Stewart Org. v. Ricoh*

Corp., 487 U.S. 22, 29 (1988); *Affymetrix, Inc. v. Synteni, Inc.*, 28 F. Supp. 2d 192, 208 (D. Del. 1998).

Unless the balance of convenience ***strongly*** favors transfer, the plaintiff's choice of forum should prevail. *See Shutte v. Armco Steel Corp.*, 431 F.2d 22, 25 (3d Cir. 1970). Thus, "a transfer is not to be liberally granted." *Id.* (internal quotation marks omitted). The deference afforded a plaintiff's choice of forum will ordinarily apply as long as a plaintiff has selected the forum for some legitimate reason. *See, e.g., Medtronic, Inc. v. Boston Sci. Corp.*, 587 F. Supp. 2d 648, 654 (D. Del. 2008); *Cypress Semiconductor Corp. v. Integrated Cir. Sys., Inc.*, 2001 WL 1617186, at *2 (D. Del. Nov. 28, 2001). It follows that "transfer will be denied if the factors are evenly balanced or weigh only slightly in favor of the transfer." *Angiodynamics, Inc. v. Vascular Sols., Inc.*, 2010 WL 3037478, at *2 (D. Del. July 30, 2010) (internal citations omitted).

Although "there is no definitive formula or list of the factors to consider" in assessing whether to transfer, typically a series of private and public interests are evaluated. *See Jumara v. State Farm Ins. Co.*, 55 F.3d 873, 879 (3d Cir. 1995). The private interests include: (1) plaintiff's forum preference as manifested in the original choice; (2) 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 they 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). *See id.* The public interests include: (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. *See id.* at 879-80.

III. DISCUSSION

As an initial matter, as the Court noted at the hearing (*see* Tr. at 15-16), Plaintiff's motion for leave to file a sur-reply brief in support of its opposition to Defendants' motion (*see* D.I. 29) is granted. The Court reiterates that having the parties' arguments on the issues raised by Plaintiff's motion is far more helpful in this case than would be striking the sur-reply brief. (*See* Tr. at 16) Accordingly, the Court has considered the parties' filings and arguments relating to that motion (*see* D.I. 29-1) in addressing Defendants' motion.

A. Defendants' "Submitter" Status

Defendants Pharmaceuticals, Inc., Pharma, Inc., and Pharmaceuticals, LLC seek dismissal of the claims against them because, they contend, none of these entities is a "submitter" of the NDA at issue, as that term is used in 35 U.S.C. § 271(e)(2)(A).

Section 271(e)(2)(A) makes it an act of infringement to "submit" an application "if the purpose of such submission is to . . . engage in the commercial manufacture, use, or sale" of the generic drug. An entity who "submits" an NDA has committed an "act of infringement" and is a proper defendant in a Hatch-Waxman patent lawsuit. *See Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990).

It is undisputed that Neuroscience, and not any of the other three Defendants, signed and physically submitted the NDA. (*See* Tr. at 19) An entity, however, need not sign, prepare, or file an NDA to be a "submitter." *See Helsinn Healthcare S.A. v. Hospira, Inc.*, 2016 WL 1338601, at *7 (D.N.J. Apr. 5, 2016). Rather, an entity may also "submit" an NDA if it participates in the preparation of the NDA and stands to benefit from the FDA's approval of the

application. *See Celgene Corp. v. Mylan Pharms. Inc.*, 17 F.4th 1111, 1129 (Fed. Cir. 2021) (citing *In re Rosuvastatin Calcium Patent Litig.*, 703 F.3d 511 (Fed. Cir. 2012)); *see also Adverio Pharma GmbH v. Alembic Pharms. Ltd.*, 2019 WL 581618, at *4-5 (D. Del. Feb. 13, 2019).

Novartis alleges that all four Defendants "acted collaboratively in the preparation and submission of" the NDA and "will work in concert with one another to make, use, offer to sell, and/or sell" Neuroscience's proposed product. (D.I. 1 ¶ 10) Defendants describe these allegations as "conclusory" and similar to the allegations found insufficient by this Court in *Adverio*, 2019 WL 581618, at *6, and by the Federal Circuit in *Celgene*, 17 F.4th at 1129. (*See* D.I. 10 at 6; Tr. at 22) In the Court's view, however, Novartis has not simply (and insufficiently) stated legal conclusions as to the defendants as a group; rather, it has pled facts demonstrating a plausible inference of liability as to ***each*** of the defendants. (*See* Tr. at 51) (Novartis explaining that, while Complaint contains some "group pleadings," those follow from other allegations specific to each Defendant)

For example, as to Pharmaceuticals, Inc., Novartis highlights an August 2020 securities filing[1] stating that, despite the transfer of the NDA from Pharmaceuticals, LLC to Neuroscience, the parent company, Pharmaceuticals, Inc., "still has substantial control over the product development progress and future benefits." (D.I. 20-1 Ex. 34) Defendants concede that Pharmaceuticals, Inc. is Handa's global research and development center, adding to the plausibility of Novartis' contention that Pharmaceuticals, Inc. played a significant role in

[1] Although this securities filing is not attached to the Complaint, the Court may take judicial notice of it. *See In re NAHC, Inc. Sec. Litig.*, 306 F.3d 1314, 1331 (3d Cir. 2002). Defendants do not appear to dispute the Court's ability to do so. (*See* Tr. at 32, 42)

research and development relating to the NDA. (*See* D.I. 1 ¶ 12) In particular, Novartis alleges that Pharmaceuticals, Inc. manufactured a pilot batch of the NDA product in 2018. (*Id.* ¶ 17)

As to Pharma, Inc., Plaintiff argues that Handa's pursuit of its NDA product has required all of Pharma, Inc.'s functions, which are – as alleged in the Complaint – "business development, intellectual property, and regulatory affairs" (*id.* ¶ 12). (*See* Tr. at 59) Moreover, Novartis alleges that, in submitting the NDA, Neuroscience "acted as an agent for and at the direction and control of . . . Pharmaceuticals, Inc., including through its other agent[] Handa Pharma, Inc. [i.e., Pharma, Inc.]." (D.I. 1 ¶ 22) Relatedly, Novartis asserts that the disclosure in the securities filing describing Pharmaceuticals, Inc.'s "substantial control" (D.I. 20-1 Ex. 34) over Handa's NDA product implicates Pharma, Inc., too, as Pharma, Inc. is "the intermediary necessary to exert 'substantial control'" (D.I. 16 at 11-12; *see* Tr. at 41).

As to Pharmaceuticals, LLC, Novartis alleges it is responsible for Handa's generics business (D.I. 1 ¶ 12), that it corresponded with the FDA before the NDA was submitted, and that it was listed at various times in the NDA as the "applicant" (*see* D.I. 16 at 3, 6). Novartis also claims that Neuroscience acquired the NDA on credit and suggests Pharmaceuticals, LLC will not get paid until sales of the NDA product begin. (*See id.* at 12) Moreover, Novartis asserts that both Pharmaceuticals, LLC and Pharmaceuticals, Inc. contracted with third parties for test batches of the product and to conduct various tests to be included as part of the NDA. (*See id.* at 3) Finally, Plaintiff points to financial statements stating that the Handa Group is "essentially a continuation of the legal subsidiary Handa Pharmaceuticals, LLC [i.e., Pharmaceuticals, LLC]." (*Id.* at 12) (citing, e.g., D.I. 20-1 Ex. 31 at 68, Ex. 32 at 70, Ex. 33 at 65)

Additionally, while insufficient on its own to confer "submitter" status to the three Defendants pressing this portion of the motion, there is ample evidence that they are all part of the same corporate family as Neuroscience. For example, Novartis points to common control of Defendants by Dr. Liu as well as the subsidiaries' shared office. *See Cephalon, Inc. v. Watson Pharms., Inc.*, 629 F. Supp. 2d 338, 349 (D. Del. 2009) ("Parties 'actively involved' in preparing the ANDA are deemed to have 'submit[ted]' the ANDA, regardless of whether they are the named applicant; this is especially true where the parties involved are in the same corporate family."); *see also Otsuka Pharm. Co. v. Hetero USA, Inc.*, 2020 WL 6822971, at *2-3 (D. Del. Nov. 20, 2020) (upholding complaint against "vertically integrated" non-filer that "share[d] one or more common corporate directors" with filer; parties constituted "a unitary entity and operate[d] as a single integrated business with respect to the regulatory approval, manufacturing, marketing, sale and distribution of generic pharmaceutical products;" and non-filer would "work[] in unison" with filer, including after FDA approval). This provides additional support for the Court's conclusion.

In sum, the Court disagrees with Defendants that Plaintiff has "'lump[ed] multiple defendants together without providing allegations of individual conduct.'" (*See* D.I. 10 at 6) (quoting *Adverio*, 2019 WL 581618, at *6) Rather, Plaintiff has pled facts with sufficient specificity to support its plausible allegations that each Defendant actively participated in the preparation of the NDA and intends to benefit from its approval. Accordingly, Pharmaceuticals, Inc., Pharma, Inc., and Pharmaceuticals, LLC are proper defendants in this lawsuit. The Court will deny the motion as it pertains to the claims against these three Defendants.[2]

[2] The declaration of Stephen Cary, Pharma, Inc.'s Chief Operating Officer, which Defendants urge the Court to consider, does not alter the Court's conclusion. (*See* Tr. at 23) (pointing specifically to Cary Decl. ¶ 15) First, as Plaintiff points out, the Court cannot consider this

B. Venue Under § 1400(b)

Neuroscience seeks to dismiss the claims against it on the ground that venue is improper in this District.[3] Novartis does not dispute that Neuroscience neither resides in nor has a regular and established place of business in Delaware. (*See* D.I. 1 ¶ 6) (alleging that Neuroscience is California company with its principal place of business in California) Instead, Novartis argues venue is proper because (1) Handa is using Neuroscience to manipulate venue, and (2) piercing the corporate veil to find venue in Delaware is warranted here.

1. Manipulation of Venue

First, Novartis argues that Handa created Neuroscience solely to escape venue in this District, asserting that "an experienced litigant like Handa would know [that] Hatch-Waxman litigation was likely" at the time it created Neuroscience. (D.I. 16 at 14) In a sworn declaration, however, Defendants provide an explanation for the creation of Neuroscience in July 2020, nine months before Novartis filed the Complaint. (*See* Cary Decl. ¶ 7) Handa purportedly reorganized to separate its generic and brand interests, and in the process assigned responsibility to Neuroscience for new central nervous system drug products. (*Id.*; *see also* Tr. at 20)

Handa also chose to incorporate Neuroscience in California because it is the state of Handa's "nerve center." (*See* D.I. 27 at 4-5) Defendants argue that, even if this decision were made in order to avoid being sued outside of California, business entities are entitled to consider

---

declaration in connection with the Rule 12(b)(6) motion to dismiss without converting it into a motion for summary judgment – which Defendants have not requested doing. (*See id.* at 50) Second, even if the Court were to consider the declaration, it would still reach the same conclusion, given its duty at this stage to view the allegations in the Complaint in the light most favorable to Plaintiff.

[3] Defendants do not dispute that venue as to the other three Defendants is proper. (*See* D.I. 16 at 12)

such factors when choosing their state of incorporation. *See Cradle IP, LLC v. Tex. Instruments, Inc.*, 923 F. Supp. 2d 696, 699 (D. Del. 2013). Further, they argue this case can be distinguished from *In re Samsung Electronics Co., Ltd.*, 2 F.4th 1371, 1377 (Fed. Cir. 2021), and the others on which Novartis relies, in which the ***plaintiff***, rather than the defendant, was accused of manipulating venue. *See id.* at 1377 ("[I]n ascertaining proper venue, we are not bound by a ***plaintiff's*** efforts to manipulate venue.") (emphasis added). As Novartis noted at the hearing, however, a Hatch-Waxman suit is unique in that the ***applicant*** "gets the ball rolling" – that is, the applicant (accused infringer) files an application with FDA knowing it will almost certainly trigger a process that leads to a lawsuit against it. (Tr. at 53) The Court agrees with Novartis that, in the context of this Hatch-Waxman suit, the rationale underlying *In re Samsung* has at least some application to Defendants here.

Notwithstanding this conclusion, the Court is unable to make a finding, on the record presently before it, that Handa created Neuroscience solely to escape venue. As the Court will explain in further detail below, before it can make such a finding, it will provide Novartis an opportunity to take venue-related discovery.

2. Piercing the Corporate Veil

Second, Novartis argues Handa's corporate veil should be pierced and, on this basis, too, Neuroscience should be required to litigate in this District with the other Handa companies. *See Minn. Mining & Mfg. Co. v. Eco Chem, Inc.*, 757 F.2d 1256, 1265 (Fed. Cir. 1985) ("[P]iercing the corporate veil is appropriate in order to establish venue under the patent venue statutes.").

"Corporate separateness is an issue of regional-circuit law." *Celgene*, 17 F.4th at 1125. Accordingly, Third Circuit law applies here.[4]

The test used in the Third Circuit to determine if veil piercing is warranted is often referred to as the alter ego test. *See id.* Pursuant to the applicable analysis, courts will pierce the corporate veil (i.e., disregard the corporate form) to "prevent fraud, illegality, or injustice, when recognition of the corporate entity would defeat public policy . . . , or when the parent so dominated the subsidiary that it had no separate existence." *Id.* (internal quotation marks omitted); *see also Trs. of Nat'l Elevator Indus. Pension, Health Benefit & Educ. Funds v. Lutyk*, 332 F.3d 188, 194 (3d Cir. 2003). Additional relevant considerations include: "gross undercapitalization, failure to observe corporate formalities, nonpayment of dividends, insolvency of debtor corporation, siphoning of funds from the debtor corporation by the dominant stockholder, nonfunctioning of officers and directors, absence of corporate records, and whether the corporation is merely a facade for the operations of the dominant stockholder." *Pearson v. Component Tech. Corp.*, 247 F.3d 471, 484-85 (3d Cir. 2001).

Contrary to Defendants' suggestion, an absence of fraud is not "fatal" to an effort at veil-piercing.[5] (*See* D.I. 27 at 6-7 & n.1) Rather, the presence of a number of the above factors can

---

[4] The parties appear to dispute which body of substantive law the Court should apply. Defendants rely on Third Circuit law (*see* D.I. 10 at 10-11), while Plaintiff contends that Federal Circuit law governs since the policies of the federal patent venue statute are at issue (*see* D.I. 16 at 15). Neither party, however, argues there are material differences between those Circuits with respect to the law governing corporate separateness. Defendants "don't think there's any difference" (Tr. at 36), and Novartis concedes that "the law is similar in both Circuits" (D.I. 16 at 15 n.8). To the extent there are differences, they are immaterial to the Court's analysis.

[5] Defendants note the Third Circuit has explained that "'where the conduct alleged to justify piercing the corporate veil is that the corporation as a whole is a 'sham' or 'facade,' a finding 'akin to . . . fraud' is necessary.'" (D.I. 31 at 8) (quoting *Lutyk*, 332 F.3d at 194 n.7) While Novartis does allege that Neuroscience's existence is a "sham" intended to manipulate venue, it also argues separately that Handa seeks to shield culpable parties from liability (*see* D.I. 16 at

establish that an injustice or unfairness exists and justifies veil piercing. *See Int'l Bus. Machines Corp. v. Expedia, Inc.*, 2019 WL 3322542, at *4 (D. Del. July 24, 2019), *report and recommendation adopted*, 2019 WL 4635137 (D. Del. Sept. 24, 2019); *see also Lutyk*, 332 F.3d at 194.

"Alter ego must be shown by clear and convincing evidence."[6] *Lutyk*, 332 F.3d at 194 (internal punctuation omitted). Plaintiff must show that the entities' separateness "is little more than a legal fiction," a task which is "notoriously difficult" to achieve. *Pearson*, 247 F.3d at 485. Plaintiff "must essentially demonstrate that in all aspects of the business, the two corporations actually functioned as a single entity." *Id.*

In support of its argument for veil piercing, Novartis relies heavily on a declaration from its forensic accountant, Kenneth Mathieu.[7] (*See* D.I. 16 at 16-18) (citing D.I. 17 ("Mathieu Decl.")) Mr. Mathieu describes Neuroscience's undercapitalization and insolvency, opining that the company has no money, products, or revenue, and owes large debts to others in the Handa

---

16) and aims to achieve inconsistent results with respect to the '405 patent (*see* Tr. at 57). Considering these additional allegations, the Court concludes that an absence of fraud would not necessarily be "fatal" to Novartis' veil-piercing argument.

[6] Plaintiff urges the Court to apply a preponderance of the evidence standard, citing a criminal appeal to the Eleventh Circuit in support. (D.I. 16 at 13) (citing *United States v. De La Cruz Suarez*, 601 F.3d 1202, 1217 (11th Cir. 2010) ("For purposes of venue, the government must prove by a preponderance of the evidence that the crimes occurred within the district of trial.")) Because the Court is addressing an issue of corporate separateness, it applies the regional law of the Third Circuit, including the standard of proof required in this Circuit.

[7] The parties appear to disagree as to whether the Court can consider the Mathieu declaration in resolving the dispute over venue. (*Compare* Tr. at 29 (Defendants representing they "don't really think" Court can consider it) *with id.* at 49 (Plaintiff stating that Court can "for sure" consider it in relation to venue dispute)) The Court agrees with Novartis: when confronted with a motion to dismiss for improper venue, the Court may consider evidence outside the complaint, including affidavits (like the Mathieu declaration) submitted by the plaintiff. *See Bristol-Myers Squibb Co. v. Aurobindo Pharma USA Inc.*, 2018 WL 5109836, at *2 (D. Del. Oct. 18, 2018) (citing *Bockman*, 459 F. App'x at 161).

group. (Mathieu Decl. ¶¶ 49-60) He asserts that Dr. Liu and the companies he controls (Pharmaceuticals, Inc., Pharma, Inc., and Pharmaceuticals, LLC) dominate and control Neuroscience. (*Id.* ¶¶ 61-69) He further explains that Neuroscience has no employees and appears not to pay for work by employees of other companies. (*Id.* ¶¶ 70-85) Neuroscience also purportedly has no officers and directors who are not also officers and directors of other Handa companies. (*Id.* ¶¶ 39-44, 87) Additionally, Mr. Mathieu states that Handa shuttles money among the different companies and fails to observe corporate formalities. (*Id.* ¶¶ 35-36, 47, 51-53, 58, 63-65, 80-86)

More broadly, Novartis argues that Defendants aim to shield culpable parties from liability (*see* D.I. 16 at 16) and alleges that Defendants are searching for a court to provide them with inconsistent results with respect to the '405 patent (*see* Tr. at 57; *see also id.* at 54 ("[T]his comes against the backdrop of Novartis litigating these patents; especially the '405 patent in this district for years successfully. And Handa sees that going on. And then after 15 years in the United States of doing business through a Delaware entity, all of a sudden [it] creates a California entity . . . . It looks to us that the facts are clear that this is all about manipulation.")).

Defendants respond that "[d]ismissing this action and allowing Novartis to proceed in California where it has filed an identical complaint (or transferring this action to California) is neither fraudulent, unjust, nor inequitable and does not shield any entity from liability." (D.I. 27 at 6) As the Court noted in *International Business Machines Corp. v. Expedia, Inc.*, "if the Motion is granted and [Defendants] are dismissed from this case, that does not mean that these Defendants will be able to 'shield themselves from infringement' . . . . Plaintiff could certainly pursue liability as to these Defendants in another federal district." 2019 WL 3322542, at *7.

The Court agrees with Defendants that requiring Novartis to sue elsewhere is not the type of "injustice" that, in and of itself, warrants veil piercing. *See id.*; *see also Mobil Oil Corp. v. Linear Films, Inc.*, 718 F. Supp. 260, 270 (D. Del. 1989) ("[R]equiring [Plaintiff] to enforce its patent rights against [Defendant] in another forum is not the kind of injustice – if, indeed, it is an injustice at all – which warrants piercing the corporate veil."). This, however, does not end the inquiry. That is because, largely through Mr. Mathieu's declaration, Novartis has stated a non-frivolous basis for venue. Thus, while the Court is unable to find on the present record that Delaware is a proper venue in which Novartis may proceed against Neuroscience, Novartis has made a sufficient showing to persuade the Court that venue-related discovery may reveal some "injustice" or "unfairness" of the type that piercing the corporate veil ***was*** designed to prevent.

3. Venue-Related Discovery

"[I]n a difficult case, the Court should permit venue-related discovery, to allow the adversarial process to aid the Court in making a fact-specific decision on a well-developed factual record." *Javelin Pharms., Inc. v. Mylan Labs. Ltd.*, 2017 WL 5953296, at *3 (D. Del. Dec. 1, 2017). In the context of jurisdictional discovery, the Third Circuit has instructed that "unless a plaintiff's claim is 'clearly frivolous,' jurisdictional discovery should be allowed." *Rocke v. Pebble Beach Co.*, 541 F. App'x 208, 212 (3d Cir. 2013). A plaintiff, however, may not "undertake a fishing expedition based only upon bare allegations, under the guise of jurisdictional discovery." *Eurofins Pharma US Holdings v. BioAlliance Pharma SA*, 623 F.3d 147, 157 (3d Cir. 2010). The Court applies these same standards to venue discovery. *See Expedia*, 2019 WL 3322542, at *3. To show that discovery is warranted, a party must, at a minimum, state a non-frivolous basis for venue and do so with "reasonable particularity." *E.g.*, *Eastman Chem. Co. v. AlphaPet, Inc.*, 2011 WL 6004079, at *2 (D. Del. Nov. 4, 2011). Plaintiff

has stated non-frivolous bases for venue: namely, that Handa created Neuroscience solely to escape venue or, relatedly, that Handa's conduct amounts to an "injustice" or "unfairness" that requires piercing its corporate veil.

Novartis argues that venue-related discovery will shed light on, for example, whether Neuroscience must repay loans used to pay the FDA filing fee or to purchase the NDA – and, if so, if it will repay those loans through sales of the NDA product. (*See* Tr. at 44) Mr. Mathieu also identifies several documents in Defendants' possession that could aid in the veil-piercing inquiry. (*See* Mathieu Decl. ¶ 88 & tbl.12) Moreover, Novartis alerted the Court that on November 22, 2021, Handa produced confidential documents in the related California action that Novartis believes are relevant to the instant motion. (*See* D.I. 37) Handa allegedly "refused to permit" Novartis to submit those documents to the Court for consideration. (*Id.* at 2) Through venue-related discovery, the parties can determine whether those documents will be relevant and helpful to the Court's venue analysis.

Defendants' recent disclosures in the California case further support granting venue-related discovery. None of the ten custodians identified by Defendants as most likely to have discoverable information are employed by Neuroscience, and the two electronic systems likely to contain relevant data are not owned by Neuroscience. (*See* D.I. 45 Ex. A) In Novartis' view, these disclosures support its argument that Neuroscience is not truly an independent company and was created to manipulate venue. (*See* D.I. 45 at 1-2) Novartis further argues that an absence of any public record of an agreement between Pharma, Inc. and Neuroscience to allocate salary and wages for individuals employed by Pharma, Inc. who perform work for Neuroscience suggests a failure to observe corporate formalities. (*Id.* at 2) While venue-related discovery may well, as Defendants suggest, reveal facts demonstrating the ***opposite*** (*see* D.I. 46), these

disclosures contribute to the Court's finding that Plaintiff has stated non-frivolous bases for venue.

Accordingly, the Court will deny the motion without prejudice as it pertains to whether venue in this District is proper over Neuroscience and allow Novartis to pursue venue-related discovery. While the parties are engaged in such discovery, and briefing any renewed motion to dismiss for lack of improper venue (should Neuroscience believe it has a good faith basis to do so), this case will move forward on the merits. The merits-related issues will have to be resolved eventually in some district (so discovery taken here will likely be helpful to the ultimate resolution of this case, in whichever venue the case is resolved) and, as Novartis noted, time is running on its 30-month stay. (*See* Tr. at 62)

C. Convenience Of The Forum

Finally, Defendants contend that Delaware – even if it is a proper forum, including for Neuroscience – is not a convenient forum and ask the Court to transfer the case against all of them to the Northern District of California. (*See* D.I. 10 at 12-15) In determining whether transfer pursuant to 28 U.S.C § 1404(a) is appropriate, the Court must first determine whether an action could have been brought in the proposed transferee venue. The parties agree that venue is proper in the Northern District of California. Indeed, Novartis has filed suit against all four Defendants there.

Therefore, this portion of Defendants' motion turns on the second step of the analysis, which requires a balancing of various private and public interest factors. As the moving party, Defendants bear the burden of demonstrating that the balance of convenience strongly favors transfer to the Northern District. The Court finds that Defendants have not made such a showing.

1. Private Interest Factors

The private interest factors weigh against transfer. Plaintiff prefers to litigate in this forum, and, in general, a plaintiff's choice of forum is entitled to "paramount consideration." *Shutte*, 431 F.2d at 25. While Novartis brought identical suits in this District and in the Northern District, the Northern District suit is merely a "safety suit" to protect the Hatch-Waxman 30-month stay regardless of the venue in which the suit eventually proceeds.[8] (D.I. 16 at 7) Novartis chose to file this suit in Delaware for legitimate and rational reasons, including that venue is indisputably proper against three of the four Defendants (*see id.* at 12), and much related GILENYA® litigation is proceeding or has proceeded here. In the Court's view, Plaintiff's choice of Delaware receives strong weight in the balance notwithstanding the filing of the California suit (which was simply for the purpose of preserving the automatic stay).

Defendants prefer the Northern District of California because their "nerve center" is there. (D.I. 10 at 14) Their employees, prospective witnesses, and relevant documents are there. (*Id.*) These are legitimate and rational reasons for their preference for an alternative forum. *See, e.g.*, *Papst Licensing GmbH & Co. KG v. Lattice Semiconductor Corp.*, 126 F. Supp. 3d 430,

---

[8] Under the Hatch-Waxman Act, in order to obtain the automatic 30-month stay of FDA approval of a competing drug product, a branded drug company like Novartis must file suit within 45 days after receiving notice from a generic drug company like Handa that it has filed an Abbreviated New Drug Application. *See Eli Lilly & Co. v. Teva Pharms. USA, Inc.*, 557 F.3d 1346, 1348 (Fed. Cir. 2009). A typical strategy for branded companies that anticipate potential venue or jurisdictional disputes is to file a case in their preferred district, here Delaware, and shortly thereafter (but, importantly, within the 45-day window) in a district in which they know there can be no venue or jurisdictional challenge. *See, e.g.*, *Abbott Labs. v. Mylan Pharms., Inc.*, 2006 WL 850916, at *8 (N.D. Ill. Mar. 28, 2006) (explaining appeal of "protective" ANDA suits, considering that "patent holders are stuck between a jurisdictional rock and hard place: file suit in the forum of choice but risk losing patent protection if the suit is dismissed . . . , or file suit in the only known safe forum and incur all the inconvenience of litigating the matter in a distant location").

438-39 (D. Del. 2015). Defendants' preference, however, is not given nearly the same weight as Plaintiff's. *See Intell. Ventures I LLC v. Altera Corp.*, 842 F. Supp. 2d 744, 755 (D. Del. 2012).

Novartis contends that the claim arose "with Delaware companies infringing patent rights owned by another Delaware company" (D.I. 16 at 19), while Defendants counter that the claim arose in California, from the submission of the NDA (D.I. 10 at 14). An assessment of where a patent infringement claim arose typically focuses on where the accused product was produced, designed, and manufactured. *See Papst*, 126 F. Supp. 3d at 439. As there is no evidence that Handa's NDA product was developed or will be manufactured in Delaware, this factor weighs slightly in favor of transfer.

As to "the convenience of the parties as indicated by their relative physical and financial condition," *Jumara*, 55 F.3d at 879, Defendants note that Novartis is one of the largest pharmaceutical companies in the world, while Defendants, collectively, are small pharmaceutical companies with around 50 total employees worldwide, just 10 employees in the United States, and less than $10 million[9] in average annual revenue. (Cary Decl. ¶ 10) Despite Handa's relatively smaller size and the fact that its "nerve center" is in the Northern District of California, it has not shown that "litigating in Delaware would pose a unique or unusual burden on [its] operations." *L'Athene, Inc. v. EarthSpring LLC*, 570 F. Supp. 2d 588, 592 (D. Del. 2008) (internal quotation marks omitted). Indeed, Novartis points out that Handa has litigated other Hatch-Waxman cases in this District and in nearby New Jersey without objection, and that Handa's counsel routinely appears in this Court. (*See* D.I. 16 at 19) This factor is neutral.

[9] There is a discrepancy between Mr. Cary's declaration, which estimates that this figure is "less than $10 million" (Cary Decl. ¶ 10), and Defendants' opening brief, which places this figure at "less than $5 million" (D.I. 10 at 14). Either figure demonstrates Handa's smaller size in relation to Novartis.

Finally, the parties have not identified any reason that the witnesses and documents would be unavailable in either forum.

As a whole, then, the private interest factors weigh against transfer.

2. Public Interest Factors

Defendants argue that the Court should transfer this case to the Northern District to obviate the need to resolve the pending disputes regarding the Defendants' "submitter" status and whether venue is proper over Neuroscience. (*See* D.I. 27 at 1) (citing *Pfizer Inc. v. Apotex, Inc.*, 2009 WL 2843288, at *3 (D. Del. Aug. 13, 2009) ("Courts have routinely held that both judicial economy and the interest of justice favor transfer where transferring a case would obviate a substantial question regarding personal jurisdiction.")) The Court is not persuaded by Defendants' reliance on *Pfizer*. Transferring this case would ***not*** obviate the need for some Court to resolve substantial jurisdictional questions – including whether Pharmaceuticals, Inc., Pharma, Inc., and Pharmaceuticals, LLC are "submitters" under Section 271(e)(2)(A), as well as the issue of veil piercing, as these issues are – at least according to Novartis – "directly relevant to the merits," evidently a reference to corporate state of mind, which may need to be proven as part of an indirect infringement case. (Tr. at 55) Some federal judge would have to resolve these issues regardless of where this case proceeds. Thus, practical considerations like judicial economy do not weigh in favor of transfer.

Nor do the remaining *Jumara* factors. Plaintiff contends that Delaware is the corporate "home" for most of the parties, and that Delaware has an interest in adjudicating disputes among its corporate citizens. (D.I. 16 at 20; *see Altera*, 842 F. Supp. 2d at 760) In patent infringement cases, the "local interest" factor is typically neutral, as patent litigation usually does not implicate

local interests. *See Intell. Ventures I LLC v. Checkpoint Software Techs. Ltd.*, 797 F. Supp. 2d 472, 486 (D. Del. 2011). The local interest factor here is neutral.

Defendants suggest this Court's heavy Hatch-Waxman caseload gives rise to administrative difficulty and weighs in favor of transfer. (*See* D.I. 10 at 14-15) Weighing against this concern, however, are the facts that the judges in this Court are highly experienced with Hatch-Waxman litigation and at least several judges in this District have specific familiarity with GILENYA® and Novartis' patents related to it. This factor is neutral.

The enforceability of the judgment, public policies of the fora, and the trial judge's familiarity with the applicable state law are also neutral (and the parties do not suggest otherwise).

In sum, then, the public interest factors are neutral. When combined with the fact that the private interest factors disfavor transfer, it is clear that Defendants have failed to satisfy their burden to show that the balance of convenience factors and interests of justice weigh strongly in favor of transfer. *See Shutte*, 431 F.2d at 25. Accordingly, the motion to transfer venue will be denied.

IV. CONCLUSION

For the foregoing reasons, the Court will deny with prejudice Defendants' motion as it pertains to the claims against Pharmaceuticals, Inc., Pharma, Inc., and Pharmaceuticals, LLC, and Defendants' request to transfer this case. It will deny without prejudice Defendants' motion as it pertains to whether Delaware is an appropriate forum for Novartis' claims against Neuroscience, and it will grant Novartis' request for venue-related discovery. The Court intends to enter a schedule that will require this case to proceed through discovery and toward trial in

parallel with any discovery and further litigation relating to Neuroscience and venue. An appropriate Order follows.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVARTIS PHARMACEUTICALS CORPORATION,	:	
Plaintiff,	:	
v.	:	C.A. No. 21-645-LPS
HANDA NEUROSCIENCE, LLC, HANDA PHARMACEUTICALS, INC., HANDA PHARMA, INC., and HANDA PHARMACEUTICALS, LLC,	:	
Defendants.	:	

ORDER

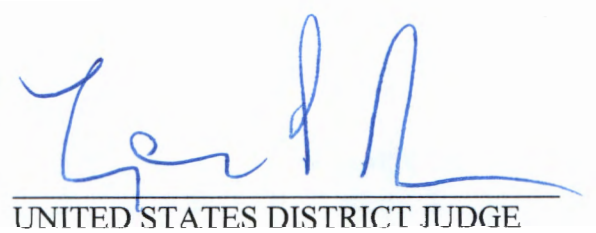
At Wilmington this **1st** day of **March, 2022**:

For the reasons set forth in the Memorandum Opinion issued this date, **IT IS HEREBY ORDERED** that:

1. Defendants' motion to dismiss and/or transfer (D.I. 9) is (i) **DENIED WITH PREJUDICE** as it pertains to the claims against Handa Pharmaceuticals, Inc., Handa Pharma, Inc., and Handa Pharmaceuticals, LLC, and Defendants' request to transfer this case; and (ii) as it pertains to whether Delaware is an appropriate venue for Novartis' claims against Handa Neuroscience, LLC, **DENIED WITHOUT PREJUDICE** to renew upon completion of discovery relating to venue.

2. The parties shall meet and confer and, no later than **March 8, 2022**, submit a proposed schedule, pursuant to which this case will proceed to discovery and toward trial simultaneously with any venue-related discovery and litigation.

3. Plaintiff's motion to file a sur-reply brief (D.I. 29) is **GRANTED** for the reasons stated by the Court during the teleconference on January 24, 2022 (*see* Tr. at 15-16).



UNITED STATES DISTRICT JUDGE