

MALLINCKRODT IP, MALLINCKRODT
HOSPITAL PRODUCTS INC., and SCR
PHARMATOP,

V.

Defendant.

C.A. No. 17-365-LPS

Plaintiff,

V.

Defendant.

C.A. No. 17-660-LPS

Pending before the Court are: (1) Defendant B. Braun Medical Inc.’s (“B. Braun” or “Defendant”) motion to dismiss the original Complaint for improper venue under Federal Rule of Civil Procedure 12(b)(3) (D.I. 12);¹ (2) B. Braun’s motion to dismiss the Amended Complaint for improper venue and for fees pursuant to 35 U.S.C. § 285 (D.I. 16); and (3) Plaintiffs Mallinckrodt IP, Mallinckrodt Hospital Products Inc., SCR Pharnatop, and Mallinckrodt IP

1

Unlimited Company's (collectively, "Plaintiffs") motion to strike portions of B. Braun's reply brief and accompanying Declaration of Rebecca Stolarick (D.I. 27).

Having considered the parties' motion briefing (*see* D.I. 16, 20, 25, 28, 33) and letter briefing in response to the Court's September 11, 2017 Oral Order (*see* D.I. 38, 39, 40, 41), and for the reasons stated below, **IT IS HEREBY ORDERED** that:

1. B. Braun's motion to dismiss the initial Complaint (D.I. 12) is **DENIED AS MOOT**.
2. B. Braun's motion to dismiss the Amended Complaint (D.I. 16) is **DENIED WITHOUT PREJUDICE** to renew after a period of venue-related discovery.
3. Plaintiffs' motion to strike (D.I. 27) is **DENIED**.
4. The parties shall meet and confer and no later than **December 21, 2017**, submit a joint status report with their position(s) as to the scope and timing of the discovery to be taken pursuant to this Order.

Fees Are Not Warranted

The Court is not persuaded that this is an "exceptional case[]" warranting an award of attorney fees to B. Braun pursuant to § 285. Putting aside that B. Braun is not (at this point) "the prevailing party," *id.*, the Court also finds that this case is not one "that stands out from others with respect to the substantive strength of a party's litigating position (considering both the governing law and the facts of the case) or the unreasonable manner in which the case was litigated." *Octane Fitness, LLC v. ICON Health & Fitness, Inc.*, 134 S. Ct. 1749, 1756 (2014). Plaintiffs' filing and maintenance of this suit in this District, while at the same time filing a "protective" suit in the Eastern District of Pennsylvania (so as not to risk losing the statutory 30-

month stay on FDA approval of B. Braun's proposed generic product) (*see* D.I. 20 at 19), is neither unreasonable nor sanctionable. This is particularly true given recent developments in connection with venue law, *see TC Heartland*, 137 S.Ct. 1514, 1516 (2017), and uncertainty as to how to apply the patent venue statute, 28 U.S.C. § 1400(b), to Hatch-Waxman patent litigation. *See, e.g., Galderma Lab. LP v Teva Pharm. USA Inc.*, C.A. No. 17-1076 (N.D. Tex. Nov. 17, 2017), slip op. at 9 (disagreeing with this Court's opinion in *BMS*, stating "there are several issues with the decision that counsel this Court away from adopting the holding that an act of infringement occurs in any district where the ANDA filer intends to market the ANDA product after it receives FDA approval").

Plaintiffs' Motion to Strike

The Court is not persuaded that B. Braun improperly introduced new evidence and arguments by way of its reply brief and the supporting Stolarick Declaration. Instead, B. Braun properly reinforced arguments and evidence already presented in its opening brief or responded to Plaintiffs' arguments raised in the answering brief.

B. Braun is Not A Delaware Resident for Purposes of Patent Venue

Venue in a patent case is governed exclusively by 28 U.S.C. § 1400(b), *TC Heartland*, 137 S.Ct. 1514, 1516 (2017), which provides: "[a]ny civil action for patent infringement may be brought 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." For purposes of § 1400(b), a defendant which is a domestic corporation "resides" only in its state of incorporation. *See TC Heartland*, 137 S.Ct. at 1517. It is undisputed that B. Braun – which is incorporated in Pennsylvania (D.I. 14 at 3; D.I. 17 at 1) – does not "reside" in Delaware.

Venue Is Potentially Proper Here Under the Second Prong of § 1400(b)

Venue is proper in this District unless B. Braun can show that the second prong of § 1400(b) is not satisfied. *See Bristol-Myers Squibb Co. v. Mylan Pharm. Inc.*, 2017 WL 3980155, at *5 (D. Del. Sept. 11, 2017) (“*BMS*”) (holding that burden is on party opposing venue). That is, Delaware is a proper venue for this lawsuit unless B. Braun can meet its burden to show either that (i) it has not committed acts of infringement in Delaware, or (ii) it does not have a regular and established place of business in Delaware. If B. Braun can show either of the foregoing is true, then venue here is improper, and the Court will have to dismiss or transfer this case. B. Braun contends it has met its burden with respect to both requirements of this second prong of § 1400(b).

The First Requirement: Acts of Infringement

B. Braun has failed to show that it has not committed acts of infringement in Delaware, given the Court’s understanding of the meaning of this statutory requirement in the context of Hatch-Waxman litigation. *See BMS*, 2017 WL 3980155, at *12 (holding that “acts of infringement” in this context include acts “the ANDA applicant non-speculatively intends to take if its ANDA receives final FDA approval, plus steps already taken by the applicant indicating its intent to market the ANDA product in this District”). B. Braun gives the Court no persuasive reason to reconsider this determination.²

²While B. Braun declares that it “has not performed any acts related to its preparation or submission of NDA No. 204957 anywhere within the State of Delaware” (D.I. 17 at 2; D.I. 26 ¶ 6), no such relationship between the regular and established place of business and the act of infringement is required for venue to be proper. *BMS*, 2017 WL 3980155, at *21 (“[N]o relationship between a defendant’s acts of infringement and its regular and established place of business is necessary to satisfy § 1400(b).”).

The Second Requirement: Regular and Established Place of Business

Venue-Related Discovery

Turning to whether B. Braun lacks a regular and established place of business in Delaware, the Court concludes that the record, at present, does not permit it to make a finding. Therefore, the Court will allow Plaintiffs to take venue-related discovery.

As the Federal Circuit recently explained in *In re Cray*, 871 F.3d 1355, 1362 (Fed. Cir. 2017), “[t]hree general requirements [are] relevant to the [regular and established place of business] inquiry: (1) there must be a physical place in the district; (2) it must be a regular and established place of business; and (3) it must be the place of the defendant. If any statutory requirement is not satisfied, venue is improper under § 1400(b).”

“In deciding whether a defendant has a regular and established place of business in a district, no precise rule has been laid down and each case depends on its own facts.” *Id.* The Federal Circuit “stress[ed] that no one fact is controlling” and all facts must be “taken together” in determining whether venue is proper. *Id.* at 1366. This suggests that, at least in 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.³

Related B. Braun Entities May Be Relevant to the Regular and Established Place of Business Inquiry

While B. Braun contends that “the record evidence shows that B. Braun does not have the required regular and established place of business in Delaware” (D.I. 39 at 3), the Court finds

³While Plaintiffs are correct that at this stage the Court must take as true Plaintiffs’ well-pled factual allegations, the Court does not agree with Plaintiffs that B. Braun “has now waived its opportunity to contest them.” (D.I. 38 at 1)

Plaintiffs’ theory – that the “places” of any B. Braun entity, including B. Braun affiliates, subsidiaries, parents, or alter egos, may be attributable to B. Braun for purposes of venue (*see* D.I. 38 at 2) – is not frivolous and justifies some limited venue-related discovery.⁴

B. Braun declares: “B. Braun . . . does not own or lease any manufacturing plants, corporate offices, facilities, or other real property in Delaware; nor does B. Braun . . . have telephone listings or mailing addresses in Delaware,” and “[n]o B. Braun . . . employee resides in the State of Delaware.” (D.I. 26 ¶¶ 3-4) Plaintiffs contend, however, that B. Braun “is part of a large corporate family comprising numerous affiliated companies that act in concert to market, sell, and lease pharmaceutical and medical device products in this District” and that “publicly available information reveals that at least *five* Braun companies are Delaware corporations, three of which are subsidiaries (in fact, the only subsidiaries) of the Braun defendant,” including Central Admixture Pharmacy Services, Inc. (“CAPS”)⁵, B. Braun Interventional Systems Inc., and B. Braun of Puerto Rico Inc. (D.I. 38 at 2) In Plaintiffs’ view, it is possible that through B. Braun’s various Delaware subsidiaries, the named defendant may be found to have a regular and established place of business in this District. (*See id.*) (“[T]he Delaware addresses associated with those subsidiaries also qualify as places from which Braun maintains a continuous physical presence in the State.”).

⁴Contrary to B. Braun’s contentions, the record here does not “set forth clear, undisputed facts in sworn declarations which establish and confirm that B. Braun does not reside, or maintain a regular and established place of business, in Delaware.” (D.I. 39 at 1) Plaintiffs allege that the places of B. Braun’s corporate family, including five Delaware affiliates, “constitute places in Delaware where Braun has a physical presence and conducts business.” (D.I. 41 at 2)

⁵B. Braun asserts that CAPS is an affiliate of B. Braun rather than a subsidiary. (D.I. 26 ¶ 5)

As this legal theory was not addressed by *Cray*, the Court sees no basis on which to find that Plaintiffs' theory as to how B. Braun might be found to have a regular and established place of business in Delaware, based on other B. Braun entities having a regular and established place of business here, to be frivolous. It does not appear that *Cray* disturbed the prior holding of the Federal Circuit in *Minnesota Mining & Manufacturing Co. v. Eco Chemicals, Inc.*, 757 F.2d 1256, 1265 (Fed. Cir. 1985), that "venue in a patent infringement case [may be] proper with regard to one corporation by virtue of the acts of another, intimately connected, corporation."

In fact, *Cray* can be read as having provided further support to the viability of Plaintiffs' theory. In *Cray*, the Federal Circuit found that a defendant's employee's home may, in some circumstances, constitute a "place of the defendant." See 871 F.3d at 1363. *Cray* approvingly cites the Federal Circuit's prior decision *In re Cordis Corp.*, 769 F.2d 733, 735 (Fed. Cir. 1985), where an employee's home was found to support a finding that the named-defendant employer had a regular and established place of business in a district. Where an employee's home is used "to store its [i.e., the named defendant's] literature, documents, and products . . . that the employees then directly took to its [the named defendant's] clients," that home may be found to be a regular and established place of business of the named defendant. *Cray*, 871 F.3d at 1362.

It may be more likely with respect to corporate entities than it is with respect to employees for a regular and established place of business to be properly treated, for venue purposes, as a regular and established place of business of a named defendant. Several of the reasons given in *Cray* for why the employee's home there was *not* a regular and established place of the employer's business seem less applicable to relationships within a corporate family. As *Cray* observed, "[e]mployees change jobs. Thus, the defendant must establish or ratify the place

of business. It is not enough that the employee does so on his or her own.” *Id.* at 1363. It seems likely that a corporate subsidiary or other corporate affiliate cannot extricate itself from a corporate family as easily as an employee can generally depart his job, or as easily as an employee may keep her job but change her personal residence. Further, unlike employees, who typically live in homes of their own choice in locations that are not at all “ratified” by their employer, it is likely more common for corporate parents to “establish” or “ratify” the place of business of their subsidiaries or other related corporate entities (with whom, for instance, they might share space). *See id.*

In the Court’s view, it follows from *Cray* that the “place” of a corporate affiliate or subsidiary of a named defendant may, in at least some circumstances, and similar to the place of a defendant’s employee, be treated as a “place of the defendant.” Among the pertinent circumstances to be considered is whether the formalities of corporate separateness are preserved.⁶ While B. Braun asserts that “CAPS and B. Braun . . . are separate companies and maintain all corporate formalities” (D.I. 26 ¶ 5), Plaintiffs dispute this contention, insisting instead that “the publicly available information shows that, at a minimum, the companies share executive officers” and “regularly work together on various projects.” (D.I. 38 at 2 n.2)

The record presently before the Court does not establish, one way or the other, whether any entity related to B. Braun – be it a parent, subsidiary, affiliate, agent, or alter ego – has any

⁶*See generally* *Sovereign IP, LLC v. AT&T, Inc.*, 2017 WL 5126158, at *1-2 (E.D. Tex. Oct. 31, 2017) (finding place of subsidiary could not be imputed to parent-defendant because formal corporate separateness was maintained); *Post Consumer Brands, LLC v. Gen. Mills, Inc.*, 2017 WL 4865936, at *2 (E.D. Mo. Oct. 27, 2017) (denying venue discovery where there was no suggestion that formal corporate separateness was not preserved); *Symbology Innovations, LLC v. Lego Sys., Inc.*, 2017 WL 4324841, at *10-11 (E.D. Va. Sept. 28, 2017) (finding formal corporate separateness prevented imputing place of subsidiary to parent-defendant).

regular and established place of business in Delaware. Nor does it address the formal corporate separateness between, or the interrelationships among, the named defendant and the related B. Braun entities, including the Delaware subsidiaries. It is appropriate, then, for Plaintiffs to have an opportunity to take discovery on these matters, and for Defendant thereafter to renew, should it wish to do so, its challenge to the propriety of venue in this District.

Physical Place in the District

As stated above, the first requirement of *Cray* is that there “must be a physical place in the district, . . . *i.e.*, a building or a part of a building set apart for any purpose or quarters of any kind from which business is conducted.” 871 F.3d at 1362 (internal quotation marks omitted). While a “virtual space” or “electronic communications from one person to another” will not suffice, the “‘place’ need not be a ‘fixed physical presence in the sense of a formal office or store.’” *Id.* All that is required is that there is a “physical, geographical location in the district from which the business of the defendant is carried out.” *Id.*

The Court disagrees with Plaintiffs’ assertion that B. Braun “has a physical presence in Delaware through its appointment of an agent for the service of process in Delaware.” (D.I. 41 at 1; *see also* D.I. 38 at 1) B. Braun appointed an agent for service of process in Delaware in order to do business here (*see* D.I. 14 ¶ 7; *see also* 8 Del. C. § 132(a) (“Every corporation shall have and maintain in this State a registered agent . . . ”)), and “simply doing business in a district or being registered to do business in a district is insufficient, without more, to make that district a regular and established place of business for any particular entity,” *BMS*, 2017 WL 3980155, at *16. Plaintiffs contend that “the address of Braun’s registered agent constitutes a physical ‘place’ in Delaware from which Braun has a physical presence and conducts Delaware business.”

(D.I. 41 at 1). The Court, however, views the appropriate analysis as far more complex – and multi-factored – than Plaintiffs do. *See also BillingNetwork Patent, Inc. v. Modernizing Med., Inc.*, 2017 WL 5146008, at *2 (N.D. Ill. Nov. 6, 2017) (“It is likewise irrelevant that, incident to Defendant’s registration to do business in Illinois, it has appointed an agent for service of process in this state; that also has no bearing on whether Defendant maintains a physical place of business in this District.”); *Symbology Innovations*, 2017 WL 4324841, at *9 (holding that appointing registered agent to accept service of process in district “fail[s] to support a finding that venue is proper under § 1400 (b)” because it has no “bearing on whether [Defendant] maintains a physical place within the District”); *id.* (“Consideration of the appointed agent is especially inappropriate because the patent venue statute was intended to eliminate the abuses engendered by subjecting defendants to suit wherever they could be served.”).

Still, under Plaintiffs’ broader theory, which could attribute physical places in Delaware of any B. Braun affiliate to the named defendant in this case, it is possible that discovery of the relationships amongst the various B. Braun entities, and of the Delaware places of business of those various entities, may show that this requirement is satisfied.

Regular and Established Place of Business

Second, the place “must be a regular and established place of business.” *Cray*, 871 F.3d at 1360.

To be “regular,” the business should, for example, “operate[] in a steady, uniform, orderly, and methodical manner.” *Id.* at 1362 (internal quotation marks omitted); *see also id.* at 1363 (“[A] five-year continuous presence in the district demonstrates that the business was established for purposes of venue.”) (citation omitted). Simply “conduct[ing] business” from a

place in the district or engaging in “sporadic activity cannot create venue.” *Id.* at 1362, 1365-66; *see also id.* at 1363 (“[A] business that semiannually displayed its products at a trade show in the district had only a temporary presence.”) (citation omitted).

For a place of business to be “established,” it must have some degree of permanence. *See id.* (“‘[E]stablished’ . . . contains the root ‘stable,’ indicating that the place of business is not transient. It directs that the place in question must be settled certainly, or fixed permanently.”) (internal quotation marks omitted); *see also id.* at 1363 (“[W]hile a business can certainly move its location, it must for a meaningful time period be stable, established.”).

It follows that transient, sporadic visits to a District – for instance, to a courthouse to participate in litigation – are not of sufficient permanence or steadiness to be “regular” or “established.” Furthermore, the fact that B. Braun “leases medical equipment” in Delaware that is “installed and maintained in the District by Braun employees” (D.I. 38 at 3) is insufficient, without more, to show that B. Braun has a physical place of business in Delaware. The Delaware hospitals housing this equipment do not appear, as the record now stands, to be a “place of the defendant,” as there is (as yet) no indication that B. Braun “establish[ed] or ratif[ied] the[se] place[s] of business” or “exercise[d] other attributes of possession or control over the place.” *Cray*, 871 F.3d at 1363. Still, discovery may reveal that some portion of one or more hospitals in Delaware – i.e., “a building or a part of a building set apart for any purpose or quarters of any kind from which business [of the defendant] is conducted,” *id.* at 1362 (internal quotation marks omitted) – is dedicated to B. Braun (or one of its corporate affiliates) so it may operate its machines. If so, this could contribute to a finding that B. Braun has a regular and established place of business in Delaware.

Under Plaintiffs' theory, which could attribute the Delaware "regular and established" physical places "of business" of any B. Braun affiliate to the named defendant in this case, it is possible that discovery of the relationships amongst the various B. Braun entities, and of the Delaware places of business of those various entities, may show that this requirement is satisfied.

Of the Defendant

The third *Cray* requirement is that "the regular and established place of business must be the place of the defendant." *Id.* at 1363 (internal quotation marks omitted). The "place *of the defendant*," therefore, must "not [be] solely a place of the defendant's employee." *Id.* (emphasis added). The defendant "must establish or ratify the place of business. It is not enough that the employee does so on his or her own." *Id.*

In determining whether a place of business is a place of the defendant, "[r]elevant considerations include whether the defendant owns or leases the place, or exercises other attributes of possession or control over the place." *Id.* Furthermore, any conditions the employer places on the employee's location or use of the employee's place are more likely to make that a place that may properly be considered a place of the defendant. *Id.* ("Another consideration might be whether the defendant conditioned employment on an employee's continued residence in the district or the storing of materials at a place in the district so that they can be distributed or sold from that place."). Further considerations include "[m]arketing or advertisements . . . , but only to the extent they indicate that the defendant itself holds out a place for its business." *Id.* "[I]f an employee can move his or her home out of the district at his or her own instigation, without the approval of the defendant, that would cut against the employee's home being considered a place of business of the defendant." *Id.*

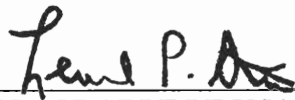
It follows that a courthouse is not a place “of the defendant.” *Id.* The courthouse is not owned or leased by B. Braun; nor does B. Braun exercise other attributes of possession or control over the courthouse.

Still, under Plaintiffs’ theory, which could attribute Delaware physical places of any B. Braun affiliate to the named defendant in this case, it is possible that discovery of the relationships amongst the various B. Braun entities, and of the Delaware places of business of those various entities, may show that this requirement is satisfied.

Conclusion

Consequently, and contrary to B. Braun’s assertion, Plaintiffs’ request for venue discovery has not been “mooted by B. Braun’s sworn declarations and/or flatly rejected by the *Cray* and *BMS/BSC* decisions.” (D.I. 40 at 2) Instead, as Plaintiffs describe, venue-related discovery is necessary “to explore the business activities of Braun and its Delaware affiliates including their relationship to Braun.” (D.I. 41 at 2) The Court has determined that deciding the pending motion to dismiss on the present record would not be a reasonable and appropriate method of proceeding to resolve the important, novel venue questions that are now before it. Accordingly, after receiving specific input from the parties, the Court will order venue-related discovery, to proceed contemporaneously with the remainder of this case as it proceeds on the merits.

December 14, 2017
Wilmington, Delaware



HONORABLE LEONARD P. STARK
UNITED STATES DISTRICT JUDGE