IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BRISTOL-MYERS SQUIBB COMPANY and PFIZER INC.,	:	
Plaintiffs,	:	
v.	:	C.A. No. 17-379-LPS
MYLAN PHARMACEUTICALS INC.,	:	
Defendant.	:	

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OPINION

September 11, 2017
Wilmington, Delaware

STARK, U.S. District Judge:

Presently before the Court is Mylan Pharmaceuticals Inc.'s ("MPI" or "Defendant") motion to dismiss for improper venue in light of the Supreme Court's recent decision in *TC Heartland LLC v. Kraft Food Group Brands LLC*, 137 S. Ct. 1514 (2017). (D.I. 14)

It is undisputed that after *TC Heartland*, which held that a corporate defendant "resides" only in its state of incorporation for purposes of determining where venue is proper in a patent case, *see* 28 U.S.C. § 1400(b), MPI, a West Virginia corporation, can no longer be said to "reside" in Delaware. *TC Heartland* did not, however, address the second prong of § 1400(b), which makes venue proper in a district "where the defendant has committed acts of infringement and has a regular and established place of business."

MPI, which has submitted an Abbreviated New Drug Application ("ANDA") to the United States Food and Drug Administration ("FDA") for permission to market and sell a generic version of one of Plaintiffs' patent-protected drug products, bears the burden to show that it does not satisfy the requirements of the second prong of § 1400(b). Given the language of the statute giving rise to Plaintiffs' cause of action, 35 U.S.C. § 271(e)(2), as well as the unique realties of ANDA-related patent litigation, MPI has failed to meet its burden to show that it has not committed acts of infringement in Delaware. However, the record is less clear with respect to whether MPI has a "regular and established place of business" here. Accordingly, the Court will permit expedited venue-related discovery so that it may thereafter determine if venue is proper here. In the meantime, this case – which is related to two dozen other cases relating to the same branded pharmaceutical, Eliquis® – will proceed on the merits.

Therefore, for the reasons set forth below, the Court will deny MPI's motion to dismiss

for improper venue, without prejudice to MPI having an opportunity to renew its motion should it believe, after expedited venue-related discovery is complete, it can meet its burden to show that it does not have a "regular and established place of business" in Delaware.

I. BACKGROUND

This is a patent infringement action brought by Bristol-Myers Squibb Co. and Pfizer Co. (collectively, "BMS" or "Plaintiffs") under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the "Hatch-Waxman Act." 21 U.S.C. § 355(j). Defendant MPI submitted an ANDA to market a generic version of BMS' Eliquis®, 2.5 mg and 5 mg strength apixaban tablets ("ANDA product"). (D.I. 1 at ¶ 2) BMS asserts Orange Book-listed[1] U.S. Patent Nos. 6,967,208 and 9,326,945, which generally describe and claim chemical compounds, including apixaban, and apixaban formulations.

MPI is a corporation organized under the laws of West Virginia, having its principal place of business in Morgantown, West Virginia. (D.I. 16 at ¶ 3) MPI "is in the business of making and selling generic pharmaceutical products, which it distributes in the State of Delaware and throughout the United States." (D.I. 1 at ¶ 10) MPI is registered with the Delaware Board of Pharmacy as a licensed "Pharmacy - Wholesale" and "Distributor/Manufacturer CSR." (*Id.* at ¶ 9) However, MPI does not have any manufacturing plants, corporate offices, facilities, other real property, telephone listings, mailing addresses, or employees in Delaware. (*See* D.I. 16 at

[1]The FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* – commonly called the "Orange Book" – includes a listing of approved drug products and, among other things, information about the patents that cover each drug product. *See Intendis GMBH v. Glenmark Pharm. Inc., USA*, 822 F.3d 1355, 1359 (Fed. Cir. 2016); *see also* 21 U.S.C. § 355(b)(1); 21 C.F.R. §§ 314.3, 314.53.

¶ 2)[2]

On March 2, 2017, MPI notified BMS that it had submitted its ANDA to the FDA pursuant to § 505(j) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(j). (D.I. 1 at ¶ 20) The notice letter stated that MPI seeks approval from the FDA to engage in the commercial manufacture, use, and sale of the MPI ANDA product before the expiration of the patents-in-suit. (*Id.* at ¶ 21)

On April 5, 2017, BMS initiated the present action by filing the complaint here in the District of Delaware. BMS' complaint alleges that MPI's submission of the ANDA "to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the [MPI] ANDA product prior to the expiration" of BMS' patents constituted a technical act of infringement under 35 U.S.C. § 271(e)(2)(A). (*Id.* at ¶¶ 28, 34) The complaint further alleges that, upon FDA approval of MPI's ANDA, MPI will infringe, either literally or under the doctrine of equivalents, BMS' patents "by making, using, offering to sell, and selling the [MPI] ANDA product in the United States and/or importing said product into the United States, or by actively inducing and contributing to infringement . . . by others, under 35 U.S.C. § 271(a)-(c), unless enjoined by the Court." (*Id.* at ¶¶ 31, 36)

Also in the complaint, BMS alleges that "[v]enue is proper in this Court under 28 U.S.C. §§ 1391 and/or 1400(b), including because, *inter alia*, [MPI] is subject to personal jurisdiction in this district, as set forth above, has committed an act of infringement and will commit further acts

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[2]The Court views the statements in this paragraph as being essentially uncontested facts. However, if venue-related discovery should reveal a dispute as to any factual statement that is contained in any portion of this Opinion about any Mylan entity, the parties may bring that to the Court's attention at a later point in this case.

of infringement in this judicial district . . . [and] has a regular and established place of business in this judicial district." (*Id.* at ¶ 15) BMS further alleges that MPI "has committed an act of patent infringement under 35 U.S.C. § 271(e)(2) and intends a future course of conduct that includes acts of patent infringement in Delaware," elaborating that MPI "will make, use, import, sell, and/or offer for sale the [MPI] ANDA product in the United States, including in Delaware, prior to the expiration of the patents-in-suit." (*Id.* at ¶ 12)

On May 10, 2017, MPI answered the complaint and, among other things, asserted improper venue as an affirmative defense. (*See* D.I. 10 at 12)

On May 22, 2017, the Supreme Court issued its decision in *TC Heartland*, "hold[ing] that a domestic corporation 'resides' only in its State of incorporation for purposes of the patent venue statute," adding that "amendments to § 1391 did not modify the meaning of § 1400(b)." 137 S. Ct. at 1517. The Supreme Court did not construe the second prong of § 1400(b), which makes venue in a patent case proper where a defendant "has committed acts of infringement and has a regular and established place of business."

On July 25, 2017, MPI moved to dismiss for improper venue under Federal Rule of Civil Procedure 12(b)(3), contending that venue is not proper under either the residency or place of business prongs of § 1400(b). (D.I. 14) Plaintiffs do not contend that MPI's motion is untimely.

Briefing on the motion was completed on August 18, 2017. (*See* D.I. 15, 21, 25) The Court heard oral argument on August 24, 2017. (*See* D.I. 35 ("Tr."))[3]

[3]At the motions hearing, both Chief Judge Stark and Magistrate Judge Burke presided. The hearing concerned not just the motion pending in the instant case, but also similar post-*TC Heartland* venue motions pending in other cases. (*See* D.I. 20) Judge Stark has been tremendously assisted in considering the pending motion by the efforts of Judge Burke.

II. LEGAL STANDARDS

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). Rule 12(b)(3) authorizes a party to move to dismiss a lawsuit for improper venue. 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). Venue in a patent infringement action is governed solely and exclusively by the patent venue statute, 28 U.S.C. § 1400(b). *See TC Heartland*, 137 S. Ct. at 1516. The general venue statute, 28 U.S.C. § 1391(c), does not have any application in a patent case. *See id.* at 1521.

If the Court grants a Rule 12(b)(3) motion based on improper venue, the Court "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." 28 U.S.C. § 1406(a).[4]

Generally, "it is not necessary for the plaintiff to include allegations in his complaint showing that venue is proper." *Great W. Mining & Mineral Co. v. ADR Options, Inc.*, 434 F. App'x 83, 86-87 (3d Cir. 2011). Hence, when confronted with a motion to dismiss for improper venue, the Court may consider both the complaint and evidence outside the complaint. *See* 14D Wright & Miller, Federal Practice & Procedure § 3826 (4th ed. 2017). The Court will accept any venue-related allegations in the complaint as true, unless those allegations are contradicted by the defendant's affidavits. *See Bockman v. First Am. Mktg. Corp.*, 459 F. App'x 157, 158 n.1 (3d

[4]While § 1406(a) authorizes the Court to either dismiss or transfer a suit brought in an improper venue, for simplicity this Opinion will refer to the improper venue motion as a "motion to dismiss."

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 (affirming District Court's dismissal of complaint "because Defendants satisfied their burden of showing improper venue by offering evidence that the wrongful acts alleged in the Complaint did not occur in Pennsylvania, and Plaintiffs failed to rebut that evidence").

Courts are not uniform in their views as to which party bears the burden of proof with respect to venue. Some hold that a plaintiff must prove that venue is proper in its chosen district, while others hold instead that a defendant must prove that such district is an improper venue. *See* 14D Wright & Miller, Federal Practice & Procedure § 3826 (4th ed. 2017) ("There are many cases – predominantly, but not exclusively, from the Third and Fifth Circuits – holding that the burden is on the objecting defendant to establish that venue is improper, because venue rules are for the convenience and benefit of the defendant."). At present, it appears the majority view is that "when the defendant has made a proper objection, the burden is on the plaintiff to establish that the chosen district is a proper venue." *Id.* Notably, however, the Court of Appeals for the Third Circuit – the Circuit in which this District is located – has expressly held that the moving party has the burden of proving that venue is improper. *See Myers v. Am. Dental Ass'n*, 695 F.2d 716, 724 (3d Cir. 1982) ("[O]n a motion for dismissal for improper venue under Rule 12 the movant has the burden of proving the affirmative defense asserted by it."); *see also Great W. Mining*, 434 F. App'x at 87 ("Because improper venue is an affirmative defense, the burden of proving lack of proper venue remains – at all times – with the defendant.").

While the parties here are in agreement as to what the Third Circuit has held with respect

to the burden on venue motions, they disagree as to whether Third Circuit law governs the pending motion. BMS contends that Third Circuit law applies, while MPI insists that, rather, the Court must apply the law of the Court of Appeals for the Federal Circuit. Notably, however, MPI concedes that there is no Federal Circuit precedent as to either (i) whether Federal Circuit law controls a motion to dismiss for improper venue, or (ii) which party bears the burden of proof on such a motion.

MPI does cite to *Hoover Group, Inc. v. Custom Metalcraft, Inc.*, 84 F.3d 1408 (Fed. Cir. 1996), which observed that "[v]enue is based on the facts alleged in the well-pleaded complaint," *id.* at 1410 (citing *Dody v. Brown*, 659 F. Supp. 541, 544 n.2 (W.D. Mo. 1987); *McGhan v. F.C. Hayer Co.*, 84 F. Supp. 540, 541 (D. Minn. 1949)). But *Hoover* does not purport to answer the questions this Court faces now. In *Hoover*, the Federal Circuit did not make clear whether it was applying Federal Circuit law or regional-circuit law.[5] Nor did *Hoover* make any statement as to which party bears the burden of proof on venue issues. Thus, there appears to be no binding Federal Circuit decision on these points.

The Federal Circuit, when reviewing a district court's decision, applies the law of the regional circuit where that district court sits for non-patent issues but applies its own law for issues of substantive patent law. *See In re Queen's Univ. at Kingston*, 820 F.3d 1287, 1290 (Fed. Cir. 2016). Thus, to determine whether Federal Circuit law controls which party has the burden here, the Court must examine whether the issue is one that is unique to patent law.

Procedural matters generally are not considered to be unique to patent law. *See Versata*

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[5]*Hoover*'s citations to non-patent, district court opinions in the Eighth Circuit suggests that the Federal Circuit was applying regional-circuit law. *See* 84 F.3d at 1409-10 (noting appeal was from decisions of United States District Court for District of Nebraska).

Software, Inc. v. Callidus Software, Inc., 780 F.3d 1134, 1136 (Fed. Cir. 2015); *Bd. of Trs. of Leland Stanford Junior Univ. v. Roche Molecular Sys., Inc.*, 583 F.3d 832, 840 (Fed. Cir. 2009). Still, "a procedural issue that is not itself a substantive patent law issue is nonetheless governed by Federal Circuit law if the issue pertains to patent law, if it bears an essential relationship to matters committed to [the Federal Circuit's] exclusive control by statute, or if it clearly implicates the jurisprudential responsibilities of [the Federal Circuit] in a field within its exclusive jurisdiction." *Midwest Indus., Inc. v. Karavan Trailers, Inc.*, 175 F.3d 1356, 1359 (Fed. Cir. 1999) (internal citations, alterations, and quotation marks omitted).

In the Court's view, the issue of which party bears the burden of proof on a venue challenge is a procedural, non-patent issue controlled by the law of the regional circuit. Such a challenge must comply with, and is brought pursuant to, the Federal Rules of Civil Procedure. By operation of the Federal Rules of Civil Procedure, the venue challenge must be brought in a responsive pleading or as a separate motion under Rule 12(b)(3) – and the burden-of-proof allocation is properly viewed as simply another procedural aspect of a venue dispute. A motion for improper venue under Rule 12(b)(3) is akin to other motions authorized by the Federal Rules of Civil Procedure, such as Rule 12(b)(6) motions to dismiss for failure to state a claim and motions for judgment as a matter of law. The procedural aspects of these types of motions are controlled by regional-circuit law. *See K-Tech Telecomms., Inc. v. Time Warner Cable, Inc.*, 714 F.3d 1277, 1282 (Fed. Cir. 2013) ("Because it raises a purely procedural issue, an appeal from an order granting a motion to dismiss for failure to state a claim upon which relief can be granted is reviewed under the applicable law of the regional circuit."); *Finjan, Inc. v. Secure Computing Corp.*, 626 F.3d 1197, 1202 (Fed. Cir. 2010) (reviewing "denial of post-trial motions for JMOL

and new trial under regional circuit law").

That venue motions are procedural – and therefore governed by the law of the regional circuit – is true even though the substantive questions at issue may be controlled exclusively by Federal Circuit law. *See, e.g.*, *In re TLI Commc'ns LLC Patent Litig.*, 823 F.3d 607, 610 (Fed. Cir. 2016) (applying "regional circuit law to the review of motions to dismiss for failure to state a claim under Rule 12(b)(6)" on issue of whether Rule 12's plausibility standard had been met, even where motion to dismiss was based on purported failure of patentee to claim patent-eligible subject matter under 35 U.S.C. § 101). Hence, while the substance of a venue challenge in a patent case will turn on § 1400(b), subject matter that is controlled by Federal Circuit law, the Federal Rules – as opposed to a patent-unique statute – provide the procedural vehicle for such a challenge.[6] *Cf. Atlas IP, LLC v. Medtronic, Inc.*, 809 F.3d 599, 604-05 (Fed. Cir. 2015) (applying Federal Circuit law to issues of finality because applicable statute, 28 U.S.C. § 1295(a)(1), is unique to patent law).

Accordingly, the Court will apply Third Circuit law to the procedural aspects of Defendant's improper venue motion, which places the burden on Defendant to prove improper venue. *See, e.g.*, *Koninklijke Philips N.V. v. ASUSTeK Comput. Inc.*, 2017 WL 3055517, at *2

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[6]This is not inconsistent with the Federal Circuit's application of its own law to issues of personal jurisdiction. *See Acorda Therapeutics Inc. v. Mylan Pharm. Inc.*, 817 F.3d 755, 759 (Fed. Cir. 2016), *cert. denied*, 137 S. Ct. 625 (2017). The Federal Circuit has long considered personal jurisdiction to be an issue "intimately related to substantive patent law" because it "is a critical determinant of ***whether*** and in what forum a patentee can seek redress for infringement of its rights." *Beverly Hills Fan Co. v. Royal Sovereign Corp.*, 21 F.3d 1558, 1564 (Fed. Cir. 1994) (emphasis added). Venue, however, is not about "whether" a patentee can seek redress, only about "where." More importantly, *Acorda* and *Beverly Hills Fan* are considering whether Federal Circuit law controls the ***substance*** of a personal jurisdiction challenge, not the procedural vehicle (i.e., a motion under Rule 12(b)(2)) used to bring such a challenge.

(D. Del. July 19, 2017); *Graphics Props. Holdings Inc. v. Asus Comput. Int'l, Inc.*, 964 F. Supp. 2d 320, 324 (D. Del. 2013). However, all issues of interpretation of § 1400(b), a patent-specific statute, are controlled by Federal Circuit law. *See Midwest Indus.*, 175 F.3d at 1359; *see also* D.I. 25 at 9-10 (Defendant agreeing on this point); Tr. at 49-50 (Plaintiffs agreeing on this point).[7] Therefore, the Court will look to Federal Circuit precedent to understand and apply the provisions of § 1400(b). *See In re Cordis Corp.*, 769 F.2d 733, 737 (Fed. Cir. 1985).

III. DISCUSSION

The patent venue statute, 28 U.S.C. § 1400(b), provides:

> Any civil action for patent infringement may be brought in the judicial district [1] where the defendant resides, or [2] [(a)] where the defendant has committed acts of infringement and [(b)] has a regular and established place of business.

It is undisputed that under the Supreme Court's recent decision in *TC Heartland*, venue in this case is not proper in Delaware under the "resides" portion of the statute, as MPI is incorporated in West Virginia. (*See* D.I. 21 at 3, 8 n.7) MPI, therefore, "resides" in West Virginia, not Delaware.

The parties' dispute, then, is whether venue is proper in Delaware in accordance with the second prong of § 1400(b). Venue in Delaware is proper under this portion of the statute unless MPI can show either that (a) MPI has not committed acts of infringement in Delaware, or (b) MPI does not have a regular and established place of business in Delaware. The Court will

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[7]Because the motions hearing was consolidated with numerous other cases, the Court's citation to the transcript of the hearing should not be taken to mean that counsel for the particular Plaintiff or Defendant in the captioned case here expressly made this statement. Where the Court has cited to "Plaintiff" or "Defendant" having said something at the hearing, it is with respect to a point on which the particular party in the captioned case here has advocated the same position or has otherwise endorsed the position being noted.

address each of these requirements in turn.

A. Acts of Infringement

1. Analysis

The first requirement of the second prong of § 1400(b) is that "the defendant has committed acts of infringement" in this District. The parties do not point to any cases applying this statutory language to a patent infringement case brought under the Hatch-Waxman Act. Nor is the Court aware of any case on point. The issue appears to be one of first impression.

The Court begins with the language of the statute, which is written in the present perfect tense: "where the defendant ***has committed*** acts of infringement." § 1400(b) (emphasis added). The Supreme Court has emphasized the importance of analyzing "Congress' choice of verb tense to ascertain a statute's temporal reach." *Carr v. United States*, 560 U.S. 438, 448-49 (2010); *see also Cullen v. Pinholster*, 563 U.S. 170, 182 (2011) ("This backward-looking language requires an examination of the state-court decision at the time it was made."); *United States v. Wilson*, 503 U.S. 329, 333 (1992) ("Congress' use of a verb tense is significant in construing statutes. By using these verbs in the past and present perfect tenses, Congress has indicated that computation of the credit must occur after the defendant begins his sentence.") (internal citations omitted).

But Congress' choice of verb tense in the patent venue statute creates an almost impenetrable problem in the particular context of Hatch-Waxman patent litigation. This is because the temporal focus of the Hatch-Waxman infringement analysis is the future, ***not*** – as is true in essentially all other patent infringement suits – the past, or even the present. In a Hatch-Waxman suit, the subject of the dispute is the generic drug product that the defendant ***will*** manufacture and sell and offer for sale ***in the future*** (after obtaining FDA approval); a Hatch-

Waxman suit is ***not*** about a generic product the defendant ***has sold*** or ***is selling***. *See Acorda Therapeutics Inc. v. Mylan Pharm. Inc.*, 817 F.3d 755, 760 (Fed. Cir. 2016). Thus, on the surface there appears to be a complete mismatch between the backward-looking nature of the patent venue statute and the forward-looking nature of Hatch-Waxman litigation.[8]

One aspect of the temporal mismatch between § 1400(b) and the Hatch-Waxman Act bears particular emphasis: much of the backward-looking, historical conduct that constitutes patent infringement in a typical patent lawsuit is expressly and statutorily deemed non-infringing in the context of Hatch-Waxman litigation. This is due to the "safe harbor" provision of Hatch-Waxman, 35 U.S.C. § 271(e)(1), which provides:

> It shall ***not*** be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

(Emphasis added) Thus, a generic drug company that "has committed" the otherwise infringing acts of making, using, offering to sell, selling, or importing infringing drug products is deemed by statute ***not*** to have committed an act of infringement so long as these actions are reasonably related to the anticipated or actual submission of an ANDA. *See Merck KGaA v. Integra*

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[8]In some ways, the forward-looking nature of an infringement case under the Hatch-Waxman Act is similar to an action for a declaratory judgment of non-infringement or invalidity of a patent. "Venue in a declaratory judgment action for patent noninfringement and invalidity is governed by the general venue statute, 28 U.S.C. § 1391(b) and (c), and not the special patent infringement venue statute, 28 U.S.C. § 1400(b)." *U.S. Aluminum Corp. v. Kawneer Co.*, 694 F.2d 193, 195 (9th Cir. 1982); *Horne v. Adolph Coors Co.*, 684 F.2d 255, 260 (3d Cir. 1982); *Emerson Elec. Co. v. Black & Decker Mfg. Co.*, 606 F.2d 234, 238 (8th Cir. 1979); *Gen. Tire & Rubber Co. v. Watkins*, 326 F.2d 926, 929 (4th Cir. 1964); *Barber-Greene Co. v. Blaw-Knox Co.*, 239 F.2d 774, 776 (6th Cir. 1957). Hence, the Court has not found much help in declaratory judgment cases in answering the questions presented here.

Lifesciences I, Ltd., 545 U.S. 193, 202 (2005) ("[W]e think it apparent from the statutory text that § 271(e)(1)'s exemption from infringement extends to all uses of patented inventions that are reasonably related to the development and submission of any information under the [Federal Food, Drug, and Cosmetic Act].").

What, then, does Hatch-Waxman define as an act of infringement? The submission of an ANDA to the FDA, if the ANDA seeks approval before the expiration of a patent covering the branded drug to which the generic product is bioequivalent. Thus, § 271(e)(2) provides:

> It shall be an act of infringement to submit . . . [an ANDA] for a drug claimed in a patent or the use of which is claimed in a patent . . . if the purpose of such submission is to obtain approval [from the FDA] to engage in the commercial manufacture, use, or sale of a drug . . . claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

This "highly artificial act of infringement" precipitates litigation between the branded drug company and the generic drug company for the express purpose of resolving patent disputes ***before*** a generic drug product is launched. *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990).[9]

Hence, with the Hatch-Waxman Act, and specifically § 271(e), Congress determined that in the context of generic drug development, the submission of the ANDA by the applicant – but not the acts that lead to the submission, which would otherwise be prototypical "acts of

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[9]The ANDA applicant is required by statute to provide notice to the owner of the New Drug Application ("NDA") relating to the branded drug to which the generic product is bioequivalent. *See* 21 U.S.C. § 355(j)(2)(B). If the owner of the NDA files a patent infringement suit within 45 days after receiving such notice, the FDA's authority to give final approval to the ANDA is automatically stayed for 30 months. *See id.* § 355(j)(5)(B)(iii). These specific, expedited, statutory deadlines are aimed at maximizing the opportunities for resolving the drug companies' patent disputes before the generic drug product can be marketed. *See Apotex, Inc. v. Thompson*, 347 F.3d 1335, 1338-39 (Fed. Cir. 2003).

infringement" – is an act of infringement. Congress created this particularized framework in order to trigger expedited patent litigation between branded and generic drug manufacturers ***before*** the generic drug is launched into the market to compete with the branded drug.

Despite the "artificial" starting point for a Hatch-Waxman lawsuit, the litigation that results from an ANDA submission is not about whether the documents submitted to the FDA are somehow unlawful. Rather, the ANDA-related litigation is all about whether a valid patent "***[will or] will not*** be infringed by the manufacture, use, or sale of the new drug for which the application is submitted," which is effectively the same type of analysis involved in a typical patent infringement inquiry. 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (emphasis added). Crucially, in a Hatch-Waxman lawsuit, the patent infringement inquiry is necessarily based on future events that will occur following FDA approval, events that have not yet actually occurred. Therefore, as the Federal Circuit "has long recognized," "the infringement inquiry called for by § 271(e)(2) is 'whether, if a particular drug ***were*** put on the market, it ***would*** infringe the relevant patent' in the usual, non-artificial sense." *Acorda*, 817 F.3d at 760 (quoting *Bristol-Myers Squibb Co. v. Royce Labs., Inc.*, 69 F.3d 1130, 1135 (Fed. Cir. 1995)); *see also Ferring B.V. v. Watson Labs., Inc.-Florida*, 764 F.3d 1401, 1408 (Fed. Cir. 2014) ("The ultimate infringement inquiry provoked by such filing is focused on a comparison of the asserted patent claims against the product that is likely to be sold following ANDA approval and determined by traditional patent law principles.").

From all of this, the Court concludes that in the context of Hatch-Waxman litigation, the "acts of infringement" an ANDA filer "has committed" includes all of the acts that would constitute ordinary patent infringement if, upon FDA approval, the generic drug product is

launched into the market. The submission of an ANDA is a stand-in that serves to move forward in time the infringement and invalidity challenges that otherwise would come later in time, such as after approval or marketing of the ANDA drug. *See Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1569 (Fed. Cir. 1997) ("The only difference in actions brought under § 271(e)(2) is that the allegedly infringing drug has not yet been marketed and therefore the question of infringement must focus on what the ANDA applicant will likely market if its application is approved, an act that has not yet occurred."). Despite the fact that allegedly-infringing products have yet to be approved and marketed, the patent infringement inquiry concerns the real-world impact and consequences that would flow from the approval of an ANDA, the submission of which is the triggering act that allows for the infringement suit in the first instance. *See Acorda*, 817 F.3d at 760. Thus, an applicant submits an ANDA with full knowledge of the effect of its application and with the objective of marketing its drug product in the event that the application is approved. All of this, in the Court's view, must be taken into account in the venue analysis.

In reaching this conclusion, the Court has relied heavily on the Federal Circuit's recent decision in *Acorda*. *Acorda* holds that for purposes of determining personal jurisdiction in a Hatch-Waxman case, the Court must consider all future acts the ANDA filer non-speculatively intends to commit upon receiving final FDA approval for its ANDA product. *See id.* at 762 (explaining that submission of ANDA brings with it all future acts that "reliably, non-speculatively predict" activities by ANDA filer). In the Court's view, it follows that the Court must also consider such future acts when evaluating, for venue purposes, the "acts of infringement" that the ANDA filer "has committed."

While not directed to venue, but instead to personal jurisdiction,[10] the *Acorda* decision nevertheless provides the best guidance as to how the Federal Circuit is likely to resolve the question now before the Court. *See id.* at 755. *Acorda* concerned whether this Court had specific personal jurisdiction over two Mylan entities (MPI and Mylan, Inc.) in a patent infringement action brought under the Hatch-Waxman Act. *See id.* at 757. The Federal Circuit concluded that MPI was subject to specific personal jurisdiction, as its suit-related conduct created a substantial connection to Delaware, and no other considerations made the exercise of jurisdiction unreasonable. *See id.* at 763.

Crucially, in reaching this decision, the Federal Circuit explained that MPI's "ANDA filings are tightly tied, in purpose and planned effect, to the deliberate making of sales in Delaware (at least) and ***the suit is about whether that in-State activity will infringe valid patents***." *Id.* (emphasis added). "The Hatch-Waxman Act recognizes the close connection between an ANDA filing and the real-world acts that approval of the ANDA ***will*** allow and that ***will*** harm patent-owning brand-name manufacturers." *Id.* (emphasis added). "Likewise, an ANDA filer's paragraph IV certification regarding patents addresses the real-world actions for which approval is sought – specifically, whether those actions would infringe." *Id.* To accomplish the goals of the Hatch-Waxman Act, "Congress added § 271(e)(2) as a special means of litigating patent scope and validity only when such a declaration has been made by an ANDA

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[10]Venue and personal jurisdiction are two different, although related, constructs. "The jurisdiction of the federal courts – their power to adjudicate – is a grant of authority to them by Congress and thus beyond the scope of litigants to confer. But [venue,] the locality of a law suit – the place where judicial authority may be exercised – though defined by legislation relates to the convenience of litigants and as such is subject to their disposition. This basic difference between the court's power and the litigant's convenience is historic in the federal courts." *Neirbo Co. v. Bethlehem Shipbuilding Corp.*, 308 U.S. 165, 167-68 (1939).

filer – which has, by its filing, confirmed its ***plan*** to commit real-world acts that ***would make it liable*** for infringement if it commits them without the patentees' permission and it is wrong in its challenges to patent scope or validity." *Id.* at 761 (emphasis added). "And the economic realities of preparing an ANDA confirm that filing realistically establishes a ***plan*** to market." *Id.* (emphasis added). Thus, "Mylan's [and MPI's] ANDA filings, including its certifications regarding the patents at issue here, [we]re thus suit-related, and they ha[d] a substantial connection with Delaware because they reliably, non-speculatively ***predict[ed] Delaware activities by Mylan***." *Id.* at 762 (emphasis added).

In *Acorda*, the Federal Circuit rejected Mylan's contention "that a rigid past/future dividing line governs the minimum-contacts standard" for purposes of personal jurisdiction, indicating that "Mylan d[id] not show that a State is forbidden to exercise its judicial power to prevent a defendant's planned future conduct in the State, but must wait until the conduct occurs." *Id.* Instead, the Federal Circuit determined that "[a]s long as the connection to the planned acts is close enough, the subject of such actions readily fits the terms of the minimum-contacts standard – conduct purposefully directed at the State that gives rise and is related to the suit." *Id.*

In *Acorda*, the connection between the filing of Mylan's ANDA and its future conduct in Delaware was sufficiently close to provide a basis for personal jurisdiction in Delaware. As the Federal Circuit stated:

> Mylan seeks approval to sell its generic drugs throughout the United States, including in Delaware, and it is undisputed that Mylan plans to direct sales of its generic drugs into Delaware. The complaints in these cases allege that Mylan's generic drugs would be distributed and sold in Delaware and that Mylan intends to commercially manufacture, use, and sell the generics upon

> receiving FDA approval. As Mylan admits, it develops drugs for the entire U.S. market and does some business in every State, either directly or indirectly. . . . And even if Mylan does not sell its drugs directly into Delaware, it has a network of independent wholesalers and distributors with which it contracts to market the drugs in Delaware. Such directing of sales into Delaware is sufficient for minimum contacts.

Id. at 763.

In the Court's view, the best, most reasonable conclusion after *Acorda* is that an ANDA filer's future, intended acts must be included as part of the "acts of infringement" analysis for purposes of determining if venue is proper under the patent venue statute. In *Acorda*, the Federal Circuit plainly held that intended, planned, future acts that ***will*** occur in a district in the future (after FDA approval) are acts that ***must be considered now*** in determining whether an ANDA filer has sufficient contacts with that district ***right now*** to make Hatch-Waxman litigation in such a district appropriate from a jurisdictional perspective. *See, e.g.*, *id.* at 760 ("[T]he minimum-contacts standard is satisfied by the particular actions Mylan has already taken – its ANDA filings – for the purpose of engaging in that injury-causing and allegedly wrongful marketing conduct in Delaware."). It follows, in the Court's view, that the same approach must apply in the context of a venue analysis: ***planned, future acts*** that the ANDA filer ***will take*** in this District ***must be considered now*** in determining whether venue is proper here. In the context of Hatch-Waxman, therefore, such future acts are properly considered part of the "acts of infringement" that "the defendant has committed" within the meaning of § 1400(b).

An act of infringement under the Hatch-Waxman Act is, as Congress determined, different from the acts of infringement that give rise to other types of patent infringement actions. "Th[e] statutory provisions [of § 271] treat the ANDA filer as distinctive, and what distinguishes

it is that it has, ***by its filing, reliably confirmed a plan to engage in real-world marketing***." *See id.* at 761 (emphasis added). ANDA litigation is prospective in nature, with no allegedly-infringing product being marketed or sold at the time litigation commences. Accordingly, Congress defined infringement in a special way to create an "artificial" act of infringement under § 271(e)(2): submitting an ANDA. *See Eli Lilly*, 496 U.S. at 676-78.

Indeed, as MPI emphasizes, there typically will ***never*** be an act of ***actual*** infringement in an ANDA case. If the ANDA filer prevails in the litigation, there is no infringing activity because the Court will have held that the patent claims either were not infringed or were invalid. Conversely, if the patentee prevails, the ANDA filer will not be permitted to obtain final FDA approval and sell its ANDA product until after the listed patents expire. *See* 35 U.S.C. § 271(e)(4)(A).[11] But the implication to be drawn from these facts cannot be that the second prong of § 1400(b) can never have any application in a Hatch-Waxman suit, simply because no real "act of infringement" has been (or even will be) committed. There is no basis to believe that Congress intended for the second prong of § 1400(b) to have essentially no application in Hatch-Waxman cases or that, in Hatch-Waxman cases, Congress intended venue to be proper solely and exclusively where the defendant resides. Indeed, despite the unique nature of the Hatch-Waxman

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[11]An exception to this may be an at-risk launch, which can happen if the litigation remains pending after the 30-month stay of approval has concluded. In that case, the FDA may approve the ANDA product before the litigation is resolved, giving the ANDA filer the option of launching its generic product before the Court has ruled on infringement and/or invalidity. *See Sanofi-Aventis v. Sandoz, Inc.*, 405 F. App'x 493, 495 (Fed. Cir. 2010). When an at-risk launch happens, however, the plaintiff may amend its pleadings to add infringement claims under § 271(a) and request a jury trial, so its claims are no longer the forward-looking kind contemplated by § 271(e)(2). *See, e.g., Sepracor Inc. v. Dey L.P.*, 2010 WL 2802611, at *1 (D. Del. July 15, 2010).

Act, there is no special venue statute for these cases.[12] Therefore, § 1400(b) clearly and unambiguously applies in all patent cases, including Hatch-Waxman cases. Hence, it would be wrong to construe "acts of infringement" in a manner that effectively nullifies the second prong of § 1400(b) in Hatch-Waxman cases. *See Williams v. Taylor*, 529 U.S. 362, 364 (2000) ("[C]ourts must give effect, if possible, to every clause and word of a statute."); *United Sav. Ass'n of Texas v. Timbers of Inwood Forest Assocs., Ltd.*, 484 U.S. 365, 375 (1988) (rejecting interpretation that would result in "a practical nullity" of a statutory provision).

Another reason the Court has reached the conclusions set out above is that no more persuasive conclusion has revealed itself. The position advocated by MPI is certainly flawed. MPI emphasizes that § 1400(b) makes venue proper only where a defendant already "has committed" acts of infringement, and argues that because MPI has not sold, offered for sale, or done anything else yet in Delaware with respect to its ANDA product, it cannot be found to "have committed" any act of infringement here, meaning venue is improper.

As already noted, this interpretation would have the consequence of rendering the second prong of § 1400(b) effectively a nullity in Hatch-Waxman cases, violating norms of statutory construction. The Court has not been directed to any reason why this portion of the statute should be inapplicable to any type of patent case. To the contrary, one purpose of § 1400(b) was

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[12]While there is no ANDA-specific venue provision for patentees bringing suit under § 271(e)(2), there ***is*** a specific venue provision for ANDA filers who seek a declaratory judgment of non-infringement or invalidity with respect to an Orange-Book listed patent which the NDA holder chooses not to assert against the ANDA filer within the 45-day period for suing and obtaining the 30-month stay. *See* 21 U.S.C. § 355(j)(5)(C)(i)(II). Venue over these declaratory judgment claims is limited to where the patent holder "has its principal place of business or a regular and established place of business." *Id.* The venue analysis in such a suit does not consider "acts of infringement" as the defendant is the patentee, not an alleged infringer.

to make venue proper in districts other than simply where the defendant resides, *see Brunette*, 406 U.S. at 712-13 & n.13, and there is no reason to conclude that this statutory purpose is any less applicable in a Hatch-Waxman case.

MPI also suggests that the act of infringement occurs either where the submission is made (i.e., with the FDA in Bethesda, Maryland),[13] or where the submission is made from (e.g., where the ANDA applicant places the ANDA in the mail or presses a button to submit it electronically), or where the center of gravity of the work associated with the preparation and submission of the ANDA took place. (*See* Tr. at 16) ("[T]he proper forum is certainly where the ANDA was submitted, per [§ 271](e)(2), and if that orbit goes a little bit further than that, it would be where the work in preparation of that ANDA, where that center of gravity was in terms of the work going into that ANDA, where that actually occurred.") To support its contention, MPI draws on caselaw involving transfer of venue (from one proper venue to another proper and more convenient venue) under 28 U.S.C. § 1404(a), in which courts have looked to where the ANDA was prepared and submitted from as part of determining where the claim arose. *See, e.g.*, *Abbott Labs. v. Roxane Labs., Inc.*, 2013 WL 2322770, at *19 (D. Del. May 28, 2013); *Intendis, Inc. v. River's Edge Pharm., LLC*, 2011 WL 5513195, at *4 (D.N.J. Nov. 10, 2011); *Pfizer Inc. v. Sandoz Inc.*, 2010 WL 256548, at *5 (D. Del. Jan. 20, 2010); *Pfizer Inc. v. Apotex, Inc.*, 2009 WL 2843288, at *3 n.5 (D. Del. Aug. 13, 2009).[14] But MPI offers no persuasive reason for why

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[13]*But see Zeneca Ltd. v. Mylan Pharm., Inc.*, 173 F.3d 829, 832 (Fed. Cir. 1999) (holding that submitting ANDA application to FDA is insufficient basis for finding personal jurisdiction in Maryland).

[14]The cases MPI relies on do not discuss § 271(e)(1)'s safe harbor, even though they consider (as relevant for purposes of a transfer analysis) acts that ordinarily fall within the scope of the safe harbor. *See, e.g.*, *Intendis*, 2011 WL 5513195, at *3-4 ("Defendant argues that the

the Court should expand the scope of the "acts of infringement" inquiry to include preparatory activities that are explicitly ***not*** infringing acts under § 271(e)(1)'s safe harbor. Nor does MPI offer a persuasive reason for why, if the "acts of infringement" are something more than just the submission of an ANDA, the pertinent "acts of infringement" should not be understood as something broader than what MPI seems to have arbitrarily selected.[15]

The Court recognizes that there are problems with its interpretation and application of § 1400(b) in the context of Hatch-Waxman cases. First, and most prominently, is the verb tense in the statutory language: "where the defendant ***has committed*** acts of infringement." (Emphasis added) But the focus in Hatch-Waxman litigation is, as the Federal Circuit (applying § 271(e)(2)) mandates, on whether the proposed ANDA product will in the future infringe a valid patent. In the Court's view, again, this means that the non-speculative future acts of the ANDA filer must be deemed, for purposes of the litigation, to have already occurred. Therefore,

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center of gravity of this case lies in Georgia because the infringing product was conceived by Defendant in Georgia and tested and developed mainly in Georgia. . . . Given that this is an infringement action based on an ANDA filing, there is less infringing activity (e.g., production, marketing, sales, etc.) than in a typical infringement action. Nonetheless, the Court still finds that Plaintiffs' claim arises out of Defendant's activity in Georgia – the location of the operative facts.").

[15]Another act that every generic defendant "has committed" prior to the lawsuit is the sending of a certified notice to the holder of the NDA informing that holder that an ANDA relating to an Orange Book-listed patent has been submitted to the FDA. *See* 21 U.S.C. § 355(j)(2)(B). Nothing in § 271(e)(2) indicates that this required notice is an act of infringement. Still, the receipt of such a notice can have very real, substantial consequences to the holder of the NDA, including wherever that notice is received and wherever the NDA holder is present. *See Acorda*, 817 F.3d at 772 (O'Malley, J., concurring) ("[T]he targeted nature of an ANDA filing – which is intended to challenge a particular patent owned by a known party with a known location – makes the case at hand just like that in *Calder* – the harm is targeted only to these Delaware companies, occurs only in Delaware, and is only triggered by the filing of the ANDA.").

although unusual, the Court concludes that in Hatch-Waxman cases, the appropriate way to read § 1400(b) in light of § 271(e)(2) is that "acts of infringement" the defendant "has committed" include all those non-speculative, future acts the ANDA filer will take after its ANDA receives final FDA approval.

Another arguable defect in this analysis is that it effectively accords a different meaning to "acts of infringement" in the Hatch-Waxman context than in the non-Hatch-Waxman context. While this may well be an odd conclusion, the Court believes it is the proper conclusion given that Congress has statutorily defined the "act of infringement" differently in the Hatch-Waxman context than in all other patent contexts.[16]

Moreover, it could be argued that the Court's analysis is not consistent with the Supreme Court's instruction that § 1400(b) "is [not] to be given a 'liberal' construction." *Schnell v. Peter Eckrich & Sons, Inc.*, 365 U.S. 260, 264 (1961). In the Court's view, its reading of "acts of infringement" is not an expansive, liberal construction of the patent venue statute. Instead, it is simply the result of trying to understand and give meaning to the statutory language "acts of infringement" in the context of the Hatch-Waxman Act.

To conclude otherwise would not only be inconsistent with *Acorda* and the realities of Hatch-Waxman litigation, it would also render the second prong of § 1400(b) essentially a nullity

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[16]Other patent-related statutes also expressly treat Hatch-Waxman cases differently, lending further support to a "Hatch-Waxman-specific reading" of § 1400(b). For instance, the provision governing joinder in patent cases, 35 U.S.C. § 299(a), provides: "With respect to any civil action arising under any Act of Congress relating to patents, ***other than an action or trial in which an act of infringement under section 271(e)(2) has been pled***, parties that are accused infringers may be joined in one action as defendants or counterclaim defendants, or have their actions consolidated for trial, only if" certain conditions – which are inapplicable to Hatch-Waxman cases – are met (emphasis added).

in Hatch-Waxman cases. Moreover, the contrary conclusion would be inconsistent with the purposes of the Hatch-Waxman Act. (*See* D.I. 21 at 10) (BMS arguing "it would make little sense to allow a generic company to use the risk-free, pre-launch litigation scheme in the Hatch-Waxman Act to escape a forum that would undoubtedly be appropriate if its alleged infringement were litigated post-launch")[17]

Accordingly, the Court concludes that an applicant's submission of an ANDA, in conjunction with other 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, must all be considered for venue purposes, and can be sufficient to demonstrate that the ANDA-filing Defendant "has committed" "acts of infringement" in this District.[18]

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[17]From a policy perspective (which, of course, is not part of the statutory interpretation question at issue here, and does not impact the Court's conclusions), MPI's reading of § 1400(b), if adopted, would threaten the Court's ability to expeditiously resolve the merits of a Hatch-Waxman lawsuit within the statutorily-set period of the 30-month stay. If each generic filer has the right to insist that it be sued only where it resides (because the second prong of § 1400(b) is essentially a nullity in Hatch-Waxman cases), then in the frequent situation in which there are multiple ANDA filers but they do not all reside in the same district, the patentee will be required to file and maintain largely identical suits in multiple districts. This will increase the time and expense that is required to resolve these cases on the merits and could result in inconsistent judgments. While the Joint Panel on Multidistrict Litigation might, in these circumstances, be expected to create more Hatch-Waxman multidistrict litigations ("MDLs"), the process of creating an MDL often involves litigation (adding time and expense) and, even once created, cases are transferred to an MDL only for pretrial purposes. *See* 28 U.S.C. § 1407(a). They must be transferred back to the transferor districts for trial, unless a party waives its right to be transferred back. *See id.*

[18]In practice, this likely means that in a patent suit brought pursuant to the Hatch-Waxman Act, and specifically where the patentee alleges infringement in violation of § 271(e)(2), the accused infringer "has committed" "an act of infringement" in every district in which it intends to sell its generic product upon final FDA approval. This does not, of course, mean that venue is proper in every district, as the second prong of § 1400(b) also requires that the

2. Application

Applying these conclusions here, the Court finds that the "acts of infringement" requirement of § 1400(b) is satisfied. Having rejected MPI's statutory arguments, MPI is left with only its minimal challenge to BMS' factual allegations. BMS alleges in its complaint that venue is proper because "[MPI] has committed an act of patent infringement under 35 U.S.C. § 271(e)(2) [i.e., the submission of the ANDA] and intends a future course of conduct that includes acts of patent infringement in Delaware. . . . [MPI] will make, use, import, sell, and/or offer for sale the [MPI] ANDA product in the United States, including in Delaware, prior to the expiration of the patents-in-suit." (D.I. 1 at ¶ 12; *see also id.* at ¶ 15) MPI does not rebut these allegations. It is, thus, undisputed that "[i]f MPI's apixaban ANDA is approved, MPI will . . . direct sales of its apixaban product into Delaware." (D.I. 21 at 9) Because MPI's "ANDA filings and its distribution channels establish that [MPI] plans to market its proposed drugs in Delaware and the lawsuit is about patent constraints on such in-State marketing," *Acorda*, 817 F.3d at 762-63, this Court considers MPI's ANDA submission to be an "act of infringement" that "has [been] committed" in Delaware for purposes of application of § 1400(b).

MPI points out that "[t]he ANDA was prepared in West Virginia by MPI and electronically submitted by MPI to the FDA in Maryland." (D.I. 16 at ¶ 6) MPI further emphasizes that "there has been no manufacture, sale, or offer for sale of generic apixaban products that are the subject of [MPI's] ANDA . . . in the United States or Delaware." (*Id.* at ¶ 8) But these facts do not persuade the Court that MPI has not committed infringing acts here, for the reasons explained at length above.

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venue be one in which the defendant has a "regular and established place of business."

Accordingly, MPI has not carried its burden to demonstrate that it has not committed acts of infringement in this District. Therefore, the Court must next address the remaining prong of § 1400(b)'s non-resident venue test.

B. Regular and Established Place of Business

1. Analysis

In order for venue to be proper under the second prong of § 1400(b), the defendant must also have "a regular and established place of business" in the district.

Because for so long it was so easy to establish proper venue under the residency prong of § 1400(b) based on the Federal Circuit's decision in *VE Holding Corp. v. Johnson Gas Appliance Co.*, 917 F.2d 1574 (Fed. Cir. 1990) – which held that a corporate defendant "resides" wherever there is personal jurisdiction over it, which includes anywhere it sells (or, in a Hatch-Waxman case, intends after FDA approval to sell) the infringing product – courts have not, until very recently, had much occasion to address where a defendant has a regular and established place of business. *See, e.g.*, *Hemstreet v. Caere Corp.*, 1990 WL 77920, at *2 (N.D. Ill. June 6, 1990) (describing 14 relevant factors); *Braden Shielding Sys. v. Shielding Dynamics of Texas*, 812 F. Supp. 819, 822 n.3 (N.D. Ill. 1992); *Johnston v. IVAC Corp.*, 681 F. Supp. 959, 964 (D. Mass. 1987). Now that *TC Heartland* has abrogated *VE Holding*, the issue of how to determine what is and is not a regular and established place of business is arising before courts with increased frequency. *See, e.g.*, *Hand Held Prods., Inc. v. Code Corp.*, 2017 WL 3085859, at *4 (D.S.C. July 18, 2017) (comparing facts to those of prior appellate court decisions); *Raytheon Co. v. Cray, Inc.*, 2017 WL 2813896, at *10-14 (E.D. Tex. June 29, 2017) (analyzing prior precedent and deriving four-factor test).

The words of the statute, which must be the Court's starting point, provide clear guidance as to what is required: a (i) place of business that is (ii) regular and (iii) established. As the Supreme Court has held, "[t]he language of this special statute is clear and specific." *Schnell*, 365 U.S. at 262. Further, "the Supreme Court has stated that the provisions of § 1400(b) are not to be liberally construed." *In re Cordis*, 769 F.2d 733, 736 (Fed. Cir. 1985); *see also Schnell*, 365 U.S. at 263 ("[F]or us to enlarge upon the mandate of the Congress as to venue in such patent actions would be an intrusion into the legislative field."). The Court is further assisted in understanding these requirements by the Federal Circuit's 1985 decision in *In re Cordis*, 769 F.2d at 733, which marks the most recent, precedential case applying the "regular and established place of business" prong of § 1400(b).[19]

In *Cordis*, a pacemaker business incorporated and having its principal place of business in Florida was sued in Minnesota for patent infringement. *See id.* at 734. After the District Court found that venue was proper in Minnesota, the accused infringer, Cordis, filed a petition for a writ of mandamus. The Federal Circuit denied the petition, finding that the District Court had not clearly abused its discretion in determining that Cordis' business activities in Minnesota amounted to it having a regular and established place of business there. *See id.* at 737.

Cordis employed in Minnesota two full-time sales representatives, who worked from home offices where they maintained a stock of Cordis inventory. *See id.* at 735. Hospitals

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[19]As the Court will note, *Cordis* is a decision issued on a mandamus petition, on which the Court of Appeals applies a more deferential standard of review than on a direct appeal. *See, e.g.*, *Cordis*, 769 F.2d at 737 ("[I]f a rational and substantial legal argument can be made in support of the rule in question, the case is not appropriate for mandamus, even though on normal appeal, a court might find reversible error."). Still, *Cordis* is best data point this Court presently has and, notably, no precedential decision has been cited that is inconsistent with *Cordis*. (*See also* Tr. at 27-28, 30-31, 46, 57) (parties all relying on *Cordis*)

wanting to purchase Cordis pacemakers could contact these Minnesota sales representatives to obtain Cordis products. *See id.* The salespeople also acted as technical consultants and were present in the operating room during a significant number of implantation surgeries in Minnesota. *See id.* Cordis hired a secretarial service in Minnesota to answer a local phone number as "Cordis Corporation" and to receive mail in the business' name. *See id.* Cordis, however, was not registered to do business in Minnesota, did not have a bank account there, and did not own or lease any office, house, or other property in the state. *See id.*

In its mandamus petition, Cordis invoked its lack of a fixed physical location as dispositive of the question whether it had a regular and established place of business in Minnesota. *See id.* at 736. The Federal Circuit explicitly rejected this contention, holding that "in determining whether a corporate defendant has a regular and established place of business in a district, the appropriate inquiry is whether the corporate defendant does its business in that district through a ***permanent and continuous presence*** there and ***not*** . . . whether it has a ***fixed physical presence*** in the sense of a ***formal office or store***." *Id.* at 737 (emphasis added).

In reaching its decision that a "fixed physical presence in the sense of a formal office or store" is not required to satisfy § 1400(b), the Federal Circuit contrasted Cordis' circumstances with those involved in two appellate cases that predated the creation of the Federal Circuit. In *Phillips v. Baker*, 121 F.2d 752 (9th Cir. 1941), the Ninth Circuit affirmed a District Court's determination that venue was improper in the Northern District of California for a business with its only office in Florida. The defendants there were in the business of providing pre-cooling services to agricultural shippers, which involved installing the defendants' pre-cooling apparatus in a customer's empty refrigerated railroad car, operating the apparatus as the car was loaded,

removing the apparatus, and then moving the apparatus to the location of another customer. *See id.* at 754. The Ninth Circuit found that the defendants' business in the district was not permanent, as the defendants "merely conduct precooling operations in a box car temporarily standing at a railroad siding, which car is there one day and gone the next; [they] also move from place to place according to the locations of the various shippers." *Id.* at 756. In *Cordis*, 729 F.2d at 736-37, the Federal Circuit concluded that "[t]he facts in *Phillips* indicated that the company's presence within the district was merely temporary, and there was no way to contact its representatives except by communication with the home office in Florida," making the facts of *Phillips* "very different" from those of Cordis.

The other case considered in *Cordis* is *University of Illinois Foundation v. Channel Master Corp.*, 382 F.2d 514 (7th Cir. 1967). There the defendant, Channel Master, was a New York corporation, with a manufacturing plant and headquarters in Ellenville, New York; it was sued for patent infringement in the Northern District of Illinois. *See id.* at 515. Channel Master had a single sales employee who lived in Illinois, who promoted the sales of Channel Master products by "doing business at home by phone calls and mail, and going out at times to solicit sales." *Id.* at 516. Further, "[h]is office coincide[d] with his family bedroom at home where he ha[d] a typewriter and an adding machine, but no company records or files, no stock in trade, no displays, no samples, and no showroom;" "he conducted no demonstrations of the products." *Id.* The Seventh Circuit concluded that these circumstances did not give rise to a regular and established place of business for Channel Master in the Northern District of Illinois.

In comparing these facts to Cordis' business operations, the Federal Circuit noted that "[u]nlike Cordis' representatives who continually maintain a stock of its products within the

district, the sales representative in *Channel-Master* kept no stock or samples of the products." *Cordis*, 769 F.2d at 737. Moreover, while Channel Master's sales representative "conducted seminars with distributors to promote his employer's products, there was no evidence to demonstrate that such activities were carried on concerning the specific product which was the subject of the infringement action." *Id.* These factual differences supported the District Court's conclusion that Cordis had a regular and established place of business in the judicial district, whereas Channel Master did not.

But in holding that no fixed physical presence in the sense of a formal office or store is required, *Cordis* should not be understood as eliminating the statutory requirement that a defendant have some regular and established "***place*** of business" in the venue. On its face, the statutory language requires that the defendant at least have a "place" in which it does business in the district – e.g., a place authorized by the defendant where some part of the defendant's business is done. This requirement of a place was recognized by Judge Wright of this District even before *Cordis*. In *Clopay Corp. v. Newell Cos.*, 527 F. Supp. 733, 740 (D. Del. 1981), Judge Wright construed § 1400(b) as requiring that "a defendant must be 'regularly engaged in carrying on a substantial part of its ordinary business on a permanent basis in a physical location within the district over which it exercises some measure of control'" (quoting *Mastantuono v. Jacobsen Mfg. Co.*, 184 F. Supp. 178, 180 (S.D.N.Y. 1960)).

Consistent with what Judge Wright had already determined before *Cordis*, the Court understands *Cordis* to mean that while no fixed space in the sense of a formal office or store is necessary, some ***physical*** presence is nevertheless required. *Cordis*' analysis focused on the defendant's ***physical*** presence in the district, considering not just whether Cordis had a brick-

and-mortar location in Minnesota but also whether Cordis had employees, products, and product literature there. *See Cordis*, 769 F.2d at 735. *Cordis*' explanation that there needs to be a "permanent and continuous presence" in a district further confirms that the corporate defendant is required to have some sort of meaningful physical manifestation in the district. But as *Cordis* also demonstrates, this inquiry is factually driven and dependent on the circumstances of the case. *See also Clopay*, 527 F. Supp. at 740 ("No single factor is controlling in such an evaluation.").

Additional data points are discernable in other cases.[20] This additional guidance is principally in the form of examples of business activities that are ***not***, in and of themselves, sufficient to amount to a regular and established place of business, or to a permanent and continuous presence.

First, 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. *See, e.g.*, *Gaddis v. Calgon Corp.*, 449 F.2d 1318, 1320 (5th Cir. 1971); *Knapp-Monarch Co. v. Casco Prods. Corp.*, 342 F.2d 622, 624-25 (7th Cir. 1965); *LoganTree LP v. Garmin Int'l, Inc.*, 2017 WL 2842870, at *1 (W.D. Tex. June 22, 2017). This is clear from

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[20]The parties have cited two Supreme Court decisions relating to § 1400(b), but both are so factually distinct from the facts involved here that these opinions, unfortunately, provide the Court little assistance in resolving the instant dispute. *See Schnell*, 365 U.S. at 260 (affirming dismissal of manufacturer for improper venue, as manufacturer's defense of its customer – in a venue where that customer resided – did not make venue proper for non-resident manufacturer); *W.S. Tyler Co. v. Ludlow-Saylor Wire Co.*, 236 U.S. 723, 725 (1915) (finding manufacturer, whose plant and home office were in St. Louis, lacked regular and established place of business in New York, as its New York conduct consisted solely of paying a single part-time salesman who solicited orders and forwarded them to St. Louis, paying a portion of rent on a room for the salesman, paying a portion of wages for a stenographer to support salesman, and shipping goods for one sale to a purchaser in New York).

TC Heartland, 137 S. Ct. at 1519, in which the Supreme Court described its earlier decision in *Fourco Glass Co. v. Transmirra Products Corp.*, 353 U.S. 222 (1957), as holding that § 1400(b)'s use of the word "resides" "negat[es] any intention to make corporations suable, in patent infringement cases, where they are merely doing business" (internal quotation marks omitted). Moreover, until 1988, the general venue statute, 28 U.S.C. § 1391(c), made venue proper in a non-patent case in any district where a corporate defendant was merely "doing business," yet Congress adopted § 1400(b) to specifically and exclusively govern venue in patent cases and did not include "doing business" in § 1400(b) as a basis for venue in patent cases. *See TC Heartland*, 137 S. Ct. at 1518-19; *Fourco*, 353 U.S. at 228.

Second, simply demonstrating that a business entity has sufficient "minimum contacts" with a district for purposes of personal jurisdiction does not necessarily mean that the entity has a regular and established place of business in the district. *See LoganTree*, 2017 WL 2842870, at *1; *IP Co. v. Tropos Networks, Inc.*, 2012 WL 12906154, at *2 (N.D. Ga. Oct. 5, 2012); *HomeBingo Network, Inc. v. Chayevsky*, 428 F. Supp. 2d 1232, 1249 (S.D. Ala. 2006); *IPCO Hosp. Supply Corp. v. Les Fils D'Auguste Maillefer S.A.*, 446 F. Supp. 206, 208 (S.D.N.Y. 1978). A defendant may have sufficient minimum contacts with a state such that exercising jurisdiction over such defendant comports with due process without that defendant doing any regular business in the district, let alone doing business resulting in the type of continuous and permanent presence required to satisfy § 1400(b).

Further, maintaining a website that allows consumers to purchase a defendant's goods or products within the district does not, by itself, demonstrate that the defendant has a regular and established place of business in the district. *See, e.g., Nike, Inc. v. Skechers U.S.A., Inc.*, 2017

WL 3389022, at *2 (D. Or. June 30, 2017); *LoganTree*, 2017 WL 2842870, at *2. A website, which by its very nature can generally be accessed anywhere at anytime by anyone, cannot alone constitute the type of continuous and permanent presence in the district required by § 1400(b). To hold otherwise would essentially turn any cell phone, laptop, or computer into a regular and established place of business for any company with a website from which a consumer can access information or purchase products online. *Cf. CollegeSource, Inc. v. AcademyOne, Inc.*, 653 F.3d 1066, 1075-76 (9th Cir. 2011) ("If the maintenance of an interactive website were sufficient to support general jurisdiction in every forum in which users interacted with the website, 'the eventual demise of all restrictions on the personal jurisdiction of state courts' would be the inevitable result."); *GTE New Media Servs. Inc. v. BellSouth Corp.*, 199 F.3d 1343, 1350 (D.C. Cir. 2000) ("GTE's theory of jurisdiction rests on the claim that . . . mere accessibility of the defendants' websites establishes the necessary 'minimum contacts' with this forum. . . . [U]nder this view, personal jurisdiction in Internet-related cases would almost always be found in any forum in the country. We do not believe that the advent of advanced technology, say, as with the Internet, should vitiate long-held and inviolate principles of federal court jurisdiction."); *McNeil v. Bahamasair Holdings Ltd.*, 2006 WL 1699487, at *5 (W.D. Pa. June 20, 2006) ("To hold that the possibility of ordering products from a website establishes general jurisdiction would effectively hold that any corporation with such a website is subject to general jurisdiction in every state."); *Hsin Ten Enter. USA, Inc. v. Clark Enters.*, 138 F. Supp. 2d 449, 460 (S.D.N.Y. 2000) ("The guiding principle is that the creation of a website . . . should not permit suit in every judicial district in the United States."). It is self-evident that a website operable by others unaffiliated with the defendant is not the type of "place" contemplated by Judge Wright in

Clopay, as a website is not "a physical location over which [the defendant] exercises some measure of control." 527 F. Supp. at 740.

Finally, a regular and established place of business does not arise solely from a defendant simply shipping goods into a district – whether to an individual or for distribution by third parties. *See Simpson Performance Prods., Inc. v. NecksGen, Inc.*, 2017 WL 3616764, at *3 (W.D.N.C. Aug. 23, 2017) ("[W]hile Plaintiff's Amended Complaint contains allegations supporting the conclusion that Defendant conducts some business in . . . North Carolina by selling products in and shipping products to North Carolina, Plaintiff's allegations fall far short of permitting the inference that Defendant maintains a 'permanent and continuous presence' in North Carolina."); *OptoLum, Inc. v. Cree, Inc.*, 2017 WL 3130642, at *6 (D. Ariz. July 24, 2017) (concluding that defendant did not have regular and established place of business in Arizona although it sold infringing products at Home Depot stores there). Just as maintaining a website that allows a consumer anywhere to purchase a defendant's goods is not sufficient for venue purposes under § 1400(b), neither is shipping a product that such a consumer ordered (over the internet, for instance) sufficient. *See, e.g.*, *Nike*, 2017 WL 3389022, at *2 (finding that "direct internet sales is unlikely to lead to relevant evidence on whether Defendant has a 'regular and established place of business' in Oregon").

This last conclusion is further supported by longstanding precedent that "maintaining an exclusive distributorship" or "establishing and maintaining some control over a chain of exclusive, independent distributors" within a forum does not create a regular and established place of business. *See Dual Mfg. & Eng'g, Inc. v. Burris Indus., Inc.*, 531 F.2d 1382, 1387 (7th Cir. 1976). It follows, then, that sending products for distribution within a district, without more,

also fails to establish a continuous and permanent presence there. *See LoganTree*, 2017 WL 2842870, at *2.

Pulling all of this together, the Court will proceed to analyze whether a defendant has a regular and established place of business in Delaware in the following manner. Based on both the statutory language of § 1400(b) and *Cordis*, 729 F.2d at 737, the Court must determine whether a defendant has a regular and established place of business by conducting a fact-intensive inquiry focused on whether the defendant does its business in this District through a permanent and continuous presence here. It is clear from *Cordis* that a "fixed physical presence" in the sense of a "formal office or store" is not required, although some physical presence is needed. If all that is revealed by the record is that the defendant is registered to do business here, or only maintains a website that is accessible in Delaware, or simply ships goods to unaffiliated individuals or third-party entities here, then this District is an improper venue for the lawsuit.

2. Application

Turning to the record presently before the Court, the Court is unable to determine whether MPI has a regular and established place of business in Delaware. Before the Court will evaluate whether MPI can show that it lacks a regular and established place of business here, the Court will provide BMS an opportunity to take venue-related discovery.

Although MPI is incorporated in West Virginia and has its principal place of business in Morgantown, West Virginia (D.I. 16 at ¶ 3), MPI is part of the Mylan family of companies (collectively, "Mylan"), which have a nationwide and global footprint (*see* D.I. 22 Ex. B at 1). "In the United States, the world's largest pharmaceutical market, Mylan products fill one out of every 13 prescriptions dispensed – brand-name or generic." (*Id.* at 2) Mylan has had "[m]ore

generic drug applications approved by FDA over the last two years than any other company." (*Id.*) To get its generic drugs to consumers, Mylan "leverage[s] a broad network of local and global access channels that include physicians, institutions, governments, retailers and wholesalers." (*Id.*) The Mylan family of companies includes at least 55 U.S. subsidiaries, of which more than 40 are incorporated in Delaware. (*See* D.I. 22 Ex. F at 10-16) MPI, specifically, has at times admitted that it "does business in the state of Delaware" (D.I. 22 Ex. O at ¶ 7) and that "its products have been sold in this judicial district" (D.I. 22 Ex. P at ¶ 5).

Within the Mylan family, MPI appears to serve the role of securing regulatory approval for many of Mylan's generic products. MPI holds nearly 80% of Mylan's ANDAs and NDAs listed in the Orange Book. (*See* D.I. 22 Ex. D, E)

MPI's position in bringing generic drugs to market includes filing Paragraph IV certifications and provoking patent infringement litigation.[21] In doing so, MPI is a frequent litigant in federal court in Delaware. In the past ten years, MPI has appeared in more than 100 cases in the District of Delaware. (*See* D.I. 22 Ex. N) MPI even recently persuaded the United States District Court for the Northern District of West Virginia – in MPI's state of incorporation – to transfer a case brought under the Hatch-Waxman Act to the District of Delaware. *See Teva Pharm. USA, Inc. v. Mylan Pharm., Inc.*, 2017 WL 958324, at *7 (N.D. W. Va. Mar. 10, 2017). For at least the past ten years, there has been at least one Mylan action pending in this District at any given time. (*See* D.I. 22 Ex. N)

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[21]Paragraph IV refers to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), which imposes the requirement on an ANDA filer to provide notice to the holder of an NDA that an ANDA has been submitted and that it takes the position that the patents protecting the drug that is the subject of the NDA are not infringed by the proposed generic product and/or are invalid.

And the litigation in which the Mylan entities are involved here – almost exclusively Hatch-Waxman cases, triggered by Mylan's (often MPI's) provocation of a suit by an NDA holder, after receiving Mylan's (often MPI's) Paragraph IV certification, after a Mylan entity has filed an ANDA – is not "run-of-the-mill" litigation, that may or may not be of material significance to Mylan's overall business.[22] Instead, Mylan's business model is in large part predicated upon participating in a large amount of litigation, since almost all of the generic drugs Mylan seeks to market in the U.S. are bioequivalent to drugs that are covered by Orange Book-listed patents. Hence, it appears that a key to Mylan's success in the generic drug business is its constant involvement in Hatch-Waxman litigation. Historically, the largest number of Hatch-Waxman cases each year are filed in the District of Delaware.[23] These facts must weigh into the assessement of whether MPI has a continuous and permanent presence, and therefore a regular and established place of business, in Delaware.

Beyond MPI's role as Mylan's ANDA filer and being a frequent Hatch-Waxman litigant in Delaware, MPI has obtained the right to do business in Delaware, including for "[p]harmaceutical manufacturing, distribution and sales." (D.I. 22 Ex. G) MPI is licensed as a

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[22]"Merely litigating" in a district is something that, by itself, does not give rise to jurisdiction or venue. For example, "the Supreme Court has [] held that where a corporate defendant had no place of business within a jurisdiction, its actions in assuming control of patent litigation against one of its customers did not constitute a waiver of the venue requirement of 28 U.S.C. § 1400(b) so as to permit it to be named as party defendant." *Cordis*, 769 F.2d at 736 (citing *Schnell*, 365 U.S. at 262). The type of litigation being discussed in *Cordis*, however, is not the constant, regular litigation in this District that MPI provokes under the Hatch-Waxman Act as an integral part of its generic drug business.

[23]Published reports indicate that approximately three-quarters of all ANDA patent cases filed between 2009 and 2015 were filed either in Delaware (which had the most ANDA cases) or New Jersey. *See, e.g.*, Brief *Amicus Curiae* of the General Pharmaceutical Association in Support of Petitioner at 11 & n.6, *TC Heartland*, 137 S. Ct. 1514 (No. 16-341).

"Pharmacy - Wholesale" and "Distributor/Manufacturer CSR" in Delaware, allowing it to distribute and manufacture controlled substances in the State. (D.I. 22 Ex. H, I) Additionally, MPI reported several promotional "in-kind" payments to physicians during 2016, indicating that MPI has targeted some Delaware physicians. (*See* D.I. 22 Ex. J)

MPI emphasizes several aspects of its business that are not present in Delaware, including that "MPI does not own or lease any manufacturing plants, corporate offices, facilities or other real property in Delaware; MPI does not have telephone listings or mailing addresses in Delaware; and MPI does not have any employees working in Delaware." (D.I. 16 at ¶ 2) MPI also declares that it had no sales in Delaware during 2016 and to date in 2017, that it does not sell products to any distributors or wholesalers in Delaware, and that it has no control over where its products are sold after it sells them to distributors and wholesalers. (*See id.* at ¶ 7; D.I. 26 at ¶¶ 2-4)

Taking all of the foregoing into consideration, the Court is unable to determine at this time whether MPI can show that venue is improper in Delaware. The apparent facts on which MPI relies are not dispositive of whether MPI has a regular and established place of business here. MPI essentially asks the Court to ignore the realities of the business it is in. As counsel for BMS explained, "the business of Mylan involves challenging patents held by innovators, and they have done that repeatedly in this jurisdiction." (Tr. at 50) MPI, as a frequent ANDA filer, appears in front of this Court with regularity for the purpose of getting its generic drugs on the market, and when that litigation concludes in a way that is favorable for MPI, those generic drugs are distributed to and used by Delaware residents through a distribution network that has been established for that purpose. In the Court's view, this business reality is a pertinent consideration

in assessing whether MPI has a regular and established place of business in Delaware. The fact is that a great deal of activity that appears to be key to MPI's business does occur – regularly, in an established manner, continuously and seemingly permanently – in this District.[24]

MPI does business here, is registered to do business here, and ships goods that regularly end up in this District. While BMS has been unable to this point to identify a "fixed physical presence in the sense of a formal office or store" that MPI maintains in Delaware, this is not required. Also, although the record does not reveal any physical presence here that is particularly and exclusively MPI's, MPI is part of a corporate family that includes approximately 40 Delaware entities (among them corporations that, under *TC Heartland*, "reside" in Delaware for patent venue purposes), and MPI has targeted at least some Delaware physicians, consistent with Mylan having an integrated distribution network for all its generic products.

Given all of the foregoing, the Court cannot say that MPI does ***not*** have a regular and established place of business in Delaware. It may turn out that MPI can ultimately meet its burden to show it lacks a regular and established place of business here, but the Court will not be able to make a final determination until after providing BMS an opportunity to take discovery. Therefore, as further explained below, the Court will deny MPI's motion to dismiss without prejudice to MPI having an opportunity to renew its venue challenge after venue-related discovery is completed.

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[24]It bears repeating that "the 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*, 406 U.S. at 710. MPI's consistent presence in this Court may mean that Delaware is neither an inappropriate nor inconvenient forum for MPI.

C. Relationship between Acts of Infringement and Regular and Established Place of Business

The Court must also consider whether the facts giving rise to the "acts of infringement" that satisfy the second prong of § 1400(b) must be related to the facts that satisfy the "regular and established place of business" portion of that same test. In other words, does § 1400(b) require that the defendant's "regular and established place of business" in this District be used, at least in part, to commit (or to have committed) acts of infringement in this District? While MPI insists that there must be such a relationship, BMS disagrees. (*Compare, e.g.,* Tr. at 28-29 *with id.* at 69-70)

As noted, under § 1400(b) venue is proper in a judicial district "where the defendant has committed acts of infringement ***and*** has a regular and established place of business" (emphasis added). The Federal Circuit has yet to address explicitly whether those requirements must be connected, such that a defendant's regular and established place of business within a district results in or gives rise to its infringing acts. Courts that have considered the question have reached differing results. *Compare Bourns, Inc. v. Allen-Bradley Co.*, 1971 WL 17177, at *2 (N.D. Ill. Apr. 5, 1971) ("The statute requires only that the defendant have committed acts of infringement in the district and have a regular and established place of business there; there is no requirement that the two factors be related.") *with Scaramucci v. FMC Corp.*, 258 F. Supp. 598, 602 (W.D. Okla. 1966) ("[T]here must be some reasonable or significant relationship between the accused item and any regular and established place of business of the accused in the judicial district."). It appears that a majority of cases has determined that no relationship is required. *See Gaddis*, 449 F.2d at 1320; *Shelton v. Schwartz*, 131 F.2d 805, 808-09 (7th Cir. 1942); *Raytheon*,

2017 WL 2813896, at *6-7 (collecting cases). On this issue, the Court agrees with what appears to be the majority view.

The statutory language supports this conclusion. Section 1400(b) provides that venue is proper "where a defendant has committed acts of infringement and has a regular and established place of business." So long as the two requirements are satisfied in a particular district – that is, so long as the defendant has committed acts of infringement in the district and has a regular and established place of business in that same district – venue is proper. The statute does not state that in order for venue to be proper the defendant is to have committed acts of infringement in a district "arising from" a regular and established place of business in that district. The statute is silent as to any necessity of relationship or connection between the two requirements. The Court does not read this statutory silence to contain an implicit nexus requirement. *See generally Cent. Bank of Denver, N.A. v. First Interstate Bank of Denver, N.A.*, 511 U.S. 164, 183-85 (1994) ("[I]t is not plausible to interpret the statutory silence as tantamount to an implicit congressional intent to impose . . . liability.").

The Court acknowledges that there is language in *Cordis* that may suggest that the Federal Circuit contemplated some required relationship between the acts of infringement and the regular and established place of business. In contrasting the facts of *Cordis* with a previous case, *Channel Master*, the Federal Circuit stated that "while there was evidence that the sales representative [in *Channel Master*] conducted seminars with distributors to promote his employer's products, there was ***no evidence to demonstrate that such activities were carried on concerning the specific product which was the subject of the infringement action***." *Cordis*, 769 F.2d at 737 (emphasis added). While the *Cordis* Court was indisputably alluding to a

relationship between Cordis' infringing acts and its place of business, its statement does not purport to impose a requirement that such a relationship must exist. The relationship that did exist in *Cordis* supported the Federal Circuit's decision to deny the mandamus relief sought there by Cordis, which was challenging venue as being improper. But neither the Federal Circuit in *Cordis*, nor the Seventh Circuit in *Channel Master*, confronted the question of whether a relationship is required.[25]

Thus, the Court concludes that no relationship between a defendant's acts of infringement and its regular and established place of business is necessary to satisfy § 1400(b). Therefore, here, MPI's contention that "[n]o Delaware-incorporated subsidiaries of MPI had any involvement with [MPI's] ANDA . . . or MPI's generic apixaban tablets (2.5 mg and 5 mg) that are the subject of [MPI's] ANDA" is of no legal significance. (D.I. 26 at ¶ 7) The question is whether MPI has committed acts of infringement in Delaware and has a regular and established place of business in Delaware, not whether MPI's Delaware business committed, or had a role in committing, the infringing acts. Hence, any lack of relationship between the "acts of infringement" MPI has committed in this District and any regular and established place of business MPI may have here does not provide a basis to find Delaware to be an improper venue.

D. Venue-Related Discovery

Finally, BMS requests that unless the Court denies MPI's motion with prejudice, BMS be granted leave to take expedited venue-related discovery. (*See* D.I. 21 at 20) As the Court is not

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[25]In *Channel Master*, the Seventh Circuit had found insufficient evidence that the employer sold ***any*** product from the district at issue, and so found insufficient evidence that the defendant had a regular and established place of business in that district. The case presented no occasion for the Court to consider whether a relationship is necessary between a regular and established place of business and acts of infringement.

denying MPI's motion with prejudice – but, rather, is doing so without prejudice – the Court will grant the leave sought by BMS.

"[W]here issues arise as to jurisdiction or venue, discovery is available to ascertain the facts bearing on such issues." *Oppenheimer Fund, Inc. v. Sanders*, 437 U.S. 340, 351 n.13 (1978). 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). The law is equally clear, however, that a plaintiff may not "undertake a fishing expedition based only upon bare allegations, under the guise of jurisdictional discovery." *Eurofins Pharma U.S. Holdings v. BioAlliane Pharma SA*, 623 F.3d 147, 157 (3d Cir. 2010). 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." *See, e.g.*, *Eastman Chem. Co. v. AlphaPet, Inc.*, 2011 WL 6004079, at *2 (D. Del. Nov. 4, 2011).

Applying this law to the facts in the record here, the Court concludes that it should permit BMS to take venue-related discovery of MPI. Neither party presents a clearly frivolous claim as to whether MPI has a regular and established place of business in Delaware. Most of the pertinent evidence is in the possession and control of MPI (and other Mylan entities), and it is appropriate for BMS to have an opportunity to discover and test such evidence before the Court finally resolves this issue. As it may be that, after development of the record, MPI will be able to demonstrate conclusively that it does not have a regular and established place of business in this District, the denial of MPI's motion will be without prejudice to MPI having an opportunity to renew its motion following the expedited, venue-related discovery the Court will permit BMS to take.

Such discovery will include understanding the relationships among the 40 Delaware Mylan entities and MPI. *See Minn. Mining & Mfg. Co. v. Eco Chem, Inc.*, 757 F.2d 1256, 1265 (Fed Cir. 1985) ("[V]enue in a patent infringement case [may be] proper with regard to one corporation by virtue of the acts of another intimately connected, corporation."). It will also consider whether MPI (or any Mylan entity) has sales representatives who come to Delaware, who meet with doctors and hospitals here, what they do here, and how often they do it. The venue-related discovery may also include attempting to understand "the way that the industry operates, the way that sales are made, [and how] marketing and promotions are done." (Tr. at 53) Further, it will explore details of MPI's (or another Mylan entity's) operations with wholesalers like McKesson, AmericsourceBergen, or Cardinal Health. (*See* D.I. 21 at 16) Finally, discovery will consider the extent to which MPI has relationships with "end users," such as pharmacies and physicians in Delaware, "that are aimed at incentivizing them to purchase MPI products from wholesalers and distributors." (*Id.* at 17)[26]

In the meantime, while the parties are engaged in expedited venue-related discovery, and briefing any renewed motion to dismiss for lack of improper venue that MPI should choose to file, this case will move forward on the merits. The merits-related issues will (all agree) have to be resolved eventually in some district. Because (importantly here) two dozen related cases are pending in this District and venue is not questioned in any of them, those related cases should inarguably move forward. For now, this case against MPI can and should most efficiently

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[26]These are examples of discovery topics that strike the Court as likely to be relevant to the regular and established place of business analysis. It will be for the parties, initially, to determine the full scope of the discovery to be undertaken, bringing any disputes to the Court's attention through its standard Discovery Matters procedures.

proceed in this District, along with the related cases, in hopes that the statutory goal of resolution of the merits issues prior to the time the FDA is permitted to approve MPI's ANDA is still achievable.[27]

IV. CONCLUSION

For the reasons stated above, the Court will deny without prejudice MPI's motion to dismiss for improper venue. MPI has committed acts of infringement in Delaware based on its submission of an ANDA to the FDA, with the intention and for the purpose of selling products in Delaware that would allegedly infringe BMS' patents. The Court is not yet able to determine whether MPI lacks a regular and established place of business in Delaware. Hence, the Court will permit venue-related discovery and allow MPI to renew its venue challenge after such discovery is completed. An appropriate Order follows.

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[27]The stay in this case expires on June 28, 2020 (*see* D.I. 3), running longer than the usual 30 months because it is based on the relatively recent date of approval of Plaintiffs' NDA covering Eliquis®. *See* 21 U.S.C. § 355(j)(5)(F)(ii) ("[I]f an action for patent infringement is commenced during the one-year period beginning forty-eight months after the date of the approval of the subsection (b) application, the thirty-month period referred to in subparagraph (B)(iii) shall be extended by such amount of time (if any) which is required for seven and one-half years to have elapsed from the date of approval of the subsection (b) application.").