IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
SHERMAN DIVISION

SNYDERS HEART VALVE LLC,	§	
	§	
Plaintiff,	§	
	§	
v.	§	**Case No. 4:16-cv-00812-ALM-KPJ**
	§	
ST. JUDE MEDICAL S.C., INC., ET AL.,	§	
	§	
Defendants.	§	

REPORT AND RECOMMENDATION
OF UNITED STATES MAGISTRATE JUDGE

Before the Court is Defendants St. Jude Medical S.C., Inc., St. Jude Medical, Cardiology Division, Inc., and St. Jude Medical, LLC's (collectively, "Defendants") Motion for Summary Judgment of Improper Venue (the "Motion for Summary Judgment") (Dkt. 178). Plaintiff Snyders Heart Valve LLC ("Plaintiff") filed a response in opposition (Dkt. 184); Defendants filed a reply (Dkt. 192); and Plaintiff filed a sur-reply (Dkt. 193). After considering the Motion, the responses, the relevant authorities, and the oral argument on December 18, 2017, the Court finds the Motion for Summary Judgment (Dkt.178) should be **GRANTED**.

I. FACTUAL AND PROCEDURAL BACKGROUND

On October 25, 2016, Plaintiff filed this lawsuit alleging Defendants' Portico transcatheter aortic valve system (the "Portico Products") infringe U.S. Patent No. 6,540,782 (the "'792 Patent"), titled "Artificial Heart Valve," issued on April 1, 2003, and U.S. Patent No. 6,821,297, (the "'297 Patent"), titled "Artificial Heart Valve, Implementation Instrument and Method Therefor," issued on November 23, 2004. The Portico Products are currently in Food and Drug Administration ("FDA") clinical trials to obtain approval for sales in the United States. *See* Dkt. 178 at 7. Commercial sales and marketing of the Portico Products in the United States prior to

FDA approval are prohibited. *Id*. The Heart Hospital Baylor Plano, which is located in the Eastern District of Texas (the "District"), is one of several clinical trial sites for the Portico Products. *Id*. As of March 30, 2017, there were ten sales to The Heart Hospital Baylor Plano for clinical trials. *Id*. Defendants assert they have not made, used, sold, or offered for sale, or imported, in or from the District, any Portico Products for commercial purposes. *Id*. Defendants further assert the Portico Products were designed and manufactured only in Minnesota and were distributed internationally only from Minnesota. *Id*. at 8. These facts are either undisputed by Plaintiff, or if disputed, the disputes are immaterial. *See* Dkt. 184 at 17-19.

Defendants filed a Motion to Dismiss for Improper Venue (the "Motion to Dismiss") (Dkt. 33), which was denied on May 12, 2017. *See* Dkt. 98. Based on prevailing law at the time, the Court found that venue was proper because Plaintiff had made a *prima facie* showing that Defendants would be subject to personal jurisdiction in this District. *Id*. (citing *VE Holding Corp. v. Johnson Gas Appliance Co.*, 917 F.2d 1574, 1578 (Fed. Cir. 1990) *abrogated by TC Heartland LLC v. Kraft Foods Grp. Brands LLC*, 137 S. Ct. 1514 (2017). Under *VE Holding*, "venue in a patent infringement case include[d] any district where there would be personal jurisdiction over the corporate defendant at the time the action [ ] commenced." *VE Holding*, 917 F.2d at 1583.

Just ten days after the Court denied Defendants' Motion to Dismiss, the Supreme Court decided *TC Heartland*, reversed the Federal Circuit's decision in *VE Holding*, and reiterated its holding in *Fourco Glass Co. v. Transmirra Prods. Corp.*, 353 U.S. 222, 229 (1957), providing that "§ 1400(b) is the sole and exclusive provision controlling venue in patent infringement actions [ ] and that it is not to be supplemented by the provisions of 28 U.S.C. § 1391(c)." *TC Heartland*, 137 S. Ct. at 1520 (citations omitted).

TC Heartland did not address the second prong of § 1400(b), which makes venue proper in any judicial district "where the defendant has committed acts of infringement and has a regular and established place of business." 28 U.S.C. § 1400(b). "Thus, post-*TC Heartland*, venue is proper in the case of a corporate patent defendant where, (a) the corporation is incorporated, or (b) the defendant has committed acts of infringement and has a regular and established place of business." *iLife Techs., Inc. v. Nintendo of Am., Inc.*, 2017 WL 2778006, at *4 (N.D. Tex. 2017).

On May 30, 2017, Defendants filed a "Motion to Reconsider the Court's May 12, 2017 Order Denying St. Jude's Motion to Dismiss for Improper Venue (Dkt. 98) and St. Jude's Renewal of Same" (the "Motion to Reconsider") (Dkt. 110, Sealed). In the Motion to Reconsider, Defendants argued that venue is improper under either prong of § 1400(b) because no defendant resides in and no acts of infringement occurred in this District. *See* Dkt. 110, Sealed, at 11. Defendants also argued that to the extent any sales of accused products occurred in this District, those sales are subject to the safe harbor provision of 35 U.S.C. § 271(e)(1).

The undersigned subsequently entered a report and recommendation (the "Report") (Dkt. 165) containing proposed findings of fact and conclusions of law and recommending the Motion to Reconsider (Dkt. 110, Sealed) be denied. Because the first prong of § 1400(b) does not apply to Defendants,[1] the Report focused primarily on the second prong: whether the alleged infringement occurred in this District. In this case, the second prong turns on whether all sales of the accused products in the District are subject to the safe harbor provided in § 271(e)(1). Finding that by asserting the protection of the safe harbor statute Defendants have asserted an affirmative defense,

[1] The Motion to Reconsider asserted (and Plaintiff did not controvert) that St. Jude Medical S.C., Inc., is incorporated in Minnesota; St. Jude Medical, Cardiology Division Inc., is incorporated in Delaware; and St. Jude Medical, LLC, is organized under the laws of Delaware. *See* Dkt. 110. As explained above, *TC Heartland* makes clear that for purposes of the first prong of § 1400(b), "in the case of a corporate defendant, venue is proper where the corporation is incorporated." *TC Heartland*, 137 S. Ct. at 1521.

and Plaintiff should not be required to negate an affirmative defense, the Report concluded that the issue could not be decided at the motion to dismiss stage. *See* Dkt. 165. As the Report explained, the safe harbor statute is not a blanket exemption if there are "factual questions" and "other challenged activities." *See* Dkt. 165 (citing *Amgen, Inc. v. Int'l Trade Comm'n*, 565 F.3d 846, 854 (Fed. Cir. 2009)). The Report was adopted by United States District Judge Amos L. Mazzant, III, on October 12, 2017, and thus, became the findings and conclusions of the Court. *See* Dkt. 188. Subsequent to the filing, but prior to the adoption of the Report, Defendants filed the present Motion for Summary Judgment.

II. LEGAL STANDARD

Summary judgment is appropriate when, viewing the evidence and all justifiable inferences in the light most favorable to the non-moving party, there is no genuine issue of material fact and the moving party is entitled to judgment as a matter of law. FED. R. CIV. P. 56(c); *Hunt v. Cromartie*, 526 U.S. 541, 549 (1999). The appropriate inquiry is "whether the evidence presents a sufficient disagreement to require submission to a jury or whether it is so one-sided that one party must prevail as a matter of law." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 251-52 (1986).

The party moving for summary judgment has the initial burden to prove there are no genuine issues of material fact for trial. *Provident Life & Accident Ins. Co. v. Goel*, 274 F.3d 984, 991 (5th Cir. 2001). In sustaining this burden, the movant must identify those portions of pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, which it believes demonstrate the absence of a genuine issue of material fact. *Celotex Corp. v. Catrett*, 477 U.S. 317, 325 (1986). The moving party, however, "need not negate the elements of the nonmovant's case." *Little v. Liquid Air Corp.*, 37 F.3d 1069, 1075 (5th Cir.

1994) (en banc). The movant's burden is only to point out the absence of evidence supporting the nonmoving party's case. *Stults v. Conoco, Inc.*, 76 F.3d 651, 655 (5th Cir. 1996).

In response, the nonmovant's motion "may not rest upon mere allegations contained in the pleadings, but must set forth and support by summary judgment evidence specific facts showing the existence of a genuine issue for trial." *Ragas v. Tennessee Gas Pipeline Co.*, 136 F.3d 455, 458 (5th Cir. 1998) (citing *Anderson*, 477 U.S. at 255-57). Once the moving party makes a properly supported motion for summary judgment, the nonmoving party must look beyond the pleadings and designate specific facts in the record to show there is a genuine issue for trial. *Stults*, 76 F.3d at 655. The citations to evidence must be specific, as the district court is not required to "scour the record" to determine whether the evidence raises a genuine issue of material fact. E.D. TEX. LOCAL R. CV-56(d). Neither "conclusory allegations" nor "unsubstantiated assertions" will satisfy the nonmovant's burden. *Stults*, 76 F.3d at 655.

III. EVIDENCE PRESENTED

Defendants have submitted the following evidence in support of their Motion for Summary Judgment:

1) Exhibit A: Excerpts from the deposition of Richard Olson ("Olson")[2] taken on May 9, 2017 (the "Olson Depo.");

2) Exhibit B: Copy of the court order in *Prolacta Bioscience, Inc. v. Ni-Q, LLC,* CV 17-04071 SJO (Ex), Central District of California, August 7, 2017;

3) Exhibit C: Declaration of Richard Olson accompanied by the following exhibits:

    a. Exhibit 1: News Release titled, "St. Jude Medical Announces First Implants in US Study of the Portico Transcatheter Aortic Heart Valve System;"

    b. Exhibit 2: Excerpt from the 10-Q submitted by St. Jude Medical, Inc. to the Securities and Exchange Commission in November 2016;

[2] Olson is the Divisional Vice President, Product Development, which is the entity that acquired the three Defendants in this case: St. Jude Medical, Cardiology Division Inc.; St. Jude Medical S.C., Inc.; and St. Jude Medical, LLC. *See* Dkt. 178-4, Sealed.

c. Exhibit 3: Annual Progress Report for Portico™ Re-Sheathable Transcatheter Aortic Valve System US IDE Trial;

d. Exhibit 4: Copy of printouts of the clinicaltrials.gov website for the trial, "Portico Resheathable Transcatheter Aortic Valve System US IDE Trial (PORTICO IDE);"

e. Exhibit 5: Copy of Packing Lists, showing shipments of the PorticoTM products to The Heart Hospital Baylor Plano from St. Jude Medical S.C., Inc.;

See Dkts. 178-2-178-10, Sealed.

Plaintiff has submitted the following evidence in opposition to Defendants' Motion for Summary Judgment:

1) Exhibit 1: September 2017 Stipulation of Plaintiff and Defendants;

2) Exhibit 2: Sanders v. Johnson, Civil Action N. H-04-881, Southern District of Texas, Houston Division, September 26, 2005;

3) Exhibit 3: March 2017 Stipulation of Plaintiff and Defendants;

4) Exhibit 4: Excerpts from the Olson Depo.;

5) Exhibit 5: Sales Spreadsheet;

6) Exhibit 6: Excerpts from the deposition of Aaron Staloch ("Staloch")[3] taken on June 15, 2017 (the "Staloch Depo.");

7) Exhibit 7: Defendants' responses to Plaintiff's First Set of Interrogatories;

8) Exhibit 8: Printout from St. Jude website listing headquarters in Plano, Texas; and

9) Exhibit 9: Printout from KDC Website.

See Dkts. 184-2-184-9, Sealed.

IV. ANALYSIS

Although Plaintiff raises a number of procedural challenges to Defendants' Motion for Summary Judgment (*see* Dkt. 184 at 6-11), the Court finds that summary judgment in this case

[3] Although not entirely clear based on the excerpts provided, Staloch appears to be a 30(b)(6) designee of Defendants. *See* Dkt. 184-6, Sealed

turns on the legal issue of the relevance of the § 271(e)(1) safe harbor defense in determining whether venue is proper and whether the safe harbor is an "all-or-nothing" defense. *See, e.g.*, Dkt. 178 at 6; *see also* Hearing Transcript ("Hrg. Tr.") at 6. If all of Defendants' challenged activities in the District are covered by the safe harbor, there can be no acts of infringement in the District, and venue is thus improper. On this basis, Defendants seek to have the case dismissed or transferred to the District of Minnesota. *See* Dkt. 178.

Plaintiff counters that § 271(e)(1) is irrelevant for purposes of determining whether venue is proper and takes the position that its *allegations* of infringing activity in the District—as required under §1400(b)—are sufficient to defeat summary judgment of Defendants' safe harbor defense. *See* Dkt. 184 at 12. Plaintiff also argues that because the clinical trials safe harbor is all or nothing, Defendants' commercial activity outside this District effectively revokes the safe harbor protection for activities in this District. *Id.* As will be explained below, Plaintiff's argument is not supported by the law. The Federal Circuit has made clear that for purposes of the safe harbor, each accused activity must be analyzed separately. *See Amgen*, 565 F.3d 846.

A. PLAINTIFF'S PROCEDURAL CHALLENGES TO THE MOTION

Plaintiff argues that Defendants' Motion for Summary Judgment is procedurally improper and untimely. Plaintiff first argues—incorrectly—that the Court's findings and conclusions in the Report (Dkt. 165) foreclosed further briefing on the issue of acts of infringement in the District. *See, e.g.*, Dkt. 184 at 10. However, nothing stated in the Report prevents Defendants from establishing on summary judgment what they could not establish at the motion to dismiss stage. In fact, the opposite is true.[4] Nor does the Report purport to resolve Defendants' venue challenge

[4] Analyzing *Ventrassist Pty Ltd. v. Heartware, Inc.*, 377 F. Supp. 2d 1278, 1287 (S.D. Fla. 2005), the Report concluded that even though *Ventrassist* was decided on a Rule 12(b)(6) motion for failure to state a claim, rather than a 12(b)(3) motion to dismiss for improper venue, its reasoning still applied on the issue of overcoming an affirmative defense. *See* Dkt. 165 at 10.

on the merits as Plaintiff asserts. *See* Dkt. 184 at 10. The Report states that at the motion to dismiss stage, "[P]laintiff is entitled to conduct discovery" and "should not have to negate Defendants' affirmative defense to overcome [a] venue challenge." Dkt. 165 at 10.

Plaintiff has now taken discovery and must demonstrate there is evidence that at least some of Defendants' activities in this District fall outside the safe harbor. "Where the jurisdictional issue cannot be decided without the ruling constituting at the same time a ruling on the merits of the case, the case should be heard and determined on its merits through regular trial procedure." *McBeath v. Inter-Am. Citizens for Decency Comm.*, 374 F.2d 359, 363 (5th Cir. 1967). Thus, contrary to Plaintiff's position, it is appropriate to take up the venue issue again now, and Defendants are entitled to ask for a determination on the merits with respect to § 271(e)(1).

Furthermore, nothing in the law suggests that venue should not be revisited once a noninfringement determination is made on the merits. Federal Rule of Civil Procedure 56 clearly permits affirmative defenses to be raised in a motion for summary judgment. FED. R. CIV. P. 56(a) ("A party may move for summary judgment, identifying each claim or defense on which summary judgment is sought."). In *Dow Chemical Co. v. Monsanto Co.*, 315 F. Supp. 416, 418-19 (S.D. Ohio 1970), the court rejected the plaintiff's argument that a preliminary determination "sets at rest that question forever." *Id*. at 419. "[W]hen the fact of noninfringement appears on the record, venue is deficient and the case must be dismissed." *Id*.

As the *Dow* court explained, there is a distinction between "preliminary examination" of venue at the motion to dismiss stage and "subsequent findings" based on the merits (which is the case here). The *Dow* court also observed that it is not unusual for "a preliminary determination of pro infringement" to be "followed by a merit determination of noninfringement." *Id*. at 418 (as is also the case here). The *Dow* court initially determined that it had jurisdiction and venue but later

held a separate trial on the issue of whether the defendant's activity in the district infringed, and concluded there was no infringement in the district, and thus, venue was improper. *Id*.

Plaintiff argues in its response that *Dow* has no bearing on the present case based on the Federal Circuit's holding in *In re Cordis Corp.*, 769 F.2d 733 (Fed. Cir. 1985), *cert. denied*, 474 U.S. 851. *See* Dkt. 184 at 8-9. Plaintiff contends that *In re Cordis* stands for the proposition that "the issue of infringement is not reached on the merits in considering venue requirements." *Id*. at 9. Plaintiff misconstrues the Federal Circuit's holding, as the court did not hold that infringement is *never* reached on the merits in a venue determination.

In re Cordis involved a motion to dismiss for improper venue. The question before the Federal Circuit was whether venue was proper in a district where the defendant corporation had no "specific permanent physical location" but employed two full-time sales representatives who maintained home offices. *In re Cordis*, 769 F.2d at 736. Thus, the issue of infringement on the merits was not before the court, which is why the court "express[ed] no opinion on whether there ha[d] been infringement." *Id*. at 737. As the Federal Circuit stated, "that is a question to be determined at trial"—or otherwise on the merits. *Id.* As explained above, a merit determination may lead to disposition on the merits based on "subsequent findings" after a "preliminary determination" of venue at the motion to dismiss stage. That is the case here, and the Court finds no disharmony between *In re Cordis* and *Dow*.

Plaintiff also takes issue with Defendants' reliance on *Schroeder v. Owens-Corning Fiberglas Corp.*, 326 F. Supp. 594, 597 (C.D. Cal. 1971), arguing this case is also inapplicable. *See* Dkt. 184 at 9-10. Although conceding in its response that *Schroeder* was decided on a motion for summary judgment of improper venue, Plaintiff attempts to distinguish *Schroeder* on the basis that in that case, the defendants' improper venue defense had not been fully heard on an earlier

motion. *Id*. First, *Schroeder* does appear to reference a prior claim of improper venue, "which was first asserted by motion prior to [Defendant's] Answer." *Schroeder,* 325 F.Supp at 596-97. Second, even were that not the case, whether or not there was a prior claim of improper venue is not the relevant issue here. Rather, *Schroeder* was cited for the proposition that venue issues can be decided after the case has advanced past the motion to dismiss stage—and they can be decided on a merit determination under the second prong of § 1400(b), which states that venue is proper "where the defendant has committed acts of infringement and has a regular and established place of business."

Plaintiff continues to argue—unpersuasively—that mere *allegations* of infringement are sufficient to survive summary judgment here. However, just as in *Schroeder*, Defendants' improper venue defense is now ripe for determination on the merits based on whether, pursuant to § 1400(b), there is any genuine issue of material fact regarding acts of infringement in the District. As will be explained below, the answer to that question has now been established by the summary judgment evidence.

Other courts have reached similar conclusions when addressing venue after the motion to dismiss stage. *See, e.g*, *Olberding v. Ill. Cent. R. Co.*, 346 U.S. 338, 340 (1953) (reversing verdict for plaintiff after jury trial in an improper venue); *Lexecon Inc. v. Milberg Weiss Bershad Hynes & Lerach*, 523 U.S. 26, 41 (1998) (explaining "reversal with new trial is required . . . [where] venue is precluded by the governing statute"); *S.E.C. v. Johnson*, 650 F.3d 710, 716 (D.C. Cir. 2011) (reversing judgment after jury trial as remedy for improper venue); *Gogolin & Stelter v. Karn's Auto Imports, Inc.*, 886 F.2d 100, 103-05 (5th Cir. 1989) (vacating judgment and remanding for transfer or dismissal under 28 U.S.C. § 1406(a)).

The Court also notes that in opposing Defendants' Motion for Reconsideration of the Motion to Dismiss for Improper Venue, Plaintiff relied on *Amgen,* 565 F.3d 846. *See* Dkt. 125 at 9; *see also* Dkt. 165 at 9. *Amgen* held, *inter alia*, that when the parties dispute whether the safe harbor applies as a matter of law, that dispute goes to the merits of the claim. *Amgen*, 565 F. Supp. 2d at 853-54. Plaintiff cannot now disregard authority that it previously relied on to withstand Defendants' 12(b)(6) challenge.

B. ACTS OF INFRINGEMENT AND THE SECTION 271(E)(1) SAFE HARBOR

As previously explained, venue is proper under the second prong of § 1400(b) "where the defendant has committed acts of infringement and has a regular and established place of business." Defendants argue that any sales of accused products that occurred in the District are subject to the safe harbor provision of 35 U.S.C. § 271(e)(1):

> 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.

35 U.S.C. § 271(e)(1). As one court explained, by enacting the safe harbor provision:

> Congress made a fully self-conscious choice between two directly competing interests: continuing full protection of the rights of patent holders, on the one hand, and, on the other, assuring access by the public to medically beneficial new products at truly competitive market prices (i.e., lower prices) immediately after the expiration of the terms of relevant patents.

Intermedics, Inc. v. Ventritex, Inc., 775 F. Supp. 1269 (N.D. Cal. 1991), *aff'd sub nom.*, 991 F.2d 808 (Fed. Cir. 1993).

The safe harbor provided by § 271(e)(1) 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 of 1938. *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 202

(2005); *see also, e.g., Momenta Pharm., Inc. v. Teva Pharm. USA Inc.*, 809 F.3d 610, 619 (Fed. Cir. 2015) ("[N]otwithstanding the legislative focus on activities occurring prior to the approval of generic drugs, the § 271(e)(1) exemption applies to medical devices and is not restricted to pre-approval activities . . . ." (internal citations and quotation marks omitted)).

As explained above, the safe harbor statute is not a blanket exemption if there are "factual questions" and "other challenged activities." *See Amgen,* 565 F.3d at 854. However, Plaintiff cannot rest on a mere allegation of infringement at the summary judgment stage. Now that discovery has been taken, Plaintiff must demonstrate there is evidence that at least some of Defendants' activities in this District fall outside the safe harbor. If there is no dispute that all of Defendants' activity here consists solely of involvement in a clinical trial statutorily exempted from infringement under § 271(e)(1), venue is improper. By the statute's express terms, such clinical trial activity does not constitute "an act of infringement." *Id*.

Plaintiff's argument that the safe harbor defense is irrelevant to venue under § 1400(b) (*see* Dkt. 184 at 13) is not supported by the law. According to Plaintiff, its mere allegations of infringing acts in the District make venue proper under § 1400(b), whether or not Defendants ultimately prevail on the safe harbor defense. *See id*. Not so. Both the venue statute and the safe harbor statute speak of "acts of infringement," not acts of "alleged" infringement, as Plaintiff would have it. If Plaintiff were right, any venue limitation could be overcome by simply making infringement accusations in the forum of the plaintiff's choice, regardless of the defendant's actual activities in that particular forum. This is contrary to law. Once the defendant comes forward with evidence that venue is improper, the plaintiff cannot rely on mere venue allegations in its complaint to maintain its chosen venue. *See Pierce v. Shorty Small's of Branson Inc.*, 137 F.3d 1190, 1192 (10th

Cir. 1998) (well-pleaded facts are accepted as true "only to the extent that such facts are uncontroverted by defendant's affidavit").

Moreover, the Court has already provided extensive analysis regarding the availability and applicability of a venue defense on the merits of the infringement claim even if such a claim survived "a preliminary determination of pro infringement" at the motion to dismiss stage. *See supra* Section. IV.A, *Dow Chemical Co. v. Monsanto Co.*, 315 F. Supp. 416.

Plaintiff has not alleged any facts showing activities in this District other than those statutorily exempted from infringement by § 271(e)(1). Although Plaintiff argues that Defendants stipulated to all the necessary facts of infringement (*see, e.g.*, Dkt. 175 at 2), Plaintiff's argument does not accurately reflect what is stated in the stipulation. The stipulation states: "Defendants will not contest in this case that this is a district where Defendants have sold accused products. (Defendants may, however, argue that any such sales are not acts of infringement, pursuant to 35 U.S.C. 271(e)(1))." Dkt. No. 43-1 at 1. Therefore, the stipulation does not support Plaintiff's claim of proper venue.

Plaintiff next argues that the safe harbor defense is "all or nothing" and to the extent Defendants make and sell accused products elsewhere in the United States for commercial purposes,[5] such uses are not "solely for uses reasonably related" to seeking FDA approval and Defendants are not entitled to any exemption at all under § 271(e)(1). Citing *American Standard Inc. v. Pfizer Inc.*, 722 F. Supp. 86, 103 (D. Del. 1989), as support, Plaintiff contends that if an "accused infringer makes or sells products for multiple uses, at least one of which is not related to

[5] *See, e.g.*, Dkt. 184 at 11 (citing Dkt. 184-4 (testifying valves built in the U.S. are distributed to commercial regions such as Europe and Canada); Dkt. 184-5 (distinguishing between commercial and non-commercial sales in Dkt. 184-6)).

FDA approval, then the exemption under section 271(e)(10 is lost completely." *See* Dkt. 184 at 14. However, the Court is not persuaded that *American Standard* supports Plaintiff's argument.

In *American Standard*, the defendants made accused products for both investigational and non-investigational uses. *Id*. Noting no difference in the products designed for investigational uses and those designed for non-investigational uses, the court concluded that the accused products were not used solely for investigative purposes. *American Standard*, 722 F. Supp. at 103. As an initial matter, the court in *American Standard* did not ultimately decide whether the accused products made for investigational use fell within the safe harbor.[6] *See id*. It is inherent in the court's analysis, however, that the safe harbor *could have* applied in the case of either activity. That is not the case here, as the infringing activity alleged by Plaintiff involves Defendants' sales overseas from outside the District. *See* Dkt. 192 at 10 ("[T]he valves implanted in the E.D. Texas have nothing to do with the valves made in Minnesota and sold overseas."). Accordingly, the relevant question here is not whether Defendants engaged in uses outside the District that are not "solely" or "reasonably related" to seeking FDA approval, but rather, whether Defendants have engaged in any such uses in *this* District so that venue is proper.

Furthermore, the Court finds clear direction in *Amgen* that each use of a patented invention "must be evaluated separately to determine whether the [Section 271(e)(1)] exemption applies." *Amgen*, 565 F.3d at 852; *see also NeoRx Corp. v. Immunomedics, Inc.*, 877 F. Supp. 202, 206 (D.N.J. 1994). In *NeoRx*, the court applied a two-part test: "(1) whether the activity at issue is a potentially infringing one; and (2) whether the exemption applies to that activity." *Id*. There, the court examined five activities, and concluded that some of the accused products fell within the safe harbor, while some of them did not, even though the accused products were all the same group

[6] Furthermore, the court did not need to resolve the issue because it ultimately held the patent was invalid and unenforceable. *See American Standard*, 722 F. Supp. at 152.

of products. *Id*. at 204 n.1, 206, 214; *cf. Classen Immunotherapies, Inc. v. Elan Pharm., Inc.*, 786 F.3d 892, 898 (Fed. Cir. 2015) (holding the defendant's clinical activities and FDA submissions fell under the safe harbor, but remanding for consideration of other, post-submission activities).

Based on the foregoing, the Court finds all acts of infringement in the Eastern District of Texas are solely clinical, and therefore, the § 271(e)(1) safe harbor applies despite purported non-exempt activity in Minnesota. Since there are no material factual questions on challenged activities remaining, summary judgment on the safe harbor issue is proper. Furthermore, no amount of additional discovery will change that fact. *See Paul Kadair, Inc. v. Sony Corp. of Am.*, 694 F.2d 1017, 1029-30 (5th Cir. 1983) ("[A] plaintiff's entitlement to discovery prior to a ruling on a motion for summary judgment is not unlimited, and may be cut off when the record shows that the requested discovery is not likely to produce the facts needed by plaintiff. . . .").

V. CONCLUSION AND RECOMMENDATION

For the foregoing reasons, the Court recommends that Defendants' Motion for Summary Judgment of Improper Venue (Dkt. 178) be **GRANTED**. Because this recommendation renders venue in this District deficient, the Court would have no authority to transfer the case to the District of Minnesota. Therefore, the Court recommends the case be **DISMISSED**.

Within fourteen (14) days after service of the magistrate judge's report, any party may serve and file written objections to the findings and recommendations of the magistrate judge. 28 U.S.C.A. § 636(b)(1)(C).

A party is entitled to a *de novo* review by the district court of the findings and conclusions contained in this report only if specific objections are made, and failure to timely file written objections to any proposed findings, conclusions, and recommendations contained in this report shall bar an aggrieved party from appellate review of those factual findings and legal conclusions

accepted by the district court, except on grounds of plain error, provided that the party has been served with notice that such consequences will result from a failure to object. *Id.; Thomas v. Arn*, 474 U.S. 140, 148 (1985); *Douglass v. United Servs. Auto Ass'n*, 79 F.3d 1415, 1417 (5th Cir. 1996) (en banc), *superseded by statute on other grounds*, 28 U.S.C. § 636(b)(1) (extending the time to file objections from ten to fourteen days).

SIGNED this 7th day of March, 2018.

KIMBERLY C. PRIEST JOHNSON
UNITED STATES MAGISTRATE JUDGE