IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

C R BARD, INC., BARD PERIPHERAL VASCULAR, INC.,

1:15CV218

MEMORANDUM AND ORDER

ANGIODYNAMICS INC.,

VS.

Defendant.

Plaintiffs,

This matter is before the Court on the following motions for summary judgment and motions to preclude testimony:

 Motion for Summary Judgment of Noninfringement of U.S. Patent No. 8,805,478 for Failure to Satisfy Indirect Infringement filed by AngioDynamics Inc., Filing No. 248;

2. Motion for Summary Judgment on Limitations of Damages for Failure to Mark and No Entitlement to Provisional Rights Damages filed by AngioDynamics Inc., Filing No. 249;

3. Motion for Summary Judgment Adjudication of Infringement of '417 Patent and Its Published Patent Application (The '951 Publication) filed by Bard Peripheral Vascular, Inc., Filing No. 250;

4. Motion for Summary Judgment Adjudication that the Asserted Claims are Enabled and Described Under Section 112 and No Anticipation Under Section 102 by the Iso-Med Prior Art Reference filed by Bard Peripheral Vascular, Inc., Filing No. 253; 5. Motion for Summary Judgment Adjudication that the Asserted Claims of the Patents-In-Suit Recite Patent Eligible Subject Matter Under <u>35 U.S.C. § 101</u> filed by Bard Peripheral Vascular, Inc., Filing No. 254;

6. Motion for Summary Judgment of Patent Ineligibility filed by AngioDynamics Inc., Filing No. 255;

 Motion for Summary Judgment of Invalidity filed by AngioDynamics Inc., Filing No. 256;

8. Motion to Preclude Expert Testimony of Dr. Vogelzang and Mr. Bakewell filed by Bard Peripheral Vascular, Inc., Filing No. 271;

9. Motion to Preclude the Testimony of Matthew Johnson, M.D. and Timothy Clark, M.D. filed by AngioDynamics Inc., Filing No. 274; and

10. Motion to Preclude the Testimony of Alan Cox, Ph.D. filed by AngioDynamics Inc., Filing No. 276.

I. BACKGROUND

Bard filed this lawsuit on March 10, 2015, alleging that AngioDynamics is liable for infringement of three patents: (1) U.S. Patent 8,475,417 (the "417 Patent"); (2) U.S. Patent 8,545,460 (the "460 Patent"); and (3) U.S. Patent 8,805,478 (the "478 Patent"). The '417 Patent issued on July 2, 2013. The application that led to the '417 Patent was published on September 10, 2009 as US 2009/0227951 A1 ("951 Publication"). The '951 Publication's claims are substantially identical to the '417 Patent's claims. The '460 Patent issued on October 1, 2013. The '478 Patent issued on August 12, 2014, and contains only method claims. *See* Amended Complaint, Filing No. 192.

II. STANDARD OF REVIEW

A. Summary Judgment

"The court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). The moving party bears the burden of demonstrating the absence of a genuine issue of material fact. *Matsushita Elec. Indus.* Co. v. Zenith Radio Corp., 475 U.S. 574, 586 n.10 (1986). A party asserting that a fact cannot be-or, alternatively, is-genuinely disputed must support the assertion either by citing to "particular parts of materials in the record, including depositions, documents, electronically stored information, affidavits or declarations, stipulations (including those made for the purposes of the motion only), admissions, interrogatory answers, or other materials," or by "showing that the materials cited do not establish the absence or presence of a genuine dispute, or that an adverse party cannot produce admissible evidence to support the fact." Fed. R. Civ. P. 56(c)(1)(A) & (B). If the moving party has carried its burden, the nonmovant must then "come forward with specific facts showing that there is a genuine issue for trial." Matsushita, 475 U.S. at 587 (internal quotation marks omitted). The court will "draw all reasonable inferences in favor of the nonmoving party, and it may not make credibility determinations or weigh the evidence." Reeves v. Sanderson Plumbing Prods., Inc., 530 U.S. 133, 150 (2000).

To defeat a motion for summary judgment, the non-moving party must "do more than simply show that there is some metaphysical doubt as to the material facts." *Matsushita*, 475 U.S. at 586-87. Although the "mere existence of some alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment," a factual dispute is genuine where "the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). "If the evidence is merely colorable, or is not significantly probative, summary judgment may be granted." *Id.* at 249-50 (internal citations omitted); *see also Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986) (stating entry of summary judgment is mandated "against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial").

B. Infringement

A patent is infringed when a person "without authority makes, uses, offers to sell, or sells any patented invention, within the United States ... during the term of the patent." 35 U.S.C. § 271(a). A two-step analysis is employed in making an infringement determination. *See Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995). First, the court must construe the asserted claims to ascertain their meaning and scope. *See id.* Construction of the claims is a question of law subject to de novo review. *See Cybor Corp. v. FAS Techs.*, 138 F.3d 1448, 1454 (Fed. Cir. 1998). The trier of fact must then compare the properly construed claims with the accused infringing product. *See Markman*, 52 F.3d at 976. This second step is a question of fact. *See Bai v. L & L Wings, Inc.*, 160 F.3d 1350, 1353 (Fed. Cir. 1998).

"Direct infringement requires a party to perform each and every step or element of a claimed method or product." *BMC Res., Inc. v. Paymentech, L.P.*, 498 F.3d 1373, 1378 (Fed. Cir. 2007), overruled on other grounds by *Akamai Technologies v. Limelight Networks, Inc.*, 692 F.3d 1301 (Fed. Cir. 2012). "If any claim limitation is absent from the accused device, there is no literal infringement as a matter of law." *Bayer AG v. Elan* *Pharm. Research Corp.*, 212 F.3d 1241, 1247 (Fed. Cir. 2000). If an accused product does not infringe an independent claim, it also does not infringe any claim depending thereon. *See Wahpeton Canvas Co. v. Frontier, Inc.*, 870 F.2d 1546, 1553 n.9 (Fed. Cir. 1989). However, "[o]ne may infringe an independent claim and not infringe a claim dependent on that claim." *Monsanto Co. v. Syngenta Seeds, Inc.*, 503 F.3d 1352, 1359 (Fed. Cir. 2007) (quoting *Wahpeton Canvas*, 870 F.2d at 1552) (internal quotations omitted). A product that does not literally infringe a patent claim may still infringe under the doctrine of equivalents if the differences between an individual limitation of the claimed invention and an element of the accused product are insubstantial. *See Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 24 (1997). The patent owner has the burden of proving infringement and must meet its burden by a preponderance of the evidence. *See SmithKline Diagnostics, Inc. v. Helena Lab. Corp.*, 859 F.2d 878, 889 (Fed. Cir. 1988) (citations omitted).

When an accused infringer moves for summary judgment of non-infringement, such relief may be granted only if one or more limitations of the claim in question does not read on an element of the accused product, either literally or under the doctrine of equivalents. See *Chimie v. PPG Indus., Inc.*, 402 F.3d 1371, 1376 (Fed. Cir. 2005); see also *TechSearch, L.L.C. v. Intel Corp.*, 286 F.3d 1360, 1369 (Fed. Cir. 2002) ("Summary judgment of noninfringement is ... appropriate where the patent owner's proof is deficient in meeting an essential part of the legal standard for infringement, because such failure will render all other facts immaterial."). Thus, summary judgment of non-infringement can only be granted if, after viewing the facts in the light most favorable to the non-movant, there is no genuine issue as to whether the accused product is

covered by the claims (as construed by the court). *See Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1304 (Fed. Cir. 1999).

"[A] method claim is not directly infringed by the sale of an apparatus even though it is capable of performing only the patented method. The sale of the apparatus is not a sale of the method. A method claim is directly infringed only by one practicing the patented method." *Joy Technologies, Inc. v. Flakt, Inc.*, 6 F.3d 770, 775 (Fed. Cir. 1993). Therefore, "the accused infringer must perform all the steps of the claimed method, either personally or through another acting under his direction or control."

Akamai Technologies, Inc. v. Limelight Networks, Inc., 692 F.3d 1301, 1307 (Fed. Cir. 2012).

With respect to apparatus claims, "to infringe a claim that recites capability and not actual operation, an accused device 'need only be capable of operating' in the described mode. " *Finjan, Inc. v. Secure Computing Corp.*, 626 F.3d 1197, 1204 (Fed. Cir. 2010) (citing *Intel Corp. v. U.S. Int'l Trade Comm'n*, 946 F.2d 821, 832 (Fed. Cir. 1991). However, if an apparatus claim requires "software [to] be configured in a particular way to infringe," infringement does not occur merely because the apparatus could be used in an infringing fashion. *Finjan*, 626 F.3d at 1204-05.

C. Anticipation

Under 35 U.S.C. § 102(b), "[a] person shall be entitled to a patent unless-

(1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention; or

(2) the claimed invention was described in a patent issued under section 151, or in an application for patent published or deemed published under section 122(b), in which the patent or application, as the case may be,

names another inventor and was effectively filed before the effective filing date of the claimed invention."

The Federal Circuit has stated that "[t]here must be no difference between the claimed invention and the referenced disclosure, as viewed by a person of ordinary skill in the field of the invention. In determining whether a patented invention is explicitly anticipated, the claims are read in the context of the patent specification in which they arise and in which the invention is described. *Glaverbel Societe Anonyme v. Northlake Mktg. & Supply, Inc.*, 45 F.3d 1550, 1554 (Fed. Cir. 1995). The prosecution history and the prior art may be consulted if needed to impart clarity or to avoid ambiguity in ascertaining whether the invention is novel or was previously known in the art. *Id.* The prior art need not be ipsissimis verbis (i.e., use identical words as those recited in the claims) to be anticipating. *Structural Rubber Prods. Co. v. Park Rubber Co.*, 749 F.2d 707, 716 (Fed. Cir. 1984).

A prior art reference also may anticipate without explicitly disclosing a feature of the claimed invention if that missing characteristic is inherently present in the single anticipating reference. *Continental Can Co. v. Monsanto Co.*, 948 F .2d 1264, 1268 (Fed. Cir. 1991). The Federal Circuit has explained that an inherent limitation is one that is necessarily present and not one that may be established by probabilities or possibilities. *Id.* That is, "[t]he mere fact that a certain thing may result from a given set of circumstances is not sufficient." *Id.* at 1269. The Federal Circuit also has observed that "inherency operates to anticipate entire inventions as well as single limitations within an invention." *Schering Corp. v. Geneva Pharms. Inc.*, 339 F.3d 1373, 1380 (Fed. Cir. 2003). Moreover, recognition of an inherent limitation by a person of ordinary skill in

the art before the critical date is not required to establish inherent anticipation. *Id.* at 1377. An anticipation inquiry involves two steps. First, the court must construe the claims of the patent in suit as a matter of law. *Key Pharms. v. Hercon Labs Corp.*, 161 F.3d 709, 714 (Fed. Cir. 1998). Second, the finder of fact must compare the construed claims against the prior art. *Id.* A finding of anticipation will invalidate the patent.

Applied Med. Res. Corp. v. U.S. Surgical Corp., 147 F.3d 1374, 1378 (Fed. Cir. 1998).

III. DISCUSSION

a. <u>Motion for Summary Judgment of Noninfringement of U.S. Patent No.</u> <u>8,805,478 for Failure to Satisfy Indirect Infringement filed by AngioDynamics Inc., Filing</u> <u>No. 248</u>

AngioDynamics moves for summary judgment of noninfringement, contending that Bard has failed to show a prima facie infringement. Further, AngioDynamics argues that Bard has failed to demonstrate that the Smart Port CT and Smart Port LP products meet two express claim limitations of the Asserted Claims. AngioDynamics also contends that the record fails to show actual use by a direct infringer, and Bard has not proven induced infringement of the '478 patent.

Bard responds arguing that (1) AngioDynamics already admitted that the accused products infringe the asserted claims of the '417 Patent; (2) AngioDynamics's tortured reading of the court's claim construction should be rejected in any event; and (3) AngioDynamics improperly repeats rejected non-enablement arguments in its opposition to Bard's motion for summary judgment of the '417 Patent. Bard contends that AngioDynamics is merely attempting to re-argue claim construction. Further, Bard

argues it has produced substanttial evidence of direct infringement with regard to the '478 patent.

A patentee "bears the burden of proving infringement." *Medtronic, Inc. v. Mirowski Family Ventures, LLC,* 134 S. Ct. 843, 845-46 (2014). An "infringement analysis is 'a two-step process in which'" the Court "first determine[s] the correct claim scope, and then compare[s] the properly construed claim to the accused device to determine whether all of the claim limitations are" literally present. *TechSearch, L.L.C. v. Intel Corp.*, 286 F.3d 1360, 1371 (Fed. Cir. 2002) (citation omitted). "To establish literal infringement, all of the elements of the claim, as correctly construed, must be present in the accused system." *Id.* Consequently, "specific claim limitations cannot be ignored as insignificant or immaterial in determining infringement." *Id.* at 1373.

It a appears from a review of Judge Robinson's claim construction order as well as the arguments of counsel, that Judge Robinson identified the terms and limitations in this regard. The Court will follow the instructions of Judge Robinson. The Court likewise incorporates the arguments and analysis in sections "b" and "c" herein into this section. The issues are overlapping on a number of the claims. In addition to following Judge Robinson's determinations, the Court finds that the majority of the remaining claims are material issues of fact. Both sides appear to have arguments and evidence to support their positions. It is not the role of this Court to weigh the evidence prior to trial. For these reasons, the Court finds that the motion for summary judgment must be denied and the claims will proceed to trial.

b. <u>Motion for Summary Judgment on Limitations of Damages for Failure to Mark</u> and No Entitlement to Provisional Rights Damages filed by AngioDynamics Inc., Filing <u>No. 249</u>

There are two patents at issue in this motion, the '478 patent and the '951 Publication. The '478 patent and its '951 Publication are at issue. Defendant, Counterclaim-Plaintiff, and Crossclaim/Third-Party Complaint Plaintiff AngioDynamics, Inc., moves for summary judgment. In its supporting brief, Filing No. 288, AngioDynamics argues that Bard cannot recover damages for infringement occurring before March 10, 2015, the filing date of the original Complaint, because Bard failed to provide actual or constructive notice of infringement. Bard contends that AngioDynamics must show that it provided: 1) actual notice of alleged infringement, or (2) constructive notice by adequately marking its patent-embodying products. 35 U.S.C. either requirement, Bard cannot satisfy argues AngioDynamics. §. 287(a). AngioDynamics contends that no actual notice was given until Bard filed this Complaint on March 10, 2015. AngioDynamics contends that it is undisputed that Bard failed to mark its PowerPort products until September 29, 2014, and that Bard failed to mark its Vaccess CT products until August 3, 2017, and in fact attempted to conceal this fact during discovery. Thus, AngioDynamics contends that the failure to comply with the marking requirements of 35 U.S.C. § 287(a) compels the conclusion that the Court should enter judgment finding Bard may not recover pre-suit damages.

AngioDynamics relies on § 287(a) in support of its arguments. The statute states:

Patentees ... may give notice to the public that the same is patented, either by fixing thereon the word "patent" or the abbreviation "pat.", together with the number of the patent ... In the event of failure so

to mark, no damages shall be recovered by the patentee in any action for infringement, except on proof that the infringer was notified of the infringement and continued to infringe thereafter, in which event damages may be recovered only for infringement occurring after such notice.

35 U.S.C. § 287(a).

Bard, it argues, clearly has a duty to notify the public of its embodying products. The statute serves three purposes: "(1) helping to avoid innocent infringement; (2) encouraging patentees to give public notice that the article is patented; and (3) aiding the public to identify whether an article is patented." *Arctic Cat Inc. v. Bombardier Recreational Products Inc.*, 876 F.3d 1350, 1366 (Fed. Cir. 2017) (citing *Nike, Inc. v. Wal–Mart Stores, Inc.*, 138 F.3d 1437, 1443 (Fed. Cir. 1998); *Amsted Indus. Inc. v. Buckeye Steel Castings Co.*, 24 F.3d 178, 187 (Fed. Cir. 1994) (focus is on the action of the patentee). As stated in *Arctic Cat*:

The patentee bears the burden of pleading and proving he complied with § 287(a)'s marking requirement. *Maxwell v. J. Baker, Inc.*, 86 F.3d 1098, 1111 (Fed. Cir. 1996); *see also Dunlap*, 152 U.S. at 248, 14 S.Ct. 576 ("[T]he duty of alleging and the burden of proving either [actual or constructive notice] is upon the [patentee]."). Whether a patentee's articles have been marked "is a matter peculiarly within his own knowledge" *Dunlap*, 152 U.S. at 248, 14 S.Ct. 576. If a patentee who makes, sells, offers for sale, or imports his patented articles has not "given notice of his right" by marking his articles pursuant to the marking statute, he is not entitled to damages before the date of actual notice. *Id.*; *see also* 35 U.S.C. § 287 (noting the patentee's "failure so to mark" limits his damages to those incurred after actual notice). Section 287 is thus a limitation on damages, and not an affirmative defense. *Motorola, Inc. v. United States*, 729 F.2d 765, 770 (Fed. Cir. 1984). Compliance with § 287 is a question of fact. *Maxwell*, 86 F.3d at 1111.

Arctic Cat, 876 F.3d at 1366.

AngioDynamics also argues that the patent statute prohibits recovering damages through provisional rights. AngioDynamics further contends that Congress has not chosen to provide a provisional rights exception pursuant to § 287(a). Section 154(d) provides for a reasonable royalty that takes place before the patent issues. 35 U.S.C. § 154(d). *See Rosebud LMS Inc. v. Adobe Sys. Inc.*, 812 F.3d 1070, 1075 (Fed. Cir. 2016) (court interprets actual notice requirement of § 154(d) to include actual knowledge of the published patent application).

Bard responds and argues that AngioDynamics ignores its right to seek pre-suit damages for infringement of its '478 method patent, as well as its right to seek pre-suit provisional rights damages for infringement of the '951 Publication. Section 287, contends Bard, only applies to patents that have apparatus claims, not to patents that only contain methods claims. Patent '478 is only a methods claim, and thus, Bard argues that § 287's notice requirements to not apply.

With regard to the provisional rights damages under 35 U.S.C. § 154(d) for AngioDynamic's infringement of the '951 Publication claims, products do not have to be marked, according to Bard, nor otherwise notify the infringer of infringement before requesting the provisional damages. Section 287's marking requirement, argues Bard, is wholly inapplicable to provisional damages under § 154(d). Bard concedes that it did not mark its embodying products. Section 154(d) provides for a reasonable royalty that takes place before the patent issues. 35 U.S.C. § 154(d). *See Rosebud LMS Inc.*, 812 F.3d at 1075.

The Court agrees with Bard to the extent the '478 is a method patent. Bard may seek pre-suit damages for infringement of the '478 patent beginning August 12, 2014.

Section 287 is inapplicable to method patents. "The law is clear that the notice provisions of § 287 do not apply where the patent is directed to a process or method."

Crown Packaging Tech., Inc. v. Rexam Beverage Can Co., 559 F.3d 1308, 1316 (Fed.

Cir. 2009). "In *Hanson*, 718 F.2d at 1082–83, we held that 35 U.S.C. § 287(a) did not

apply where the patentee only asserted the method claims of a patent which included

both method and apparatus claims. Hanson is factually identical to this case, and we

are therefore bound by the rule of *Hanson*." *Id.* Further, the Court stated:

However, "[t]he law is clear that the notice provisions of § 287 do not apply where the patent is directed to a process or method." *Fujitsu Ltd. v. Netgear Inc.*, 620 F.3d 1321, 1332 (Fed.Cir.2010) (quoting *Crown Packaging Tech., Inc. v. Rexam Beverage Can Co.*, 559 F.3d 1308, 1316 (Fed.Cir.2009)); *see also Crystal Semiconductor Corp. v. TriTech Microelectronics Int'l, Inc.*, 246 F.3d 1336, 1353 (Fed.Cir.2001) ("Because the [asserted] patent only claims methods, the notice provisions of § 287(a) do not apply to it."); *Am. Med. Sys., Inc. v. Med. Eng'g Corp.*, 6 F.3d 1523, 1538 (Fed.Cir.1993); *Hanson v. Alpine Valley Ski Area, Inc.*, 718 F.2d 1075, 1083 (Fed.Cir.1983) ("It is 'settled in the case law that the notice requirement of [§ 287(a)] does not apply where the patent is directed to a process or method.' " (quoting *Bandag, Inc. v. Gerrard Tire Co.*, 704 F.2d 1578, 1581 (Fed.Cir.1983))). The demarcation lines have been clear for many years: patents with only method claims do not require marking whereas patents with apparatus claims do.

In *American Medical,* we held that if a single patent contains both apparatus claims and method claims, the marking requirement applies to all the claims:

Where the patent contains both apparatus and method claims, however, to the extent that there is a tangible item to mark by which notice of the asserted method claims can be given, a party is obliged to do so if it intends to avail itself of the constructive notice provisions of section 287(a). *Am. Med.*, 6 F.3d at 1538.

ActiveVideo Networks, Inc. v. Verizon Communications, Inc., 694 F.3d 1312, 1334 (Fed.

Cir. 2012). The ActiveVideo Court concluded by reaffirming that: "if the patent is

directed only to method claims, marking is not required." *Id.* at 1335. Accordingly, to the extent the '478 patent is a methods patent, Bard may pursue its pre-notice remedies.

The Court also agrees with Bard that it may seek provisional damages for AngioDynamics's infringement of the '951 Publication's claims, beginning on the date AngioDynamics became aware of the '951 Publication until the date the '417 Patent issued on July 2, 2013. Section 154(d) is operative prior to the time the patent issues. A patentee is permitted to obtain a royalty from someone who during the time between publication and issuance infringes any of the claims in the published patent application. 35 U.S.C. § 154(d).

The Court finds the remaining claims are factual in nature, are material, and are clearly disputed. Consequently, these issues will be determined at trial.

c. <u>Motion for Summary Judgment Adjudication of Infringement of '417 Patent and</u> <u>Its Published Patent Application (The '951 Publication) filed by Bard Peripheral</u> Vascular, Inc., Filing No. 250

Pursuant to Federal Rule of Civil Procedure 56(a), Plaintiff Bard Peripheral Vascular, Inc. hereby moves the Court for summary adjudication of infringement of claims 5, 6, 12, and 13 of U.S. Patent No. 8,475,417 ("the '417 Patent") as to the Smart Port CT and LP products. Bard also moves for summary adjudication that it has met the requirements of 35 U.S.C. § 154(d) to seek provisional rights damages from AngioDynamics for its infringement of the published patent application of the '417 Patent (Patent Publication No. U.S. 2009/0227951.) With regard to the last issue, the

Court has already determined that Bard can seek provisional rights damages under 35 U.S.C. § 154(d) for the '417 patent as stated herein.

Bard contends that the '417 Patent "are directed to an assembly for identifying a power injectable vascular access port. A power injectable port is a subcutaneously implanted port that allows fluids to be injected into a patient's body via power injection, for example contrast media at high fluid flow rates when performing CT scans. The '417 Patent notes that "conventional ports" could not tolerate the pressure rates associated with power injection." Filing No. 251, at 5. The '417 Patent uses multiple methods to use the port as a power injectable. Bard contends it incorporated the inventions of the '417 Patent into its PowerPort products, first used in 2006. Bard argues that AngioDynamics copied these inventions. Bard contends that AngioDynamics has admitted to knowledge of the published application, and thus it is entitled to seek the provisional rights damages under § 154(d).

Damages under § 154(d) require showing: (1) the infringement action was filed no later than six years after the patent issues, (2) the infringer had actual notice of the published application, and (3) the invention claimed in the issued patent is substantially identical to the invention claimed in the published application. 35 U.S.C. § 154(d). The patent application for the '417 Patent was published on September 10, 2009 as U.S. 2009/0227951 ("'951 Publication"). Bard contends that AngioDynamics had actual notice of the '951 Publication before the issuance of the '417 Patent, the Smart Port CT and LP products infringe claim 6 of the '951 Publication for the same reasons they infringe claim 5 of the '417 Patent.

Dr. Timothy Clark is Bard's expert in this regard. He intends to testify and is familiar with the accused Smart Port products, as he placed somewhere in the neighborhood of one thousand of these ports in patients in the 2010 to 2013 timeframe.

AngioDynamics argues that Bard has failed to show a prima facie case and is not entitled to summary judgment on this issue. Further, AngioDynamics contends that it does not induce others to infringe the method claims of the '478 patent, because a single entity does not perform each of the method steps, and the provisional rights exception is inapplicable. This argument is based on AngioDynamics allegation that Bard materially changed the originally published claims during prosecution, has failed to prove that AngioDynamics had actual knowledge of the published application, and Bard can only ask for a reasonable royalty, not disgorgement of AngioDynamic's profits. Further, AngioDynamics contends that Bard has failed to show actual use by a direct infringer.

The Court has carefully reviewed the claims and the scope of the claims and finds that Bard is entitled to proceed with this claim to trial. However, the Court does not find that the motion for summary judgment should be granted. The patentee bears the burden of proving infringement. *Medtronic, Inc. v. Mirowski Family Ventures, LLC*, 134 S. Ct. 843, 849 (2014). There are material facts in dispute including the scope of the differences in the patent and the publication, the actual infringement, and the existence of actual knowledge on the part of AngioDynamics. *K-Tec, Inc. v. Vita-Mix Corp.*, 2010 WL 2079682, at *7 (D. Utah May 24, 2010) ("Actual notice is a question of fact for the jury.") (citation omitted). The Court will deny the motion for summary judgment, and it will allow these issues to proceed to trial.

d. <u>Motion for Summary Judgment Adjudication that the Asserted Claims are</u> <u>Enabled and Described Under Section 112 and No Anticipation Under Section 102 by</u> <u>the Iso-Med Prior Art Reference filed by Bard Peripheral Vascular, Inc., Filing No. 253</u> <u>AND Motion for Summary Judgment of Invalidity filed by AngioDynamics Inc., Filing No.</u> <u>256</u>

Bard contends the Court should grant summary judgment pursuant to Fed. R. Civ. P. 56(a) on the basis that the asserted claims of the Patents-in-Suit are enabled and adequately described under 35 U.S.C. § 112.¹ Bard also moves for summary judgment arguing that the asserted claims of the Patents-in-Suit are not anticipated by the Iso-Med prior art system or publications under 35 U.S.C. § 102. AngioDynamics moves for summary judgment based on issues regarding validity. The parties filed combined briefs in support of their respective motions and against the summary judgment motion of the other.

"The test for sufficiency of a written description is 'whether the disclosure clearly allow[s] persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed." *Crown Packaging Tech., Inc. v. Ball Metal Beverage Container Corp.*, 635 F.3d 1373, 1380 (Fed. Cir. 2011) (citations omitted). "The disclosure must 'reasonably convey[] to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date." *Id.* "The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the

¹ Bard has asserted claims 5, 6, 12, and 13 of U.S. Patent No. 8,475,417, claims 2 and 4 of U.S. Patent No. 8,545,460 and claims 3, 5, 9, and 11 of U.S. Patent No. 8,805,478.

patent coupled with information known in the art without undue experimentation." *United States v. Telectronics, Inc.*, 857 F.2d 778, 785 (Fed. Cir. 1988).

Bard first contends that AngioDynamic's motion for summary judgment should be dismissed, as its anticipation motion must fail. AngioDynamics argues that the anticipation claim is valid for a number of reasons under 35 U.S.C. § 302. AngioDynamics also indicates that Bard's arguments are factually inaccurate. The asserted claims recite identifiable features that identify an access port as being structured for power injection. Bard also argues that AngioDynamics fails to show that the prior art had the attributes that necessarily function as identifiable features. In fact, argues Bard, material disputes of fact exist as to this issue.

Bard contends that AngioDynamics has not shown anticipation claims reciting "Radiographic Letters" or a "Typographical Character". Bard argues that the dependent claims of '417 and '478 require Radiographic letters and '450 Patent talks about both. Thus, asserts Bard, AngioDynamics' motion fails as to claims 5 and 12 of the '417 Patent and claims 3 and 9 of the '478 Patent and claim 4 of the '460 Patent. Bard also argues that the Iso-med Pump does not anticipate any claims. Bard contends that AngioDynamics first stated that the Smart Port:

"was released with no indicators that could identify it as CT [i.e., power injection] compatible," even though it had attributes that may appear on an x-ray such as a shape, a septum ring, and suture holes. These are the same attributes that AngioDynamics's expert now speculates "could be used for radiographic identification." Yet AngioDynamics provides no evidence showing that they were ever used for identification. Thus, AngioDynamics is left arguing only inherent anticipation, but it ignores that inherent anticipation "may not be established by probabilities or possibilities." *HTC Corp. v. Cellular Commc'ns Equip.*, LLC, 877 F.3d 1361, 1369 (Fed. Cir. 2017).

Filing No. 285, at 6. Second Bard argues that AngioDynamics initially admitted via its expert that there was no identifiable feature for an access port, but now asks this Court to make a factual finding that the ports did in fact have identifiable features.

Further, Bard says AngioDynamics non-enablement claim is without merit. "The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation." *Telectronics, Inc.*, 857 F.2d at 785.

Bard contends the correct legal standard is set forth in its summary judgment motion which uses the undue experimentation test. Bard also moves for summary judgment contending its claims are adequately described under Section 112, and there exists no factual disputes regarding whether Bard possessed the inventions.

AngioDynamics files its motion for summary judgment, Filing No. 256, and contends Port-A-Cath anticipates the Asserted Claims; Bard's Adult Titanium anticipates all the Asserted Claims; and the specification fails to explain how any perceivable attribute or identifiable feature is, or would become, associated with power injection. AngioDynamics moves this Court to grant summary judgment of invalidity. The crux of the argument centers around whether the claimed "identifiable features", which are construed as "perceivable attributes" "that are either incorporated into the access port (e.g., radiographic markers) or separate from the access port—render the claims patentable." Filing No. 257, at 6.

After carefully reading the briefs, the evidence, and the relevant caselaw, the Court concludes that there are material facts on each of these issues that should proceed to trial. *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247-48 (1986) (a

factual dispute is genuine where "the evidence is such that a reasonable jury could return a verdict for the nonmoving party."). The Court finds the evidence presented is material and conflicting and will be determined at trial. The Court will deny both summary judgment motions.

e. Motion for Summary Judgment Adjudication that the Asserted Claims of the <u>Patents-In-Suit Recite Patent Eligible Subject Matter Under</u> 35 U.S.C. § 101 filed by <u>Bard Peripheral Vascular, Inc., Filing No. 254, AND Motion for Summary Judgment of</u> <u>Patent Ineligibility filed by AngioDynamics Inc., Filing No. 255</u>

Bard files this motion for summary judgment adjudication that the asserted claims of the patents-in-suit recite patent eligible subject matter under 35 U.S.C. § 101. First, the Supreme Court's patent-eligibility test determines whether claims are "directed to" abstract ideas. *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 134 S. Ct. 2347, 2358-59 (2014). AngioDynamics, argues Bard, errs in attempting to recognize the structural limitations of Bard's claims instead of viewing them as a "character as a whole." *Enfish, LLC v. Microsoft Corp.*, 822 F.3d 1327, 1335 (Fed. Cir. 2016). "The second step of the *Alice* test is satisfied when the claim limitations involve more than performance of well-understood, routine, and conventional activities previously known to the industry." *Berkheimer v. HP Inc.*, 881 F.3d 1360, 1367 (Fed. Cir. 2018) (internal quotations omitted) (quoting *Alice*, 134 S. Ct. at 2359). "[W]hether a claim element or combination of elements is well-understood, routine and conventional to a skilled artisan in the relevant field is a question of fact." *Berkheimer*, 881 F.3d at 1368.

Bard contends that the claims are patent eligible and summary judgment should be granted. Bard asserts that the subject matter, structural improvements to vascular access ports, are directed to tangible power-injectable access points. Bard further argues that its claims do not cover generic port labeling, but instead are specifically structured to identify the port as suitable for power injection. For these reasons, Bard asks this Court to determine that its claims are patent-eligible.

With regard to AngioDynamics' motion alleging that the asserted claims are patent-ineligible, Bard contends that this is a question of fact. The Federal Circuit has held that the *Alice* Step 2 inquiry into whether claim limitations were well-known, routine, and conventional presents a question of fact. *Exergen Corp. v. Kaz USA, Inc.*, 2018 WL 1193529, at *4-5 (Fed. Cir. March 8, 2018); *Aatrix Software, Inc., v. Green Shades Software, Inc.*, 882 F.3d 1121, 1126-30 (Fed. Cir. 2018); *Berkheimer*, 881 F.3d at 1368. AngioDynamics, however, disagrees with all arguments by Bard. AngioDynamics argues that the identifiable features cannot be a source of inventiveness too. It further argues that the claimed subject matter fails to solve a problem that is unique to the port technology and fails to describe a new approach. Thus, AngioDynamics contends the Asserted Claims are patent ineligible under 35 U.S.C. § 101.

The Court has carefully reviewed the motions, briefs in favor and in opposition, and the evidence exhibits. The Court determines that the parties are arguing over issues that are clearly factual in nature, are material, and are disputed. Accordingly, the Court shall deny both motions and will permit this issue to proceed to trial.

f. <u>Motion to Preclude Expert Testimony of Dr. Vogelzang and Mr. Bakewell filed</u> by Bard Peripheral Vascular, Inc., Filing No. 271; Motion to Preclude the Testimony of <u>Matthew Johnson, M.D. and Timothy Clark, M.D. filed by AngioDynamics Inc., Filing</u> No. 274; and Motion to Preclude the Testimony of Alan Cox, Ph.D. filed by

AngioDynamics Inc., Filing No. 276.

The Third Circuit has "explained that Rule 702 embodies a trilogy of restrictions

on expert testimony: qualification, reliability and fit":

Qualification refers to the requirement that the witness possess specialized expertise. We have interpreted this requirement liberally, holding that "a broad range of knowledge, skills, and training qualify an expert." Secondly, the testimony must be reliable; it "must be based on the 'methods and procedures of science' rather than on 'subjective belief or unsupported speculation'; the expert must have 'good grounds' for his on [sic] her belief. In sum, *Daubert* holds that an inquiry into the reliability of scientific evidence under Rule 702 requires a determination as to its scientific validity." Finally, Rule 702 requires that the expert testimony must fit the issues in the case. In other words, the expert's testimony must be relevant for the purposes of the case and must assist the trier of fact.

Schneider ex rel. Estate of Schneider v. Fried, 320 F.3d 396, 404 (3d Cir. 2003)

(internal citations omitted).

In *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 589 (1993), the "Supreme Court assigned to the district courts the responsibility of ensuring that all expert testimony" pertaining to "scientific, technical, or other specialized knowledge' under Federal Rule of Evidence ('FRE') 702" is "based on a firm scientific or technical grounding." *Uniloc U.S.A., Inc. v. Microsoft Corp.*, 632 F.3d 1292, 1315 (Fed. Cir. 2011). "The party offering the expert testimony bears the burden of proving admissibility." *EMC Corp. v. Pure Storage, Inc.*, 154 F. Supp. 3d 81, 92 (D. Del. 2016) (citing *Daubert*, 509 U.S. at 592 n.10).

An expert's opinion is reliable if it is "based on the 'methods and procedures of science' rather than on 'subjective belief or unsupported speculation'; the expert must have 'good grounds' for his or her belief." *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 742 (3d Cir. 1994) (quoting *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 590 (1993)). The Third Circuit allows "expert testimony concerning business customs and practice[.]" *U.S. v. Leo*, 941 F.2d 181, 196 (3d Cir. 1991). "Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means" a party may use to contest an opposing expert's opinion. *Daubert*, 509 U.S. at 596. Thus, a *Daubert* motion should be denied when the movant's arguments "go to the weight to be accorded" the expert's testimony "rather than its admissibility." *Kraft Foods Grp. Brands LLC v. TC Heartland, LLC*, 232 F. Supp. 3d 632, 635 (D. Del. 2017).

The "court, in its role as gatekeeper, must exclude expert testimony that is not reliable and not specialized, and which invades the province of the jury to find facts and that of the court to make ultimate legal conclusions." *Sundance, Inc. v. DeMonte Fabricating Ltd.*, 550 F.3d 1356, 1364 (Fed. Cir. 2008). With respect to the issue in this motion, "it is improper to argue claim construction to the jury" because of the high risk of jury confusion. *Cordis Corp. v. Boston Sci. Corp.*, 561 F.3d 1319, 1337 (Fed. Cir. 2009). Further, an "expert must set forth the factual foundation for his infringement opinion in sufficient detail for the court to be certain that features of the accused product would support a finding of infringement under the claim construction adopted by the court[.]" *Intellectual Sci. & Tech., Inc. v. Sony Elecs., Inc.*, 589 F.3d 1179, 1183 (Fed. Cir. 2009).

1. <u>Motion to Preclude Expert Testimony of Dr. Vogelzang and Mr. Bakewell</u> filed by Bard Peripheral Vascular, Inc., Filing No. 271 Bard moves to preclude Dr. Robert Vogelzang and Mr. Christopher Bakewell from testifying. Bard argues that these two experts misapply the law regarding the single reference standard, anticipation, obviousness, claim construction, wrongly rely on later patents, and offer opinions beyond his technical expertise. Both of these experts, argues Bard, make the same mistake with regard to non-infringing alternatives.

AngioDynamics answers, contending that the arguments made by Bard are legally and factually flawed, is a scattershot *Daubert* challenge, and much of the testimony goes to weight and not to admissibility.

The Court has carefully reviewed the arguments of the parties. The Court finds that both Dr. Vogelzang and Mr. Bakewell are qualified experts. The arguments made by Bard are in large measure those that need to be decided at trial. The experts will be required at trial to apply the correct claim constructions and will be required comply with the law. There will be no speculation. Mere disagreements will go to the weight of the evidence.² Accordingly, the *Daubert* motion is denied at this time.

2. <u>Motion to Preclude the Testimony of Matthew Johnson, M.D. and Timothy</u> <u>Clark, M.D. filed by AngioDynamics Inc., Filing No. 274</u>

AngioDynamics moves to preclude the testimony of Matthew Johnson, M.D. and Timothy Clark, M.D. AngioDynamics argues that Dr. Johnson applies a subjective knowledge requirement that is contrary to the Court's claim construction; his opinions improperly distinguish the prior art; and he seeks to read a knowledge requirement into the structural access port limitations.

² Further, a *Daubert* motion is not intended for a mini trial. It is intended to discern if the expert is in fact qualified to testify. The parties in all three of these *Daubert* motions have attempted to try many aspects of their case in these motions. This is not the proper way to argue *Daubert* motions.

Bard responds and contends AngioDynamics is attempting to undo the claim construction and misstating the facts and law. Again, as in the previous *Daubert* motion, the Court reiterates the following: these arguments primarily go to the weight of the expert testimony. To the extend the parties attempt to change the claim construction, misapply the law, or speculate, the Court will not permit it. Accordingly, the *Daubert* motion is denied at this time.

3. <u>Motion to Preclude the Testimony of Alan Cox, Ph.D. filed by AngioDynamics</u> Inc., Filing No. 276

AngioDynamics moves to preclude the testimony of Alan Cox, Ph.D, arguing that Cox offers an unrealistic and inflated opinion of damages. First, Cox fails to apportion the value of the actual patented improvement as required by law. Second, Bard would only be entitled to a reasonable royalty and lost profits, but not a disgorgement of profits as argued by Cox. Third, Dr. Cox allegedly uses inappropriate analytical techniques.

Bard contends that Dr. Cox's Georgia-Pacific analysis is appropriate under the law. Cox does not, argue Bard, advocate for disgorgement of profits. He correctly included kit components in the royalty base. Cox also, contends Bard, uses a labeling approach that is consistent with the claim construction in this case. His testimony will be based on the patent description, asserts Bard.

The Court has carefully reviewed the arguments and purported testimony of Dr. Cox. At this point the Court finds it is admissible at trial. To the extent that the testimony is not admissible at trial, an objection can be made at that time. (See footnote 3.)

THEREFORE, IT IS ORDERED THAT:

1. Motion for Summary Judgment of Noninfringement of U.S. Patent No. 8,805,478 for Failure to Satisfy Indirect Infringement filed by AngioDynamics Inc., Filing No. 248, is denied;

2. Motion for Summary Judgment on Limitations of Damages for Failure to Mark and No Entitlement to Provisional Rights Damages filed by AngioDynamics Inc., Filing No. 249, is denied;

3. Motion for Summary Judgment Adjudication of Infringement of '417 Patent and Its Published Patent Application (The '951 Publication) filed by Bard Peripheral Vascular, Inc., Filing No. 250, is denied.

4. Motion for Summary Judgment Adjudication that the Asserted Claims are Enabled and Described Under Section 112 and No Anticipation Under Section 102 by the Iso-Med Prior Art Reference filed by Bard Peripheral Vascular, Inc., Filing No. 253, is denied;

5. Motion for Summary Judgment Adjudication that the Asserted Claims of the Patents-In-Suit Recite Patent Eligible Subject Matter Under 35 U.S.C. § 101 filed by Bard Peripheral Vascular, Inc., Filing No. 254, is denied;

6. Motion for Summary Judgment of Patent Ineligibility filed by AngioDynamics Inc., Filing No. 255, is denied;

 Motion for Summary Judgment of Invalidity filed by AngioDynamics Inc., Filing No. 256, is denied;

8. Motion to Preclude Expert Testimony of Dr. Vogelzang and Mr. Bakewell filed by Bard Peripheral Vascular, Inc., Filing No. 271, is denied at this time and subject to reassertion at trial;

9. Motion to Preclude the Testimony of Matthew Johnson, M.D. and Timothy Clark, M.D. filed by AngioDynamics Inc., Filing No. 274, is denied at this time and subject to reassertion at trial; and

10. Motion to Preclude the Testimony of Alan Cox, Ph.D. filed by AngioDynamics Inc., Filing No. 276, is denied at this time and subject to reassertion at trial.

Dated this 26th day of June, 2018.

BY THE COURT:

<u>s/ Joseph F. Bataillon</u> Senior United States District Judge