

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

BARD PERIPHERAL VASCULAR, INC.,)

Plaintiff and Counterclaim-)
Defendant,)

v.)

ANGIODYNAMICS, INC.,)

Defendant and Counterclaim-)
Plaintiff.)

C.A. No. 15-218-JFB-SRF

~~UNDER SEAL~~

*Unsealed per
2/19/19 oral order*

(ut)

REPORT AND RECOMMENDATION

I. INTRODUCTION

In this patent infringement action filed by plaintiff and counterclaim-defendant Bard Peripheral Vascular, Inc. (“Bard”) against defendant and counterclaim-plaintiff AngioDynamics, Inc. (“AngioDynamics”), Bard alleges infringement of United States Patent Nos. 8,475,417 (“the ’417 patent”), 8,545,460 (“the ’460 patent”), and 8,805,478 (“the ’478 patent”) (collectively, the “patents-in-suit”). Presently before the court is the matter of claim construction. This decision sets forth the court’s recommendations of constructions for the disputed claim terms discussed in the briefing and at the *Markman* hearing held on January 9, 2019.

II. BACKGROUND

Bard brought this civil action for patent infringement against AngioDynamics on March 10, 2015, asserting causes of action for infringement of the ’417 patent, the ’460 patent, and the ’478 patent (collectively, the “patents-in-suit”). (D.I. 1 at ¶¶ 18-45) Bard’s PowerPort® ClearVUE® implantable power-injectable port products are covered by the patents-in-suit. (*Id.*

at ¶ 7) According to Bard, AngioDynamics' implantable power-injectable port products, including its Smart Port® products, infringe the patents-in-suit. (*Id.* at ¶¶ 19, 27, 35)

III. LEGAL STANDARD

Construing the claims of a patent presents a question of law, although subsidiary fact finding is sometimes necessary. *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 837-38 (2015) (citing *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 977-78 (Fed. Cir. 1995), *aff'd*, 517 U.S. 370, 388-90 (1996)). "It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (internal quotation marks omitted). "[T]here is no magic formula or catechism for conducting claim construction." *Id.* at 1324. Instead, the court may attach the appropriate weight to appropriate sources "in light of the statutes and policies that inform patent law." *Id.*

The words of the claims "are generally given their ordinary and customary meaning," which is "the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application." *Phillips*, 415 F.3d at 1312-13 (internal citations and quotation marks omitted). "[T]he ordinary meaning of a claim term is its meaning to the ordinary artisan after reading the entire patent." *Id.* at 1321 (internal quotation marks omitted); *see also Eon Corp. IP Holdings v. Silver Spring Networks, Inc.*, 815 F.3d 1314, 1320 (Fed. Cir. 2016). Claim terms are typically used consistently throughout the patent, and "usage of a term in one claim can often illuminate the meaning of the same term in other claims." *Phillips*, 415 F.3d at 1314 (observing that "[o]ther claims of the patent in question, both asserted and unasserted, can also be valuable sources of enlightenment . . . [b]ecause claim terms are normally used consistently throughout the patent . . .").

It is likewise true that “[d]ifferences among claims can also be a useful guide For example, the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim.” *Id.* at 1314-15 (internal citation omitted). This “presumption is especially strong when the limitation in dispute is the only meaningful difference between an independent and dependent claim, and one party is urging that the limitation in the dependent claim should be read into the independent claim.” *SunRace Roots Enter. Co., Ltd. v. SRAM Corp.*, 336 F.3d 1298, 1303 (Fed. Cir. 2003) (citing *Ecolab Inc. v. Paraclipse, Inc.*, 285 F.3d 1362, 1375 (Fed. Cir. 2002)).

Other intrinsic evidence, including the patent specification, “is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term.” *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). “[T]he specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess. In such cases, the inventor’s lexicography governs.” *Phillips*, 415 F.3d at 1316 (citing *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed. Cir. 2002)). It bears emphasis that “[e]ven when the specification describes only a single embodiment, the claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using words or expressions of manifest exclusion or restriction.” *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004) (internal quotation marks omitted), *aff’d*, 481 F.3d 1371 (Fed. Cir. 2007). The specification “is not a substitute for, nor can it be used to rewrite, the chosen claim language.” *SuperGuide Corp. v. DirecTV Enters., Inc.*, 358 F.3d 870, 875 (Fed. Cir. 2004).

In addition to the specification, a court “should also consider the patent’s prosecution history, if it is in evidence.” *Markman*, 52 F.3d at 980. The prosecution history, which is also “intrinsic evidence,” “consists of the complete record of the proceedings before the PTO [Patent and Trademark Office] and includes the prior art cited during the examination of the patent.” *Phillips*, 415 F.3d at 1317. “[T]he prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be.” *Id.*

A court also may rely on “extrinsic evidence,” which “consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises.” *Markman*, 52 F.3d at 980. For instance, technical dictionaries can assist the court in determining the meaning of a term to those of skill in the relevant art because such dictionaries “endeavor to collect the accepted meanings of terms used in various fields of science and technology.” *Phillips*, 415 F.3d at 1318. In addition, expert testimony can be useful “to ensure that the court’s understanding of the technical aspects of the patent is consistent with that of a person of skill in the art, or to establish that a particular term in the patent or the prior art has a particular meaning in the pertinent field.” *Id.* Nonetheless, courts must not lose sight of the fact that “expert reports and testimony [are] generated at the time of and for the purpose of litigation and thus can suffer from bias that is not present in intrinsic evidence.” *Id.* (“[C]onclusory, unsupported assertions by experts as to the definition of a claim term are not useful to a court.”). Overall, while extrinsic evidence may be useful to the court, it is less reliable than intrinsic evidence, and its consideration “is unlikely to result in a reliable

interpretation of patent claim scope unless considered in the context of the intrinsic evidence.”
Id. at 1318-19.

Finally, “[t]he construction that stays true to the claim language and most naturally aligns with the patent’s description of the invention will be, in the end, the correct construction.”
Renishaw PLC v. Marposs Societa’ Per Azioni, 158 F.3d 1243, 1250 (Fed. Cir. 1998). It follows that “a claim interpretation that would exclude the inventor’s device is rarely the correct interpretation.” *Osram GmbH v. Int’l Trade Comm’n*, 505 F.3d 1351, 1358 (Fed. Cir. 2007).

IV. CONSTRUCTION OF DISPUTED TERMS

A. Printed Matter

To determine the patentability of a claim, the court must read the claim as a whole and consider every claim limitation. *In re Gulack*, 703 F.2d 1381, 1385 (Fed. Cir. 1983). Consequently, “[d]ifferences between an invention and the prior art cited against it cannot be ignored merely because those differences reside in the content of . . . printed matter.” *Id.* However, a limitation claiming printed matter is not given patentable weight unless it is functionally or structurally related to the physical substrate. *Id.* at 1384-85. The printed matter doctrine is properly addressed during claim construction because it is a legal inquiry requiring the analysis and interpretation of the claim language. *See Praxair Distrib., Inc. v. Mallinckrodt Hosp. Prods. IP Ltd.*, 890 F.3d 1024, 1033 (Fed. Cir. 2018).

Under the first step of the printed matter analysis, the court must determine whether the challenged claim limitation is, in fact, directed to printed matter. A claim limitation is directed to printed matter “if it claims the content of information.” *In re DiStefano*, 808 F.3d 845, 848 (Fed. Cir. 2015) (concluding that “printed matter must be matter claimed for what it communicates.”). The Federal Circuit has extended this principle to verbal instructional

limitations added to a known method. *See King Pharms., Inc. v. Eon Labs, Inc.*, 616 F.3d 1267, 1279 (Fed. Cir. 2010) (extending printed matter doctrine to “informing” limitation in a method claim). In addition, claim limitations directed to mental steps may be considered printed matter lacking patentable weight if they add ineligible mental processes to ineligible information. *See Praxair*, 890 F.3d at 1033 (“To hold otherwise would make the printed matter doctrine a dead letter, requiring no more than a ‘think about it’ step to give patentable weight to a claim limitation directed to information content.”).

Once the court has determined that a claim limitation is directed to printed matter, “the next step is to ascertain whether the printed matter is functionally related to its ‘substrate.’” *Praxair*, 890 F.3d at 1032. Claim limitations directed to printed matter are not entitled to patentable weight under 35 U.S.C. § 101 absent a new feature of physical structure or a new functional relationship between the printed matter and the product with which it is associated that distinguishes the invention from the prior art. *See In re DiStefano*, 808 F.3d at 850; *In re Gulack*, 703 F.2d at 1385-86; *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1064 (Fed. Cir. 2010). A functional relationship does not exist where the printed matter and product do not depend upon each other. *See In re Bryan*, 323 F. App’x 898, 901 (Fed. Cir. 2009); *In re Ngai*, 367 F.3d 1336, 1339 (Fed. Cir. 2004).

According to AngioDynamics, the “radiographic letter” and “visually perceptible information” limitations of the patents-in-suit¹ constitute unpatentable printed matter because they are not functionally related to the port itself. (D.I. 365 at 1-2) AngioDynamics argues that

¹ The limitations directed to radiographic letters, patterns, symbols, or indicia printed on the port are found in claims 5 and 12 of the ’417 patent, claim 4 of the ’460 patent, and claims 3 and 9 of the ’478 patent. The limitations directed to information provided on an item separate from the port are found in claims 6 and 13 of the ’417 patent, claim 2 of the ’460 patent, and claims 5 and 11 of the ’478 patent.

the functionality of the claimed access port does not depend on the printed matter on the port because the printed matter merely informs practitioners about the port's intended use for power injection. (*Id.* at 4) AngioDynamics contends that the asserted method claims do not involve the performance of a concrete act in response to reading the "radiographic letter" and "visually perceptible information" limitations. (*Id.*)

In response, Bard argues that the printed matter is patentable because it is structurally and functionally related to the port itself. (D.I. 372 at 7-12, 15) According to Bard, the radiographic letters are structurally related to the port because they are incorporated into the claimed port such that using an x-ray on the subcutaneous port reveals the radiographic letters to the doctor. (*Id.* at 7-9) Bard contends that using an x-ray transforms the port by making identifying letters on the port visible when the port is subcutaneously implanted. (*Id.* at 10) Bard further contends that there is a functional relationship between the radiographic letters and the access port because the radiographic letters function to identify the port as a power injectable port, in accordance with Judge Robinson's claim construction ruling. (*Id.*)

At the first step of the analysis, the parties agree that the "radiographic letter" and "visually perceptible information" limitations in the patents-in-suit are directed to printed matter because they claim the content of information revealing that the access port is structured for power injection. (1/9/19 Tr. at 33:17-34:5) The '417 patent claims a radiographic letter perceivable via x-ray for "identifying the access port as suitable for flowing fluid at a fluid flow rate of at least 1 milliliter per second through the access port." ('417 patent, col. 30:51-31:17) Similarly, the '460 patent claims a system for identifying a power injectable vascular access port with a radiographic marker "selected from the group consisting essentially of an observable pattern, a symbol, a typographical character, an indicium, and combinations thereof." ('460

patent, col. 30:51-31:14) The '478 patent likewise claims a method of performing a power injection procedure requiring the identification of a radiographic letter. ('478 patent, col. 31:8-9, 31:41-32:2) Other dependent claims of the patents-in-suit provide that “visually perceptible information” identifying an access port as power injectable may be included on a key chain, a bracelet, a wrist band, a sticker on a patient’s chart, a patient ID card, and/or on the packaging of the access port. ('417 patent, col. 31:18-23, 32:1-6; '460 patent, col. 31:1-7; '478 patent, col. 31:16-26, 32:10-20) The court’s May 19, 2017 claim construction ruling establishes that these claimed “identifiable features” are directed to “identify[ing] an access port as being structured for power injection.” (D.I. 156 at 5-6)

At the second step of the analysis, the asserted claims relating to “visually perceptible information” constitute instructions for use which are not entitled to patentable weight because there is no functional or structural relationship between the labels, key chains, and other items and the claimed access port. (1/9/19 Tr. at 43:22-44:6) (conceding that there is no structural relationship between the port and the visually perceptible information). Instead, the “visually perceptible information” serves to inform a medical practitioner about how the claimed access port works. *See AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1065 (Fed. Cir. 2010) (holding that instructions required for FDA approval were not functionally related to the claimed drug and did not create a new, unobvious product). The Federal Circuit has concluded that instructional information of this nature lacks patentable significance. For instance, in *In re Ngai*, the Federal Circuit determined that instructions regarding how to amplify ribonucleic acids were not functionally related to the claimed kit, which was anticipated by the prior art. 367 F.3d 1336, 1339 (Fed. Cir. 2004). The Federal Circuit reasoned that, even though the instructions provided information on how to use the kit, “the printed matter in no way depends on the kit, and the kit

does not depend on the printed matter. All that the printed matter does is teach a new use for an existing product.” *Id.*

The same is true of the radiographic letter limitations in the '417 and '460 patents. In *AstraZeneca*, the Federal Circuit determined that a dispute regarding whether the substrate was the label or the claimed drug was immaterial because in both cases, “the instructions do nothing more than explain how to use the known drug.” *AstraZeneca*, 633 F.3d at 1064-65 (rejecting AstraZeneca’s argument that a physician would not know how to safely and effectively treat patients without the instructions). Similarly, the presence or absence of the radiographic letters on the claimed access port in the present case does not change the port’s power injection capabilities. Instead, the radiographic letters explain to the medical practitioner that the port may be used for power injection. The claims do not identify a particular feature of the radiographic marker that makes the port power injectable.

In this regard, the limitations of the '417 and '460 patents are similar to those considered by the Federal Circuit in *In re Marco Guldenaar Holding B.V.*, 911 F.3d 1157 (Fed. Cir. 2018). In *Guldenaar*, the claims were directed to a method of playing a dice game using markings on the die faces. The Federal Circuit determined that the markings engraved on the dice were printed matter not entitled to patentable weight because the claimed markings were not functionally related to the substrate. *Id.* at 1161 (concluding that “the markings on each of Appellant’s dice do not cause the die itself to become a manufacture with new functionality.”). Likewise, the fact that the radiographic letters are printed on the port does cause the port to become power injectable. The claimed port is power injectable regardless of the presence or absence of the radiographic letters.

The case authorities relied upon by Bard are distinguishable from the claimed invention in the present case. In *In re Miller*, the patent claimed a measuring cup with markings functionally related to the cup itself because they eliminated the need to do math to make a fractional recipe. 418 F.2d 1392 (C.C.P.A. 1969). For this reason, the claimed measuring cup could not be used to make a full recipe. Likewise, in *In re Gulack*, the Federal Circuit determined that there was a functional relationship between the printed numbers on a band and the band itself because the numbers were arranged in a unique sequence to perform mathematical operations, exploiting the endless nature of the band. 703 F.2d 1381, 1386-87 (Fed. Cir. 1983). In contrast, the radiographic markings on the claimed port in the present case do not force a practitioner to use the port in a particular way.

The patent in *In re Royka* claimed an answer sheet for use in self-instruction and testing which had confusing printed information that could be removed by an eraser. 490 F.2d 981 (C.C.P.A. 1974). The permanent printed information remaining after erasure informed the user whether the response was correct. *Id.* In this regard, the printed information itself was transformed. In contrast, the information on the radiographic marker in the present case is conveyed, but not transformed, by the x-ray.

The claimed methods in the '478 patent also fail to present a functional relationship between the radiographic letters and the port. In *Praxair*, the Federal Circuit determined that a functional relationship existed between the printed matter and the substrate where a method claim required the step of discontinuing treatment "in accordance with" a previous claim limitation "providing information and a recommendation to the medical provider to discontinue . . . treatment." *Praxair*, 890 F.3d at 1035. The asserted method claims of the '478 patent also contain sequential steps regarding the performance of a medical procedure, but they lack the

linking phrase “in accordance with,” or analogous terms such as “based on” or “as a result of,” which would functionally tie the presence of the radiographic letter or visually perceptible information to the subsequent power injection. The Federal Circuit’s ruling in *Praxair* was expressly based on “interrelating the claimed information . . . with the concrete step of discontinuing treatment because of the information” by way of the “in accordance with” language. *Id.*

Independent claim 1 of the ’478 patent is directed to a method of performing a power injection procedure comprising the steps of: (i) taking an x-ray of a subcutaneously implanted access port, (ii) identifying the indicating radiographic feature on the x-ray, and (iii) flowing a fluid through the access port at a specified rate. (’478 patent, col. 30:58-31:4) Although the first step of the method explains that the purpose of the x-ray is “to determine whether the access port includes a radiographic feature indicating that the access port is suitable for” power injection, the required action at the third step does not contain language tying it to the outcome of the preceding steps as in *Praxair*. The same is true of independent claim 8 of the ’478 patent, which is directed to a method of performing a power injection procedure comprising the steps of: (i) providing an access port, (ii) implanting the access port, (iii) taking an image of the implanted access port, (iv) identifying the access port as being suitable for power injection, and (v) injecting contrast media fluid through the access port. (’478 patent, col. 31:41-32:2) There is no requirement in the asserted method claims that the practitioner must take a specific action as a result of the information revealed on the radiographic marker.

AngioDynamics also cites the PTAB’s analysis of related Bard patents claiming the use of radiographic letters to identify a power-injectable port. (D.I. 365 at 5-7) The PTAB concluded that the inclusion of the radiographic letters did not change the port’s functionality,

and the informational content of the claimed letters does not affect the structure or function of the claimed port. (*Id.* at 5) On appeal, the Federal Circuit did not reach the PTAB's printed matter conclusion because it overturned the ruling on other grounds. *See C.R. Bard, Inc. v. AngioDynamics, Inc.*, 2018 WL 4677441, at *6 n.9 (Fed. Cir. Sept. 28, 2018). The PTAB's printed matter ruling provides additional support for the court's conclusion that the printed matter limitations in the patents-in-suit are not entitled to patentable weight.

B. Substantial Identity Under 35 U.S.C. § 154(d)

Generally, a "patentee may . . . obtain damages only for acts of infringement after the issuance of the [] patent." *Welker Bearing Co. v. PHD, Inc.*, 550 F.3d 1090, 1095 (Fed. Cir. 2008) (internal quotation marks omitted). An exception exists in cases where a patentee can prove that it qualifies for "provisional rights" under 35 U.S.C. § 154(d). Provisional rights allow a patentee to obtain a reasonable royalty from one who committed acts that would constitute infringement of the invention as claimed in the published patent application, between the date on which the application was published and the date of the patent's issuance. *See* 35 U.S.C. § 154(d)(1). However, the claims in the original published application and the issued patent must be substantially identical. *Tennant Co. v. Hako Minuteman, Inc.*, 878 F.2d 1413, 1417 (Fed. Cir. 1989). The claims of an issued patent are "identical" to their original counterparts if they are "without substantive change." *Seattle Box Co. v. Industrial Crating & Packing*, 731 F.2d 818, 827–28 (Fed. Cir. 1984) (internal quotations omitted).

In determining whether substantive changes have been made, the court must determine whether the scope of the claims is identical. *See Laitram Corp. v. NEC Corp.*, 163 F.3d 1342, 1346–47 (Fed. Cir. 1998) (citing *Slimfold Mfg. Co. v. Kinkead Indus.*, 810 F.2d 1113, 1115 (Fed. Cir. 1987)). The traditional principles of claim construction apply to the court's determination

regarding claim scope, with particular attention to the “examiner’s focus in allowing the claims” after amendment. *R&L Carriers, Inc. v. Qualcomm, Inc.*, 801 F.3d 1346, 1351 (Fed. Cir. 2015). “[I]t is the scope of the claim that must be identical, not that identical words must be used.” *Slimfold Mfg. Co., Inc. v. Kinkead Indus., Inc.*, 810 F.2d 1113, 1116 (Fed. Cir. 1987). As a result, amendments made during reexamination do not necessarily compel a conclusion that the scope of the claims has been substantively changed. *See, e.g., Bloom Eng’g Co. v. N. Am. Mfg. Co., Inc.*, 129 F.3d 1247, 1250 (Fed. Cir. 1997) (“There is no absolute rule for determining whether an amended claim is legally identical to an original claim.”). Rather, “[t]o determine whether a claim change is substantive it is necessary to analyze the claims of the original and the reexamined patents in light of the particular facts, including the prior art, the prosecution history, other claims, and any other pertinent information.” *Laitram I*, 952 F.2d at 1362–63.

AngioDynamics first contends that the claims of U.S. Patent Application Publication 2009/0227951 A1 (“the ’951 publication”) and the ensuing ’417 patent are not substantially identical because Bard surrendered claim scope by amending the claims to remove the term “about” to overcome an indefiniteness rejection. (D.I. 365 at 9-10) In response, Bard contends that the omission of the word “about” from the claims of the ’417 patent does not amount to a substantive difference because the claims identify a power injectable port with identifying features regardless of the inclusion of the word “about.” (D.I. 372 at 19)

The claims of the ’417 patent and the ’951 publication are substantially identical because the removal of the word “about” from the ’417 patent does not substantively alter the scope of the claims. *See Tennant Co. v. Hako Minuteman, Inc.*, 878 F.2d 1413, 1417 (Fed. Cir. 1989) (“Under section 252, ‘identical’ does not mean verbatim, but rather means ‘without substantive change.’”). Independent claim 1 of the ’951 publication recites a step of identifying the access

port as suitable for “a fluid flow rate of at least about 1 milliliter per second through the access port,” and “accommodating a pressure within the cavity of at least about 35 psi.” (D.I. 252, Ex. 5 at cl. 1) The examiner rejected these limitations as indefinite following the publication of the ’951 publication and prior to the allowance of the ’417 patent. (D.I. 366, Ex. 9 at 6) In response to the rejection, Bard amended the claims to remove the term “about” “[w]ithout conceding the propriety of the rejection, in the interest of compact prosecution.” (*Id.*)

As amended, the “at least 35 psi” and “at least 1 milliliter per second” limitations of the ’417 patent establish 35 psi and 1 milliliter per second as lower thresholds. (’417 patent, col. 30:50-31:6) However, the court’s May 2017 construction of the “identifiable feature” limitations provides that the identifiable features are intended to “identify an access port as being structured for power injection.” (D.I. 156 at 5) The specifications of the ’417 patent and the ’951 publication explain that an access port is structured for power injection if it can accommodate infusions “at a rate of between about 1 milliliter per second and about 5 milliliters per second,” and can also accommodate “a pressure developed within the reservoir of at least about 35 psi.” (’417 patent, col. 4:44-45, 3:38-39) Regardless of the presence or absence of the word “about,” a person of ordinary skill in the art would understand that the numerical limitations in the claims identify ports as being structured for power injection. (D.I. 373, Ex. G at ¶¶ 321-323; Ex. H at ¶¶ 108-115)

This is consistent with Federal Circuit precedent holding that claim amendments to make a claim more definite do not necessarily amount to a substantive change. *See Convolve, Inc. v. Compaq Computer Corp.*, 812 F.3d 1313, 1322 (Fed. Cir. 2016). The reexamined claims in *Convolve* were found to be substantially identical to the original claims despite an amendment to add “seek” in front of “acoustic noise” in response to a prior art rejection. *Id.* at 1323. The

Federal Circuit reasoned that the term “acoustic noise” was implicitly limited to “seek acoustic noise” prior to the amendment because the remaining claim limitations, specification, and prosecution history made clear to a person of ordinary skill in the art that the claims were limited to seek acoustic noise. *Id.* Therefore, the addition of “seek” did not substantively alter the scope of the claims. *Id.* In *Tennant Co. v. Hako Minuteman, Inc.*, the Federal Circuit held that the addition of the word “bottom” before “wall” in the reexamined claim did not amount to a substantive change because the claimed “movable first wall” was necessarily a bottom wall prior to the amendment. 878 F.2d 1413, 1417 (Fed. Cir. 1989). Interpreting the claims in light of the specification, the Federal Circuit concluded that the addition of the word “bottom” made the claim more definite without resulting in a substantive change to the scope of the original claim. *Id.*

In *Convolve* and *Tennant*, the Federal Circuit held that adding limitations to the claim language did not materially narrow the scope of the claims if the additions brought the claims in line with the intrinsic record and made explicit an implicit limitation that was always present. Similarly, the term “about” was removed in the present case to make the claims more definite, but this change did not alter the understanding of a person of ordinary skill in the art as to the fluid flow rate and pressure ranges that would make the claimed access port power injectable. For this reason, the claims of the ’951 publication and ’417 patent are substantially identical despite the claim amendment to remove “about.”

AngioDynamics also argues that Bard modified the scope of the claims by disclaiming that the first and second identifiable features could be satisfied by a single structure to overcome a prior art rejection. (D.I. 365 at 10) In response, Bard alleges that both the ’417 patent and the ’951 publication require two identifiable features, and Bard did not disclaim scope by

distinguishing a prior art reference teaching that a single identifiable feature could not be relied upon as disclosing a first and second identifiable feature. (D.I. 372 at 20)

The record before the court does not reflect a clear and unmistakable prosecution disclaimer by Bard that would substantively alter the scope of the claims. To establish prosecution disclaimer, the Federal Circuit “requires that the alleged disavowing actions or statements made during prosecution be both clear and unmistakable.” *Omega Eng’g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1325-26 (Fed. Cir. 2003). The prosecution history in the present case reveals that Bard filed an amendment to overcome a prior art rejection based on the *Fenton* reference. (D.I. 376, Ex. 104 at 6) Bard explained that “the alleged first identifiable feature and second identifiable feature are disclosed as the *same feature* by Fenton” because the *Fenton* reference disclosed “a single tactile feature.” (*Id.*) Bard distinguished the claimed invention in the present case by stating that “the claimed invention requires that the first and second identifiable features be different (i.e., the first identifies the port as suitable for flowing fluid at a fluid flow rate of at least about 1 milliliter per second, and the second identifies the port as suitable for accommodating a pressure within the cavity of at least about 35 psi).” (*Id.*) Bard did not disclaim scope during prosecution by noting that the *Fenton* reference disclosed only a single feature, while the ’417 patent discloses two features. *See Avid Tech., Inc. v. Harmonic, Inc.*, 812 F.3d 1040, 1045 (Fed. Cir. 2016) (“Where the alleged disavowal is ambiguous, or even ‘amenable to multiple reasonable interpretations,’ we have declined to find prosecution disclaimer.”). For these reasons, I recommend that the court find the claims of the ’951 publication and the ’417 patent substantially identical.

V. CONCLUSION

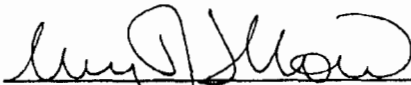
For the reasons set forth above, I recommend that the court hold that: (1) the information conveyed by the radiographic letters and separated features is printed matter, and (2) the claims of the '417 patent and the '951 publication are substantially identical.

Given that the court has relied upon material that technically remains under seal, the court is releasing this Report and Recommendation under seal, pending review by the parties. In the unlikely event that the parties believe that certain material in this Report and Recommendation should be redacted, the parties should jointly submit a proposed redacted version by no later than **February 15, 2019**, for review by the court, along with a motion supported by a declaration that includes a clear, factually detailed explanation as to why disclosure of any proposed redacted material would “work a clearly defined and serious injury to the party seeking closure.” *Pansy v. Borough of Stroudsburg*, 23 F.3d 772, 786 (3d Cir. 1994) (internal quotation marks and citation omitted). The court will subsequently issue a publicly available version of its Report and Recommendation.

This Report and Recommendation is filed pursuant to 28 U.S.C. § 636(b)(1)(B), Fed. R. Civ. P. 72(b)(1), and D. Del. LR 72.1. The parties may serve and file specific written objections within fourteen (14) days after being served with a copy of this Report and Recommendation. Fed. R. Civ. P. 72(b)(2). The objections and responses to the objections are limited to ten (10) pages each. The failure of a party to object to legal conclusions may result in the loss of the right to de novo review in the District Court. *See Sincavage v. Barnhart*, 171 F. App'x 924, 925 n.1 (3d Cir. 2006); *Henderson v. Carlson*, 812 F.2d 874, 878-79 (3d Cir. 1987).

The parties are directed to the court's Standing Order For Objections Filed Under Fed. R. Civ. P. 72, dated October 9, 2013, a copy of which is available on the court's website, <http://www.ded.uscourts.gov>.

Dated: February 8, 2019


Sherry R. Fallon
UNITED STATES MAGISTRATE JUDGE