IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

KENSEY NASH CORPORATION, SHERWOOD MEDICAL COMPANY, and ST. JUDE MEDICAL, INC. Plaintiffs	:	
v.	:	
PERCLOSE, INC.. Defendant, Counterclaimant	:	CIVIL ACTION
v.	:	NO. 98-1629
KENSEY NASH CORPORATION, SHERWOOD MEDICAL COMPANY, TYCO INTERNATIONAL (U.S.) INC. (dba THE KENDALL COMPANY), and ST. JUDE MEDICAL, INC. Counterdefendants	:	

Memorandum and Order

YOHN, J. December __, 2000

Kensey Nash Corp., Sherwood Medical Co., and St. Jude Medical, Inc. (collectively "Kensey") allege that Perclose, Inc. infringed two of their patents: U.S. Patent No. 5,676,689 (issued Oct. 14, 1997) (" '689 patent") and U.S. Patent No. 5,861,004 (issued Jan. 19, 1999) (" '004 patent"). Both patents pertain to technologies for sealing arterial punctures. Pending before the court are the parties' motions for construction of '689 Claims 1, 7, 13, 25, 27, 39, and 44 and '004 Claims 1, 10, and 18.[1]

[1] The plaintiffs originally moved for both claim construction and a summary judgment of infringement. The defendant responded with a motion for claim construction and a summary judgment of non-infringement or, in the alternative, of patent invalidity. The court denied without prejudice the summary judgment demands but left the claim construction demands

Specifically, the parties move for interpretations of "closure device" and "location detector" as used in the asserted '689 claims and "puncture closure" as used in the asserted '004 claims. Kensey submits general definitions, while Perclose submits specific definitions. After review of the relevant intrinsic evidence, I conclude that the '689 patent's prosecution history establishes that "closure device" bears a specific definition and that the '004 patent's prosecution history establishes that "puncture closure" bears a specific definition. "Location detector" as used in the '689 patent is a means-plus-function term and therefore bears the definition in the '689 patent's specification.

I. Standards for Claim Interpretation

Courts interpret patents as a matter of law. *See Vitronics Corp. v. Conceptronics, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). Although all parts of a patent are relevant to interpreting the patent, the patent's claims specifically define the scope of the patent's right to exclude, and accordingly, a determination of the scope of the patent centers on the language of the claims. *See Renishaw PLC v. Marposs Societa' Per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998). Consequently, disputes over claim interpretation are essentially disputes over the meaning of claim terms. *See id.* "The intrinsic evidence, in some cases, the extrinsic evidence, can shed light on the meaning of the terms recited in a claim, either by confirming the ordinary meaning of the claim terms or by providing special meaning for claim terms." *Id.* (citing *Vitronics*, 90 F.3d at 1583). Accordingly, disputes over claim interpretation are essentially disputes over the

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intact. *See* Order of Feb. 1, 2000 (Doc. 51). Accordingly, this opinion establishes only the meaning of the asserted claims.

meaning of claim terms. *See id.*

In determining the meaning of a claim term, the intrinsic evidence of record – the patent's asserted and unasserted claims, specification, and prosecution history – is the primary source. *See Vitronics*, 90 F.3d at 1582. Only where intrinsic evidence alone fails to resolve the meaning of a disputed claim term may extrinsic evidence be used. *See id.* at 1583;*Karlin Tech. Inc. v. Surgical Dynamics, Inc.*, 177 F.3d 968, 971 (Fed. Cir. 1999) ("[T]he court may not use extrinsic evidence to arrive at a claim construction that is clearly at odds with the construction mandated by the intrinsic evidence."). A court may, however, consider extrinsic evidence for the limited purpose of educating itself on the meaning of technical terms and terms of art. *See Vitronics*, 90 F.3d at 1582-83.

Where a claim expresses "a means or step for performing a specified function without [a] recital of structure, material, or acts in support thereof," the court must construe the claim "to cover the corresponding structure, material, or acts described in the specification and equivalents thereof." 35 U.S.C. § 112, ¶ 6 (2000). Where a claim does not use such means-plus-function language, the claim is understood as it would be understood by one of ordinary skill in the field of the patent. *See Vitronics*, 90 F.3d at 1582; *Multiform Desiccants, Inc. v. Medzam, Ltd.*, 133 F.3d 1473, 1477 (Fed. Cir. 1998).

A term bearing just one common meaning necessarily bears that meaning unless it is apparent from the patent or prosecution history that the term is specially defined. *See Renishaw*, 158 F.3d at 1249. "[W]here there are several common meanings for a claim term, [absent a special definition in the patent or prosecution history] the patent disclosure serves to point away from the improper meanings and toward the proper meaning." *Id.* at 1250. Or in other words,

patent claims must be read in light of the patent's specification. *Id.* at 1248. Finally, "[w]hen multiple patents derive from the same initial application, the prosecution history regarding a claim limitation in any patent that has issued applies with equal force to subsequent issued patents that contain the same language." *Elkay Mfr. Co. v. Ebco Mfr. Co.*, 192 F.3d 973, 980 (Fed. Cir. 1999) (citing *Jonsson v. the Stanley Works*, 903 F.2d 812, 818 (Fed. Cir. 1990)).

II. "Closure Device" as Used in the '689 Patent's Claims

Kensey submits that "closure device" as used in the claims is a general term that refers to "any type of closure device that can be arranged and positioned to enable the effective sealing of a puncture [in a vessel, lumen, or duct]." Pls. Mem.[2] at 34. Perclose submits a significantly narrower definition: a "closure device," as used in the claims, is "[a] device for sealing a percutaneous puncture in a vessel, duct, or lumen [and is] comprised of a sealing member within the puncture tract, an anchor member within the vessel, duct, or lumen, and a filament member connecting the anchor and sealing members in a pulley-like arrangement." Def.'s Mem.[3] at 35. Each party argues that the intrinsic evidence of record supports its favored definition.

Dr. Jerome Segal, a cardiologist and one of Kensey's experts, states that "closure device" can refer to any known means of wound closure, including an anchor-plug-and-filament closure, "a collagen plug, a needle and suture, a surgical staple, an adhesive, [or] a cauterization device." *See* Dec. of Dr. Jerome Segal (Doc. No. 33) at ¶ 29. The court uses Segal's declaration as an

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[2] Mem. of Law in Supp. of Pls.' Mot. for a *Markman* Ruling on Claim Interpretation (Doc. No. 33).

[3] Def./Counterclaimant Perclose, Inc.'s Mem. of P & A. Regarding Claim Construction of U.S. Patent No. 5,6776,689 and U.S. Patent No. 5,861,004 (Doc. No. 39).

indication of the term's meaning when used in isolation. Hence, at the outset, "closure device" is a general term that has one meaning.[4] It, of course, remains for the court to determine whether the term as used in the patent retains this definition.

A. Claim Language

Asserted Claims 1 and 25, the only independent claims in the patent, both use the term "closure" or "closure device." The pertinent parts of Claim 1 read as follows:

> "A system for sealing a percutaneous puncture in the wall of a [fluid-filled] vessel, duct or lumen of a living being...
>
> > the puncture comprising an opening in the wall of the vessel, duct or lumen and a tract contiguous with the opening and extending through tissue overlying the vessel, duct, or lumen,
>
> [a] said system comprising a *closure device* and a location detector,
>
> [b] said location detector being arranged for introduction into the puncture to provide a perceptible signal indicative of the location of the wall of the vessel, duct or lumen, whereupon a desired position for said *closure* with respect to the vessel, duct or lumen may be determined...
>
> [c] said *closure device* being arranged to be positioned within a portion of the puncture in accordance with said desired position to enable the effective sealing of the puncture by said *closure device*."

'689 Patent at 14:56-15:8 (emphasis and sentence division added). The pertinent parts of Claim 25 read as follows:

> "A method for sealing a percutaneous puncture in the wall of a [fluid-filled]

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[4] Perclose argues that Dr. Segal admits that "closure device" is an ambiguous term. However, the portions of deposition transcript cited to substantiate the claim fail to make Perclose's point. *See* Perclose's Opposition Mem of P. & A. on Claims Construction (*Markman*) Issues (Doc. No. 45) at 8-10. The transcript portions cited only confirm that Dr. Segal believes that "closure device" is a general term. Perclose also seems to argue that "closure device" is too vague to be meaningful. *See id.* at 6. This argument receives little substantiation, and certainly, general definitions may be vague but are not therefore meaningless.

vessel, duct, or lumen of a living being,...

> the puncture comprising an opening in the wall of the vessel, duct or lumen and a tract contiguous with the opening and extending through tissue overlying the vessel, duct or lumen, said method comprising:
>
> (a) providing a *closure device* and location detector;
>
> (b) introducing the location detector into the puncture... [so as to] provide a perceptible signal indicative of the location of the wall of the vessel, duct, or lumen, whereupon a desired position for the *closure* with respect to the vessel, duct or lumen may be determined; and
>
> (c) introducing the *closure device* within a portion of the puncture in accordance with the desired position to enable the effective sealing of the puncture by said *closure device*."

Id. at 16:47-68 (emphasis and sentence division added).

Parsing the claims' language makes more apparent the limitations imposed on the definition of "closure device." First, sections (b) of both claims state that the closure device's positioning is informed by a determination of the position of the punctured vessel, duct, or lumen wall. Second, sections (c) both claims state that the closure device envisioned by the patent is "positioned *within* a portion of the puncture" in such a way as to "enable the effective sealing of the puncture." Section (a) of Claim 1 clarifies that "puncture" refers to the opening in the vessel, duct, or lumen as well as the tract that leads to the opening. Thus, "closure device," as used in these claims, refers to the class of devices

> (1) whose positioning can be informed by the determination of the position of the punctured vessel, duct, or lumen wall; and
>
> (2) that effectuate wound closure by being positioned within a portion of the "puncture."

As compared to the definition of "closure device" as used in isolation, "closure device" as used

in the claims bears a relatively narrower definition. For example, the term, as used in isolation, could refer to a band-aid; the term as used in these claims excludes bandages. However, despite this slight narrowing, the term as used in these claims nonetheless bears a definition broader than that submitted by Perclose.

Perclose argues that the phrase "positioned within a portion of the puncture..." requires that the closure device be entirely "located in the internal luminal space of, and [be] bounded by the wall of the vessel, duct, lumen, puncture or puncture tract[.]" Def's Mem. at 29. "Closure device" cannot, according to Perclose, refer to any device that "extends through the [vessel, duct, or lumen] wall." *Id.* This interpretation of the phrase would be accurate were "puncture" to refer only to a puncture in a vessel, duct, or lumen. However, the text of Claims 1 and 25, plainly uses "puncture" differently. "Puncture" refers to the class *comprising* the "opening in the wall of the vessel, duct or lumen" and the tract leading to the opening. A class "comprising" some list of features includes all things with those features and does not exclude things that have those along with other. *See, e.g., Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261 (Fed. Cir. 1986). Hence, "puncture" refers to the vessel, duct, or lumen opening as well as the tract leading to the opening. Furthermore, although the opening and tract are the essential features of a "puncture," the use of the term does not exclude other features. Consequently, an item that is "within the puncture" must be *within* a feature, namely the opening or tract, and may also be *within* any nonessential feature, such as the body of the vessel, duct, or lumen wall.

Some of the remaining claims – all of which are dependent claims – can be read to define "closure device" consistently with or more narrowly than Claims 1 and 25. *See, e.g.*, '689 Patent at 15:24-35 (Claim 7) ("... said closure comprising a first portion and a second portion coupled to

said first portion...."); 15:56-60 ("... said closure comprises an anchor member...."). The Federal Circuit endorses the common sense rule that a dependent claim, by nature, incorporates all the limitations of the claim to which it refers[,]" *Jeneric/Pentron, Inc. v. Dillon Co., Inc.*, 205 F.3d 1377, 1383 (Fed. Cir. 2000) (citing 35 U.S.C. §112, ¶ 4 (1994)); but an independent claim does not ordinarily incorporate the limitations of a dependent claim, *see Karlin Technology Inc. v. Surgical Dynamics, Inc.*, 177 F.3d 969, 971-72 (Fed. Cir. 1999). Here, nothing in the dependent claims suggests that the general definition of "closure device" imposed by Claims 1 and 25 is inconsistent with the term's use in these dependent claims. Although a narrower definition of closure device, such as the definition suggested by Perclose, would be consistent with the use of the term in these claims, the claims' language does not necessitate such a narrow definition. Consequently, the only claim language relevant for determining the meaning of "closure device" is the language of Claims 1 and 25.

B. Specification

Perclose argues that Kensey acted as its own lexicographer and narrowly defined "closure device" in the patent's specification. Def.'s Mem. at 32-43. Kensey, on the other hand, argues that it did not act as its own lexicographer. Pls.' Mem. at 41; Pls.' Resp.[5] at 6-8. A patentee only acts as a lexicographer where the patentee "with reasonable clarity, deliberateness, and precision[]" gives a term a special definition. *Renishaw*, 158 F.3d at 1249; *accord*, *e.g.*, *Johnson Worldwide Assocs. Inc. v. Zebco Corp*., 175 F.3d 985, 989 (Fed. Cir. 1999) (Patentee must "clearly" set forth special definitions for claim terms.); *Karlin*, 177 F.3d at 973 ("The claims of a

[5] Pls.' Combined Mem. of Law in Reply to Def.'s Mem. of P. & A. Regarding Claim Construction and Def.'s Mem. of P. & A. in Supp. of Mot. for Summ. J. of Non-infringement or, Alternatively, Invalidity (Doc. No. 44).

patent are not limited to the preferred embodiments, unless by their own language.").

Here the specification does not show with clarity and precision that Kensey specially defined "closure device." Perclose points out that the specification section entitled "Detailed Descriptions of the Preferred Embodiment" states that

> "... [the] closure has three basic components, namely, a sealing member, an intra-arterial anchor member, and a positioning member.... The positioning member comprises a filament.... The [filament] connects the anchor member and the collagen plug (sealing member) via a pulley-like arrangement which serves to move the anchor and plug together, to sandwich and lock the artery wall between the anchor and plug."

'689 Patent at 5:25-28; *accord* 6:65-7:40; 5:50-61; 6:11-15. Also, as Perclose emphasizes, the patent's sheet drawings also clearly indicate an anchor, plug, and filament closure device. *See* 2:56-3:2 (figs. 1-5); 3:30-33 (figs. 19-24); 3:66-4:2 (figs. 34-35); 4:8-12 (fig. 38). Furthermore, the specification does not envision alternative embodiments that are not anchor-plug-and-filament type closures. *See id.* at 7:40-46 (The only alternative embodiment in the specification is a closure with a plug, filament, and anchor that can be radiographically imaged.).

However, the specification's "Summary of Invention" section can be read to explicitly indicate that the anchor, plug, and filament closure device is just one example of a closure device:

> "The closure device, *e.g.*, an anchoring means, sealing means, and filament means connected between the anchoring means and the sealing means, is arranged for location within a portion of the puncture at a desired portion with respect thereto, *e.g.*, the anchoring means within the vessel and the sealing means within the puncture tract, to enable the effective sealing of the puncture by the closure device."

Id. at 2:36-42 (emphasis added). Furthermore, the fact that the specialized definition to which Perclose points appears in a section of the specification entitled "Detailed Descriptions of the

Preferred Embodiment" makes it apparent that the "closure device" described therein is a preferred embodiment but not necessarily the sole embodiment.

Perclose also argues that the root term "seal-," as used in the claims, refers to preventing or obstructing the passage of fluid from the interior of a vessel, duct, or lumen into and through a puncture tract, by placing a mass of material within the puncture tract. *See* Def.'s Mem. at 32-34. In support of this specialized definition, Perclose points out that wherever "seal" or "sealing" is used in the preferred embodiment section of the specification, it is used in conjunction with a reference to a plug or sealing member and that this plug or sealing member acts as a stop in the puncture tract. *See* '689 patent at 5:25-30; 13:66-14:1. Perclose's arguments again fall short of the mark. Although "seal" may mean what Perclose suggests, the specification does not necessitate such a definition. "Seal" may be read to bear its ordinary meaning – namely as a synonym of words or phrases like "tighten," "close," "bond," or "bring together" – or a special meaning. But the regular appearance of "seal" alongside references to a plug does not clearly give "seal" a special meaning.

C. Prosecution History

Kensey argues that the prosecution history confirms that "closure device" is a general term. *See* Pls.' Mem. at 45-46. Perclose, on the other hand, argues that the prosecution history indicates that "closure device" carries a more limited meaning.[6] *See* Def.'s Mem. at 43-46. Of

[6] The bulk of Perclose's prosecution history arguments amount to patent invalidity arguments. Perclose argues that if "closure device" is understood as a general term, the application for the '689 patent fails to meet the requirements of 35 U.S.C. § 112. Perclose goes on to argue that because the court must make every attempt to construe the meaning or scope of a patent so as to preserve validity, "closure device" must be interpreted narrowly so as to meet the requirements of 35 U.S.C. § 112. In essence, Perclose urges the court to assess validity in rendering its claim construction. However, as specified in a prior order (Doc. #51), this opinion

primary significance here is the line of continuation applications from which the ‘689 patent derives. *See* ‘689 patent at 1:6-25.

The ‘689 patent issued in 1997 from an application that was filed as a continuation of the now abandoned application Serial No. 08/604,205, which in turn was filed as a continuation of the now abandoned application Serial No. 08/426, 371. This last abandoned application was a continuation of application Serial No. 07/154,882, which was a continuation of application Serial No. 07/846,322. These last two applications, respectively, yielded Patents 5,441,517 (“ ‘517") in 1993 and 5,282,827 (“ ‘827") in 1992. The earliest of these continuation applications, the 846,322 application, was a continuation-in-part of application Serial No. 789,704, which yielded Patent 5,22,974 (“ ‘974"). Hence, the ‘517 patent is the ‘689 patent’s parent and the ‘827 patent is the ‘689 patent’s grandparent. And the ‘827 patent and its progeny owe their existence, via the continuation-in-part relation, to the ‘974 patent.

Kensey explicitly defines the term “closure means” in the ‘974 patent. The ‘974 patent’s summary of invention states “[t]he closure means comprises anchoring means, sealing means, and filament means. The filament means is connected between the anchoring means and the sealing means.... The filament means is arranged to pull the anchoring means and the sealing means relative to each other to cause the sealing means to engage tissue contiguous with said puncture outside of the vessel.” ‘974 patent at 2:3-29. Given that the ‘974 patent explicitly gives “closure means” a narrow definition, it is unlikely that the application for the ‘974 patent’s application included a broader definition. Certainly, Kensey presents no arguments suggesting that the ‘974 patent’s application or prosecution history justifies a definition broader than that

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addresses only claim construction.

contained in the patent itself. Furthermore, Kensey's November 8, 1991 amendment to the application that became the '974 patent disclaims a broader definition of "closure means." In response to the PTO rejection of Claim 1 of the application, Kensey specified that "closure means" included a filament that was arranged to "move the anchoring means and the sealing means relative to each other." Furniss Dec. at PO46865.[7] The amendment was issued in order to distinguish the closure from a prior Kensey patent which described a filament that connects an anchoring means and sealing means. It is amply clear that the '974 patent's invention was limited to an anchor, plug, and filament device arranged in a pulley-like configuration.

Kensey also explicitly defines "closure means" in the same way in the '827 patent. The '827 patent's summary of invention states that the "closure means comprises anchoring means, sealing means, and filament means. The filament means is connected between the anchoring means and the sealing means.... The filament means is arranged to pull the anchoring means and the sealing means relative to each other to cause the sealing means to engage tissue contiguous with the puncture outside the vessel." '827 patent at 2:15-44. Finally, the '517 patent's summary of invention describes the "closure means" in exactly the same way. *See* '517 patent at 2:22-50. It is amply clear that the initial application's inventive concept involved a specific type of closure device.

The '689 patent does not use the term "closure means" but instead uses the term "closure device." However, the '689 patent's prosecution history establishes that the two terms must be

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[7] Kensey's November 8, 1991 Amendment in Response to PTO's March 6, 1992 Office Action in Dec. of Daniel J. Furniss in Supp. of Def./Counterclaim Perclose, Inc.'s Mem. of P.&A. Regarding Claim Construction of U.S. Patent No. 5,676,689 and U.S. Patent No. 5,861,004.

understood to be synonymous. A continuation application is based solely on the disclosures of a parent application. *See Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 550 (citing the Manual of Patent Examining Procedure § 201.07). The '827 patent's inventive concept is a design and method for use of a mechanism for sealing percutaneous incisions or punctures in blood vessels through the use of a closure means." *See, e.g.*, '827 Patent 2:10-44 (invention summary); 15:21-48 (sole independent system claim); 18:19-46 (sole independent method claim); *see also* '827 Patent Abstract. The closure means comprises "anchoring means, sealing means, and filament means, [where] said filament means [is coupled to] said anchoring means and said sealing means.... '827 Patent 15:25-29. In order for the '689 patent to refer to the '827 patent's inventive concept, "closure device" must be understood to refer to "closure means."[8] Were "closure device" a broader term than "closure means," the '689 patent would refer to a different inventive concept.

Furthermore, the '689 patent's prosecution history shows that Kensey did not seek to use "closure device" to include more than "closure means." "The prosecution history limits the interpretation of claim terms so as to exclude any interpretation that was disclaimed during prosecution." *Southwall Tech, Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1576 (Fed. Cir. 1995). Initially, the PTO's examiner determined that Kensey's initial application, if approved, would lead to a double patenting. *See* PTO Office Action Summary in Dec. of Daniel Furniss (Doc. 40) at 45776. The examiner noted that a claim in Kensey's '974 patent describes an instrument that

[8] During the Markman Hearing, Kensey's counsel stated that the closure means described in the '974 patent and the '689 patent were both "three-piece device[s]" composed of an anchor, collagen plug, and filament. *See Kensey Nash v. Perclose*, No. 98-1629 (EDPA March 2000) (Docket item 54, hearing transcript) at 37-39.

seals percutaneous punctures in blood vessel walls through use of a closure means "comprising" an "anchoring means, sealing means, and filament means, wherein the filament means is operatively connected between the anchoring means and the sealing means for moving the anchoring means and the sealing means relative to each other...." *Id.* The inventive concept disclosed by all of the claims in the '689 application covers a percutaneous vessel-puncture sealing instrument "comprising a closure device of resorbable collagen and vessel location means having a valve." *Id.* The examiner reasoned that because the term "comprising" in the '974 patent does not exclude other elements, the prior patent's "closure means" covered the class of devices referred to by the '689 patent's "closure device." In other words, the examiner understand "closure device" to be either equivalent to a "closure means" as described in the '974 patent or a particular type of "closure means." Consequently, the examiner understood "closure device" to mean a closure device comprising an anchor, plug, and filament. At no point, in the remainder of the prosecution history, does Kensey attempt to assert a broader definition for "closure device."

In sum, based on the '974 patent's application's use of "closure means," "closure device" as used in the '689 patent must necessarily refer to the class of closure devices that use an anchor, plug, and filament bound together in a pulley like arrangement whereby the filament draws the anchor and plug together so as to effectuate a seal.

III. "Location Detector" as Used in the '689 Patent

Kensey appears to submit that "location detector" as used in the claims is a general term that refers to any device capable of percutaneously locating an arterial opening through blood

visualization. *See* Pls.' Resp. at 18. Perclose submits that "location detector" as used in the claims refers to "means [which] detect[] the approximate location of the wall of a vessel, duct, or lumen [and] which comprise[] (1) an unattached 'sheath' having an open or free distal end, (2) an unattached removable elongated member that fits within the sheath, and (3) a passageway that extends from a fluid (*e.g.*, blood) entry opening or window located at or close to the distal end of [the] sheath toward the proximal portion of the location detector." Def.'s Mem. at 46. Neither party offers expert testimony to indicate that "location detector" is a technical term. Hence, the term's meaning must be found in the patent.

Asserted Claims 1 and 25, the only independent claims in the patent, both use the term "location detector." The pertinent portions of Claim 1 read as follows:

> "A system for sealing a percutaneous puncture in the wall of a [fluid-filled] vessel, duct or lumen of a living being...
>
> > the puncture comprising an opening in the wall of the vessel, duct or lumen and a tract contiguous with the opening and extending through tissue overlying the vessel, duct or lumen,
>
> [a] said system comprising a closure device and a *location detector*,
>
> [b] said *location detector* being arranged for introduction into the puncture to provide a perceptible signal indicative of the location of the wall of the vessel, duct or lumen, whereupon a desired position for said closure with respect to the vessel, duct or lumen may be determined,
>
> [c] said *location detector* comprising *means* for insertion in the puncture tract to a position at which fluid within the vessel, duct or lumen is enabled to flow from the interior thereof into said *location detector* to provide a perceptible signal...."

'689 patent at 14:56-15:4 (emphasis and sentence division added). The pertinent portions of Claims 25 read as follows:

> "A method for sealing a percutaneous puncture in the wall of a [fluid-filled] vessel, duct or lumen of a living being,...
>
> the puncture comprising an opening in the wall of the vessel, duct or lumen and a tract contiguous with the opening and extending through tissue overlying the vessel, duct or lumen, said method comprising:
>
> (a) providing a closure device and *location detector*;
>
> (b) introducing the location detector into the puncture to a position whereupon the fluid within the vessel, duct or lumen is enabled to flow from the interior of the vessel, duct or lumen into the location detector to provide a perceptible signal indicative of the location of the wall of the vessel, duct or lumen, whereupon a desired position for the closure with respect to the vessel, duct or lumen may be determined....

Id. at 16:48-61.

Again, parsing the claims' language makes more apparent the limitations imposed on the definition of "location detector." First, sections (b) of Claims 1 and 25 specify that the location detector through introduction into the puncture provides a "perceptible signal of the location of the wall of the vessel, duct or lumen." As noted earlier "puncture" comprises the opening as well as tract leading to the opening. Second, sections (c) of both claims specify that the location detector referred to has some "means that enable insertion into the puncture" such that "fluid from the vessel, duct or lumen" can flow from the interior of the vessel, duct or lumen into the location detector. Third, sections (c) also specify that it is the flow of fluids from the vessel, duct or lumen into the location detector that allows for the perceptible signal. Thus, "location detector," as used in these claims refers to the class of devices

> (1) that are introduced into the puncture, and that thereby provide a perceptible signal of the location of the vessel, duct, or lumen wall;
>
> (2) through which fluid can flow from the interior of the vessel, duct, or lumen upon insertion into the puncture;

(3) that uses the aforementioned flow of fluid to provide the aforementioned perceptible signal.

Already the ordinary language of the claims establishes a definition narrower than that submitted by Kensey. However, as yet, the definition is broader than that submitted by Perclose.

Perclose points out that the claims Claim 1 uses the word "means" and argues that therefore "location detector" must be interpreted as a means-plus-function term under 35 U.S.C. § 112, ¶ 6. Def.'s Mem. at 46-47. § 112, ¶ 6 states that "[a]n element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof." The Federal Circuit specifies that "[i]f the word 'means' appears in a claim element in association with a function, this court presumes that [35 U.S.C.] § 112, ¶ 6 applies. This presumption collapses, however, if the claim itself recites sufficient structure, material, or acts to perform the claimed function." *Micro Chemical, Inc. v. Great Plains Chemical Co., Inc.*, 194 F.3d 1250, 1257 (Fed. Cir. 1999). Here the elements of the claims, which posit means for the location detector's positioning, explicitly use the term "means" to express a function and do not recite any structure, material, or acts to perform the claimed function. The other elements of the claims, those that state that fluid flow is to create a perceptible indication of the target position, do not use the term "means" to express a function but nonetheless rely on a functional term. Namely, the other elements of the claims explain the location of the target position by reciting that the location detector is "introduced" into the puncture. Neither claim explains how fluid flow works to create a perceptible signal of the target position. Consequently, the claims use

"location detector" as a means-plus-function term.

Where a means-plus-function term recites a function to be performed rather than definite structure or material [or acts] for performing the function, the term must be construed to "cover the corresponding structure, material, or acts described in the specification and equivalents thereof." 35 U.S.C. § 112; *accord WMS Gaming Inc. v. International Game Tech.*, 184 F.3d 1339, 1347 (Fed. Cir. 1999); *see Chiuminatta Concrete Concepts, Inc. v. Cardinal Indus., Inc.*, 145 F.3d 1303, 1307-08 (Fed. Cir. 1998). The specification describes the location detector in great detail. I will outline the specification's description in brief.

The location detector has four essential elements: an introducer sheath, a conventional hemostasis valve, a sideport connected to a conventional stopcock, and a semi-tubular member. The location detector positions the closure device by positioning the introducer sheath. '689 patent at 9:13-15. The proximal end of the sheath terminates in a "conventional hemostasis valve." *Id.* at 9:11-16. The distal end of the sheath terminates in a free tubular end. *Id.* at 9: 16-17. The sideport is affixed to the valve and connected to the stopcock. *Id.* at 9:17-20. Fluid flowing into the sheath will flow through the valve and sideport to the stopcock. Fluid will flow through the stopcock, when it is in an open position. The semi-tubular member is a "conventional dilator whose outer periphery has been modified to include a longitudinally extending flat" surface. *Id.* at 9:29-31. The distal end of the member is tubular.

The member is inserted into the sheath so that the distal end of the member protrudes outside the distal end of the sheath and leaves an opening between the sheath and the longitudinally extending flat surface of the device. *Id.* at 9:36-47. A slight gap between the distal end of the member and the distal end of the sheath creates an entry into the passageway

between the extending flat and the sheath wall. *Id.* When the sheath, with member inside, is inserted into the puncture, blood (or fluid) will enter the passageway when the gap between the sheath and member enters a vessel (or duct or lumen). *Id.* at 48-10:9. The blood travels up the passageway, through the valve and sideport, and onto the stopcock. *Id.* The flow of blood through the stopcock signals the sheath's position inside the artery. *Id.* The user then removes the sheath and member until blood stops flowing through the stopcock. *Id.* This signals that the sheath is just outside the vessel. *Id.* The user closes the stopcock, withdraws the member from the sheath, and reinserts the sheath 10 mm so as to ensure that the distal end is within the artery. *Id.* The sheath can now accept insertion of the closure device. *Id.*

"Location detector" covers the embodiment described briefly above as well as two other similar embodiments of the member inserted inside the introducer sheath. *See id.* at 10:10-60. One member is similar to the one described above but has a different shape. *Id.* at 10:10-39. The second is a tubular, hollow member with an entrance port near the distal end and an outlet port that allows fluid communication with the sideport and stopcock. *Id.* at 10:40-60. The patent also contains an alternate embodiment of the introducer sheath which can be used with the above described members. *See* '689 patent 10:61-11:34. Hence, in all there are six separate embodiments of the location detector specified as preferred embodiments.

For the purposes of this claim construction, the six embodiments and their equivalents define "location detector." *See, e.g., Chiuminatta Concrete Concepts*, 145 F.3d at 1307-08. The following definition generally sums up the meaning of "location detector" as used in the '689 claims: A device comprising

(1) an introducer sheath, a conventional hemostasis valve, a sideport

connected to a conventional stopcock, and a semi-tubular member arranged within the sheath so as to allow fluid communication between distal end of the sheath and stopcock;

(2) which is used by inserting the sheath until fluid from the target vessel, duct, or lumen appears at the detector's stopcock and thereby indicates the sheath's entry into the artery and allows for an appropriate positioning of the sheath and thereby an appropriate positioning of the closure device.

This definition is in accord with the definition submitted by Perclose, but importantly, this definition is intended as nothing more than a general review of the specification's embodiments. In the event that litigation proceeds to an infringement analysis, the specification language describing the various embodiments of "location detector" and the equivalents of these embodiments shall serve to define the term.

IV. "Puncture Closure" as Used in the '004 Patent

Kensey submits that "puncture closure," as used in the claims, refers to any closure device that has a filament and that uses a knot to hold the closure in place. Pls.' Mem. at 53. Perclose submits that "puncture closure" means "a device for sealing a percutaneous incision or puncture in a vessel, duct or lumen comprised of a sealing member within the puncture tract, an anchor member within the vessel, duct or lumen, and a filament member connecting the anchor and sealing members in a pulley-like arrangement." Def.'s Mem. at 49, 5. Additionally, a "puncture closure" also has a "filament lock," which is a "combination of a knot in engagement with the sealing member and the system for exerting tension on the filament means, which includes a tag, a tamper means, and a torsion spring." Def.'s Mem. at 50.

As is evident in their favored definitions, Kensey and Perclose agree that "puncture

closure" is a specific term but disagree about the precise meaning of the term. Neither party submits that the term would have a particular meaning to one of ordinary skill in the art, and therefore, the court is guided by the meaning of the term as it is understood in the patent and in the patent's prosecution history.

A. Claim Language

The '004 patent contains six independent claims. For the purpose of defining "puncture closure," Claims 1 and 10 contain language representative of the relevant language from all of the independent claims. The pertinent parts of Claim 1 read as follows:

> A system for sealing a percutaneous puncture in the wall of a vessel, duct or lumen of a living being...
>
> [a] said system comprising... a *puncture closure*,
>
> [b] said *closure* comprising *a first portion*[,][9] at least *one extending filament portion* and *a filament lock* . . .
>
> [c] [with] said *closure* [deployed] in the puncture with said *first portion* of said *closure* within the interior of the vessel, duct or lumen and with said at least one extending filament portion extending from said *first portion* of said *closure* into the puncture tract,
>
> [d] said *closure* being arranged to be disposed at an operative position in the puncture sealing the puncture,
>
> [e] said *filament lock* comprising a knot locatable on said at least one filament portion within the puncture tract for cooperation with a portion of said closure[,] said knot, when in said puncture tract and when said first portion of said closure is within the interior of the vessel, duct or lumen, holding said closure at said operative position . . . .

[9] Kensey's brief incorporates this comma without noting its absence in the text of the claim. *See* Pls.' Mem. at 53. I find no coherent way to understand the claim without this comma, and I assume that it was erroneously left out of the text of the patent.

’004 Patent, 14:63-15:19. The language of Claim 10 that pertains to “closure device” is consistent with Claim 1 except in its description of the filament lock. The relevant portions of Claim 10 read as follows:

> ...said filament lock comprising a knot coupled to and movable with respect to said at least one filament portion within the puncture tract to a position holding said closure at said operative position....

Id., 16:38-42.

Section b of Claim 1 makes it plain that the class of devices referred to by “puncture closure” includes all devices with a first portion, one or more extending filaments, and a filament lock. Section d makes it plain that the puncture closure referred to seals the puncture by being disposed at a position within the puncture. Unlike the claims in the ‘689 patent, the ‘004 patent’s claims do not specially define “puncture.” Section c describes the position of some of the puncture closure’s essential elements and as such further limits the class of devices referred to by “puncture closure.” When the closure is deployed within the puncture, the first portion sits within the interior of the vessel, the extending filament runs from the first portion into the puncture tract. Section e of Claim 1 and the quoted portion of Claim 10 specify that the filament lock is a knot and is either located on the extending filament or is coupled to the extending filament. “Puncture closure,” based on the language in Claims 1 and 10, captures a class of devices smaller than the class suggested by Kensey but significantly larger than the class suggested by Perclose.

B. Specification

Kensey argues that Claims 1 and 10 adequately describe the term “filament lock” and that

no special construction is required. *See* Pls.' Mem. at 53-56. Perclose, however, suggests a restricted definition of "filament lock" and argues that there is no support in the specification for the broad definition of "filament lock" contained in Claims 1 and 10.[10] *See* Def.'s Mem. at 51-55. Specifically, Perclose claims that, in the preferred embodiment of the '004 patent, neither of the two knots described—a knot tied around a plug member and a slip knot formed by the filament portions of the closure—can do all that Claims 1 and 10 require of the knot comprising the filament lock. *See id*. at 54-55; *see also* '004 Patent, 7:48-49 (describing knot 68 as the knot tied around the plug member securing the filament to the plug member); '004 Patent (Figure 2 – knot 68 tied around a plug member; and Figure 6 – knot 68 configured as a slip knot). Therefore, according to Perclose, "filament lock" must mean something more than just those knots. *See* Def.'s Mem. at 54-55. Kensey clarifies its position by admitting that the filament lock in the preferred embodiment of the invention is knot 68, but disagrees with Perclose's assertion that knot 68 cannot do all that Claims 1 and 10 require of the knot comprising the filament lock. *See* Pls.' Resp. at 20-22. Thus, the real issue before the court appears to be whether or not knot 68 can do what Claims 1 and 10 require of the knot comprising the filament lock.

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[10] Perclose also points out that during the application process, Kensey amended the claims of the '004 patent to use "filament lock" instead of "locking means," suggesting that the terms have different meanings. *See* Def.'s Mem. at 51. Any different meaning would be important because the "filament lock" claimed in Claims 1 and 10 appears to describe the locking means discussed in the specification of the '004 patent. *See, e.g.*, '004 Patent, 2:49-57.

After reading the claims and the specification of the '004 patent, the interchangeability of "locking means" and "filament lock" is apparent. Furthermore, a perfectly acceptable reason for not using "locking means" in the claims is also apparent. As discussed with respect to "location detector" in the '689 patent, means-plus-function claim terms are construed in a very particular manner. If Kensey did not want to define the knot et al. in this fashion, then changing the claim language from "locking means" to "filament lock" makes sense.

The knot described in Claim 1 must be locatable on the extending filament portion. *See* '004 Patent, 15:14-15. Knot 68 can do this. In the preferred embodiment, extending filament portion 34 passes through the plug member and out of the puncture tract. *See id*., 7:36-49. Thus, using the "pulley-like connection" the plug member can be positioned at a desired location on extending filament portion 34. *Id*., 7:36. Because knot 68 is tied around the plug member, knot 68 can also be positioned at a desired location on extending filament portion 34. Thus, knot 68 is locatable on the extending filament portion. Indeed, Perclose recognizes this. *See* Def.'s Mem. at 54.

Knot 68 must also be able to hold the closure in the operative position. *See* '004 Patent, 7:16-19. Perclose argues that in the preferred embodiment, the closure is not held in place by knot 68 but by the "combination of the pushing force exerted by the tamper on the sealing means, not on knot 68, and the pulley-like pulling force exerted on the filament." Def.'s Mem. at 54. In making this argument, however, Perclose points out exactly how knot 68 holds the closure in the operative position. The "pulley-like pulling force exerted on the filament" depends on knot 68. Without knot 68, the force exerted on extending filament portion 34 by the torsion spring would be unopposed, and the anchor member would not be held in the operative position. Although knot 68 does not hold the closure in the operative position by itself, in the preferred embodiment, knot 68 is essential to accomplishing this task. Thus, knot 68 satisfies the requirements imposed by Claim 1 on the knot comprising the filament lock.

Knot 68 can quickly be shown to satisfy two of Claim 10's three requirements. Claim 10 requires that the knot comprising the filament lock be movable with respect to the extending filament portion. *See* '004 Patent, 16:38-39. In its brief, Perclose correctly acknowledges that

knot 68 is, in at least some ways, movable with respect to extending filament portion 34. *See* Def.'s Mem. at 54. Moreover, it is already plain that, in cooperation with other elements of the preferred embodiment, knot 68 holds the closure in the operative position. *See* '004 Patent, 16:40-41.

The remaining requirement of Claim 10 is that the knot comprising the filament lock be coupled to the extending filament portion. *See id*., 16:38-39. Claim 10 also reveals, however, that between the filament lock and the extending filament portion lies the first portion of the closure, which is that portion of the closure inside the vessel. *See id*., 16:32-36. In the preferred embodiment, the first portion would be made up of the anchor member and whatever filament from the pulley-like arrangement that remains inside the vessel. *See id*., 12:37-13:18. Assuming that there is some of this filament inside the vessel, knot 68 could satisfy this requirement of Claim 10. Taking the ordinary meaning of "coupled" to be connected, knot 68 is connected to the filament inside the vessel, and the filament inside the vessel is connected to extending filament portion 34. Thus, knot 68 is indirectly connected to extending filament portion 34, but connected nonetheless. For this reason, knot 68 satisfies the final requirement of Claim 10.

C. Prosecution History

Neither party analyzes the prosecution history of the '004 patent in detail. The '004 patent's application follows in the same line of continuation applications from which the '689 patent arose. The submission of the '004 patent's application immediately followed the submission of the '689 patent's application. The '004 application also arises from the same initial application, namely the '974 patent's application. It is clear the "puncture closure" is a particular type of "closure device" or "closure means." Hence, "puncture closure" refers to some

subclass among the class of devices identified by "closure device" or "closure means." Hence, a puncture closure is some particular type of anchor, plug, and filament closure.

The '004 patent's prosecution history only further confirms that a puncture closure is a type of "closure device." In rejecting Kensey's initial application for the '004 patent, the examiner specifically stated that the application shared a "common subject matter" with the '974 patent and approval of the application would result in nonstatutory double patenting. PTO's June 30, 1998 Office Action at 2.[11] The common subject was "[a] system for sealing a percutaneous puncture comprising a deployment member or carrier means, a positioning means or anchoring means, a puncture closure or closure means, a filament, a locking means having a knot...." *Id.* at 3. As relevant here, both devices must include plugs or sealing members of some sort. Furthermore both closure assemblies must be positioned by the closures' anchors. Consequently, it is clear that the PTO examiner understood "puncture closure" to include both an anchor and a plug. In response, Kensey disclaimed, under 37 CFR 1.321, the subject matter of '974, and by so doing, Kensey gave up any extension of patent protection through the '974 patent that might have resulted from the approval of the '004 application. *See* August 21, 1998 Terminal Disclaimer.[12] This disclaimer, at a minimum, serves to indicate that Kensey did not dispute that "puncture closure" and "closure means" cover the same ground.

In sum, "puncture closure" must be understood to have all the essential elements of "closure means" with the additional element of a "filament lock." "Puncture closure" must include, therefore, an anchor and plug. Furthermore, the plug can only be understood as being

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[11] In Dec. of Charles Cantine (Doc. 33) at Ex. 21.

[12] In Cantine Dec. at Ex. 21.

bound by the knot. Consequently, "puncture closure" as used in the '004 patent refers to the class of closure devices (1) that use an anchor, plug, and filament bound together in a pulley like arrangement whereby the filament draws the anchor and plug together so as to effectuate a seal and (2) that have a filament knot which holds the closure in place by holding the plug in place.

V. Conclusion

The prosecution history of the '689 patent establishes that "closure device" covers the class of closure devices that use an anchor, plug, and filament bound together in a pulley like arrangement whereby the filament draws the anchor and plug together so as to effectuate a seal. "Location detector," as a means-plus-function term, is defined by the '689 patent's specification and the equivalents of the definitions provided in the specification. The asserted '689 Claims 1, 7, 13, 25, 27, 39, and 44 use both "closure device" and "location detector" as so defined. Based on the prosecution history of the '004 claim, "puncture closure" means a "closure device," as used in the '689 claim, that bears a filament knot that holds the closure in place by holding the plug in place.