

United States District Court,
E.D. Texas, Lufkin Division.

PRESSURE PRODUCTS MEDICAL SUPPLIES, INC,
Plaintiff.

v.

ENPATH MEDICAL, INC,
Defendant.

Civil Action No. 9:06-CV-121

March 19, 2008.

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***MEMORANDUM OPINION AND ORDER CONSTRUING CLAIM TERMS OF UNITED STATES
PATENT NOS. 5,125,904 AND 5,312,355***

KEITH F. GIBLIN, United States Magistrate Judge.

Plaintiff Pressure Products Medical Supplies, Inc. ("Pressure Products") filed suit against Defendant Enpath Medical, Inc. ("Enpath") claiming infringement of United States Patent Nos. 5,125,904 ("the '904 patent") and 5,312,355 ("the '355 patent"). The court conducted a *Markman* hearing to assist the court in interpreting the meaning of the claim terms in dispute. Having carefully considered the patents, the prosecution history, the parties' briefs, and the arguments of counsel, the court now makes the following findings and construes the disputed claim terms. FN1

FN1. While this Order governs in the event of any conflict between the Order and the court's preliminary analysis at the hearing, the record may clarify the bases for the conclusions set out herein. The transcript of the claim construction hearing will be cited as "Tr. at p. ----, l. ----."

I. CLAIM CONSTRUCTION STANDARD OF REVIEW

Claim construction is a matter of law. *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996) ("*Markman II*"). "The duty of the trial judge is to determine the meaning of the claims at issue, and to instruct the jury accordingly." *Exxon Chem. Patents, Inc. v. Lubrizoil Corp.*, 64 F.3d 1553, 1555 (Fed.Cir.1995) (citations omitted), *cert. denied*, 518 U.S. 1020, 116 S.Ct. 2554, 135 L.Ed.2d 1073 (1996).

" '[T]he claims of the 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) (*en banc*) (citation omitted), *cert. denied*, 546 U.S. 1170, 126 S.Ct. 1332, 164 L.Ed.2d 49 (2006). "Because the patentee is required to 'define precisely what his invention is,' it is 'unjust to the public, as well as an evasion of the law, to construe it in a manner different from the plain import of its terms.' " *Phillips*, 415 F.3d at 1312 (quoting *White v. Dunbar*, 119 U.S. 47, 52, 7 S.Ct. 72, 30 L.Ed. 303 (1886)).

The words of a claim are generally given their ordinary and customary meaning. *Phillips* 415 F.3d at 1312. The "ordinary and customary meaning of a claim term 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." FN2 *Id.* at 1313. Analyzing "how a person of ordinary skill in the art understands a claim term" is the starting point of a proper claim construction. *Id.*

FN2. Based on the patents and their cited references, the tutorials, and the representations of the parties at the hearing, the court finds that "one of ordinary skill in the art" in this case is an interventional cardiologist, interventional radiologist, surgeon, interventionalist, or biomedical engineer or biomedical device designer and/or manufacturer with at least five years of experience working in the field.

A "person of ordinary skill in the art is deemed to read the claim term not only in context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification." *Phillips*, 415 F.3d at 1313. Where a claim term has a particular meaning in the field of art, the court must examine those sources available to the public to show what a person skilled in the art would have understood the disputed claim language to mean. *Id.* at 1414. Those sources "include 'words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art.' " *Id.* (citation omitted).

"[T]he ordinary meaning of claim language as understood by a person of skill in the art may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words." *Phillips*, 415 F.3d at 1314. In these instances, a general purpose dictionary may be helpful. *Id.*

However, the Court emphasized the importance of the specification. "[T]he 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.' " *Phillips*, 415 F.3d at 1315 (quoting *Vitronics Corp. v. Conceptronc, Inc.*, 90 F.3d 1576, 1582 (Fed.Cir.1996)). A court is authorized to review extrinsic evidence, such as dictionaries, inventor testimony, and learned treatises. *Phillips*, 415 F.3d at 1317. But their use should be limited to edification purposes. *Id.* at 1319.

The intrinsic evidence, that is, the patent specification, and, if in evidence, the prosecution history, may

clarify whether the patentee clearly intended a meaning different from the ordinary meaning, or clearly disavowed the ordinary meaning in favor of some special meaning. *See* *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979-80 (Fed.Cir.1995); *aff'd*, 517 U.S. 370, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996). Claim terms take on their ordinary and accustomed meanings unless the patentee demonstrated "clear intent" to deviate from the ordinary and accustomed meaning of a claim term by redefining the term in the patent specification. *Johnson Worldwide Assoc., Inc. v. Zebco Corp.*, 175 F.3d 985, 990 (Fed.Cir.1999).

The " 'ordinary meaning' of a claim term is its meaning to the ordinary artisan after reading the entire patent." *Phillips*, 415 F.3d at 1321. However, the patentee may deviate from the plain and ordinary meaning by characterizing the invention in the prosecution history using words or expressions of manifest exclusion or restriction, representing a "clear disavowal" of claim scope. *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1327 (Fed.Cir.2002). It is clear that if the patentee clearly intended to be its own lexicographer, the "inventor's lexicography governs." *Phillips*, 415 F.3d at 1316.

II. CONSTRUCTION OF MEANS-PLUS-FUNCTION TERMS

Where a claim includes the word "means," a presumption is invoked that it is a means-plus-function clause under 35 U.S.C. s. 112(6). *See Harris Corp. v. Ericsson Inc.*, 417 F.3d 1241, 1248 (Fed.Cir.2005). This presumption may be rebutted if the claim recites "sufficient structure for performing the claimed function" *Id.*

Determining the claimed function and the corresponding structure of means-plus-function clauses are matters of claim construction, so it is appropriate to deal with these issues at the *Markman* stage. *WMS Gaming Inc., v. Int'l Game Tech.*, 184 F.3d 1339 (Fed.Cir.1999). Claim construction of a means-plus-function limitation involves two steps. *See Medical Instrumentation and Diagnostics v. Elekta AB*, 344 F.3d 1205, 1210 (Fed.Cir.2003). The court must first identify the particular claimed function, and then look to the specification and identify the corresponding structure for that function. *Id.* "Under this second step, 'structure disclosed in the specification is corresponding structure only if the specification or prosecution history clearly links or associates that structure to the function recited in the claim.'" *Id.* (citations omitted). "While corresponding structure need not include all things necessary to enable the claimed invention to work, it must include all structure that actually performs the recited function." *Default Proof Credit Card System, Inc. v. Home Depot U.S.A., Inc.*, 412 F.3d 1291, 1298 (Fed.Cir.2005).

III. PATENT BACKGROUND AND TECHNOLOGY

The '904 and '355 patents are related to a splittable hemostatic valve and introducer sheath assembly that allows introduction of leads or catheters into a vein or artery, with the '355 patent being a continuation-in-part of the '904 patent. Because of the hemostatic valve, the introducer sheath can remain in the vein throughout an operation with the advantage of free lead exchange, easier lead manipulation, reduced blood loss, and reduced risk of air embolism. A side arm to the hemostatic valve cage provides continuous fluid drip in order to prevent clot formation in the opening of the introducer sheath.

The introducer sheath and hemostatic valve can be split apart during operation so that they can be removed from the implanted lead or catheter without having to slide either of them over the free end of the lead or catheter. By doing so, a device such as a pacemaker can be placed on the free end of the lead or catheter without interfering with the optimal use of the introducer sheath and hemostatic valve.

IV. CLAIM CONSTRUCTION

1. "Hemostatic Valve." Used in '904 patent, claims 1-11, 13, 20, 23; ' 355 patent, claims 1, 2, 4, 5, 7, 11, 14, 19, 21, 23, 25, 29.

Pressure Products contends "hemostatic valve" means "a valve that substantially reduces or minimizes the rate of blood flow and air flow." Enpath argues that the proper construction is "a valve that provides a seal around a lead or catheter to arrest or prevent the leakage of blood from the body and entry of air into the body in compliance with the industry-accepted 'hemostasis' standards and tests." The main disagreement between the parties is whether the hemostatic valve "substantially reduces" blood flow or "arrests and prevents" the leakage of blood.

The court first looks to the language of the claims. Claim 1 states that the hemostatic valve coupled to the introducer sheath comprises an assembly that has "the advantage of free lead exchange and easier lead manipulation without *substantial* bleeding, risk of air embolism ..." '904 patent, col. 7, ll. 3-8. Other claims in the '904 patent follow suit. *See* '904 patent, claim 9, reexamination certificate, col. 1, ll. 41-42 (without substantial bleeding); claim 12, col. 8, ll. 1-2 (without substantial bleeding); claim 18, col. 8, ll. 62-64 (whereby bleeding ... is substantially avoided); claim 19, col.10, ll. 6-7 (without substantial bleeding); '355 patent, claim 1, col. 10, ll. 26-26 (without substantial bleeding); '355 patent, claim 19, col. 12, ll. 36-37 (without substantial bleeding).FN3

FN3. It should be noted that the patentee did not use the term "substantial" in several claim terms. *See* '904 patent, claim 13, col. 8, ll. 11-12 (sealing said lead or catheter within said hemostatic valve to prevent bleeding); claim 13, col. 8, l. 26 (without bleeding); '355 patent, claim 14, col. 11, l. 55 (disposed into the body lumen without bleeding).

The specification explains that this is because the "assembly may remain in the vessel lumen throughout the operation without *substantial* bleeding, risk of air embolism ..." '904 patent, col. 2, ll. 65-68. This advantage is reiterated throughout the patent. *See* '904 patent, col. 5, ll. 19-21 (virtually no bleeding occurs); '904 patent, col. 5, ll. 23-25 (without any significant possibility of bleeding, clotting, risk of air embolism).

Pressure Products' proposed construction involves reducing or minimizing the *rate* of blood flow. Although practically speaking, the rate of blood flow would likely be proportional to the amount of blood produced, there is nothing in the claim language or specification to suggest that the rate of blood flow is minimized.

Turning to the competing proposal, Enpath relies heavily, if not solely, on extrinsic evidence. Enpath argues that the meaning of "hemostatic" is "arrest [ing] or check[ing] bleeding." Def. Cl. Const. Br. at 19 [Doc. # 49]. Enpath points to the definition in the Merriam-Webster's Dictionary and The McGraw-Hill Dictionary of Scientific and Technical Terms. *Merriam-Webster's Collegiate Dictionary* (1977); *The McGraw-Hill Dictionary of Scientific and Technical Terms* (4th ed., 1989). Dictionaries may be helpful but are "less significant than the intrinsic record in determining the legally operative meaning of claim language." *MBO Laboratories, Inc. v. Becton, Dickinson & Co.*, 474 F.3d 1323, 1329 (Fed.Cir.2007).

Enpath discusses the patentee's statements during reexamination to support its argument that the valve must be completely leak-free. The patentee distinguished the '904 patent from prior art solutions in that the prior art solutions place patients in "severe head-down position (Trendelenburg position which creates an extremely bloody theater of operation)" or involve "pinching the introducer with fingers to avoid blood and air leakage." Such a statement does not, as Enpath suggests, evidence an assertion that the present invention

results in a *complete* lack of blood loss. Instead, it merely indicates that the hemostatic valve would not create an "extremely bloody theater of operation."

At the *Markman* hearing and in its claim construction brief, Enpath directed the court's attention to Pressure Products' commercial embodiment of the patents-in-suit, SafeSheath. The product sheet of SafeSheath contains a statement that its hemostatic valve is "leak-free" and "seals the introducer during lead introduction positioning." Not only will the court decline to read aspects of the commercial embodiment into the claims, but the court will also note that the product sheet states that the hemostatic valve "reduces risk of blood loss and air embolism," which does not appear to support Enpath's argument.

Enpath's proposal relies upon purported "compliance with the industry-accepted 'hemostasis' standard" set forth in International Standards Organization (ISO) guidelines used by manufacturers to test and present evidence to the Food and Drug Administration (FDA). Specifically, Enpath points to two documents, the ISA 11070 and ISA 10555. Notably, these documents were first published in May 1998 and July 1996, respectively, and therefore not in existence in May 1991, the effective filing dates of the patents-in-suit as they relate to the term "hemostatic valve."

Enpath argues that importing ISO standards is necessary because use of the word "substantially" would render the claim indefinite. While construing the term "substantially," the question is not whether the word "substantially" has a fixed meaning as applied in general, but how the phrase would be understood by one of skill in the art upon reading the patent documents. *See Kizenbaw v. Case, LLC*, 179 Fed.Appx.20 (Fed.Cir.2006) (holding that expressions such as "substantially" are used in patent documents when warranted by the nature of the invention, in order to accommodate minor variations and would not necessarily render the phrase indefinite.). At the hearing, Pressure Products argued that a person of skill in the art would have understood a hemostatic valve to prevent "substantial," rather than absolute, blood leakage across the valve, based on the characteristics of the particular patient. Tr. at p. 53, ll. 1-11. Enpath agreed at the hearing that the valve would not be understood by a person of skill in the art to be absolute, and suggested "substantially complete arresting of blood" as a construction which would be appropriate. Tr. p. 56, ll. 5-8, 19-20. The court will construe this term as follows:

"Hemostatic valve" means "a valve that substantially reduces bleeding and air flow."

2. "Valve." Used in '904 patent, claims 1-11, 13, 20 & 23; '355 patent, claims 1, 2, 4, 5, 7, 11, 14, 19, 21, 23, 25 & 29.

Pressure Products argues that the term "valve" is not used to refer to anything other than a hemostatic valve and therefore need not be construed separately from the term "hemostatic valve." Enpath argues that the term "valve" should be construed as "a membrane having a passageway through which at least one lead or catheter to hinder or reduce the flow of fluid or gas past the meeting point of the membrane and the lead or catheter."

The asserted claims routinely describe both a "valve" and a "hemostatic valve" as a device that is coupled to the introducer sheath and allows introduction of at least one lead or catheter through the hemostatic valve. *See '904 patent, col. 8, ll. 7-10.* There is nothing in the language of the claims suggesting that the term "valve" includes any other limitations than those included in the "hemostatic valve." Instead, it is clear that the claims use the term "valve" and "hemostatic valve" interchangeably. *Id.* Wherever a "valve" is described, the language makes clear that it refers to "hemostatic valve." *See, e.g., '904 patent, col. 8, ll. 9-10*

("hemostatic valve ... disposing at least one lead or catheter through *said* valve.") (emphasis added).

The specification further supports this conclusion. In the '904 patent, col. 3, ll. 27-30, the patent describes an embodiment where "the introducer sheath and hemostatic valve are separate body portions coupled to each other and the element for permitting removal of the valve and sheath ..." "Valve" clearly refers to the "hemostatic valve" and "sheath" refers to the "introducer sheath."

Enpath argues that the term "valve" is ambiguous because the "Description of the Invention" uses the following terms in connection with a valve: hemostatic valve assembly **14**, valve body **16** (valve body **14** in the case of the '355 patent,) and valve membrane **22**. However, the specification actually states that valve **16** includes a valve membrane **22**, and both are part of the hemostatic valve assembly **14**. '904 patent, col. 4, ll. 63-65; '355 patent, col. 6, ll. 39-42. Nowhere does the specification state, as Enpath suggests, that the membrane is the valve itself. Therefore, the court will construe this term as follows:

"Valve" means "hemostatic valve."

3. "Hemostatic valve subassembly." Used in '904 patent, claims 20-26.

Pressure Products contends that this term should be construed as "the hemostatic valve component that is coupled to the introducer sheath component of the assembly." Enpath states that this term means "hemostatic valve subassembly, as claimed in the '904 patent, includes the valve body and the hemostatic valve."

The specification of the '904 patent does not specifically use or define this term; rather, it was used for the first time in independent Claims 20 and 23 after reexamination. Claim 20 states that the "hemostatic valve subassembly" is coupled to the introducer sheath, and that the assembly is comprised of this subassembly, the introducer sheath, and the means for allowing those two components to be removed from the lead or catheter. '904 patent, Reexamination Cert., col. 1, l. 44-col. 2, l. 5. Claim 23 describes the assembly as being comprised of the same components, and the hemostatic valve subassembly itself as being comprised of a membrane for providing a fluid-tight seal and a peel-away valve housing. '904 patent, Reexamination Cert., col. 2, ll. 16-50. Claim 1 of the '904 patent describes the sheath assembly as comprising the introducer sheath, the hemostatic valve, and the means for allowing these two components to be removed from the lead or catheter. '904 patent, col. 6, ll. 58-67, col. 7, ll. 1-2.

As a general rule, the court will presume a "difference in meaning and scope when different words or phrases are used in separate claims." *Comark Comm'ns v. Harris Corp.*, 156 F.3d 1182, 1187 (Fed.Cir.1998). This rule is not inflexible, but in order for different terms or phrases in separate claims to be construed to cover the same subject matter, the "written description and prosecution history [should] indicate that such a reading of the terms or phrases is proper." *Nystrom v. Trex. Co.*, 424 F.3d 1136, 1143 (Fed.Cir.2005).

Here, the written description of the '904 patent does not define or even mention "hemostatic valve subassembly"; the term first appears in claim 20 of the '904 Reexamination Certificate. On the other hand, the term "valve assembly" appears numerous times in the claims of the patents-in-suit and is defined in the specification of the '904 patent. *See* col. 4, ll. 55-67 and Cert. of Correction (as corrected, noting that valve assembly is "comprised of a valve body **16**, an intravenous sidearm **18** with a sidearm of valve **20**," as well as valve membrane **22**. Valve assembly **14** and splittable sheath **12** comprise the valve and sheath assembly **10**."). Enpath argues that because the common meaning of subassembly is something less than an assembly,

"hemostatic valve assembly" must be something less than the valve assembly, namely the valve body and valve.

At the claim construction hearing, Pressure Products took the position that "hemostatic valve subassembly" and "hemostatic valve" have the same meaning. Tr. at p. 69, ll. 7-21. It argues that the subassembly is coupled to the introducer sheath component, which is consistent with the construction of "valve" or "hemostatic valve." In other words, "subassembly" merely refers to the valve component coupled to the introducer sheath.

The court agrees with Pressure Products. While the applicant introduced the new term "hemostatic valve subassembly" into the claims during reexamination, the subassembly is synonymous with "hemostatic valve." Like the hemostatic valve, the subassembly is coupled to the splittable introducer sheath and, together with that sheath and the means for allowing those two components to be removed from the lead or catheter, comprises the sheath and valve assembly claimed. Under this construction, "subassembly" means a sub-part of the overall assembly claimed; this is consistent with the common understanding that a subassembly is something less than an assembly.

"Hemostatic valve subassembly" means "the hemostatic valve component that is coupled to the introducer sheath component of the assembly."

4. "A score line defined in said hemostatic valve and introducer sheath." Used in '904 patent, claims 4-8.

Pressure Products argues that this term does not need to be construed. If the court decides to construe the term, Pressure Products contends that it means "one or more notches, lines, incisions, or partial cuts in each of the hemostatic valve and introducer sheath." Pressure Products also agreed at the claim construction hearing that the lines were longitudinal. Tr. at p. 99, ll. 6-9. Enpath states that this term means "a single longitudinal groove or recess formed in the surface of the hemostatic valve and introducer sheath that extends along the entire length of both the introducer sheath and the hemostatic valve."

Claim 4 recites the assembly of claim 1 where the means for removing the valve and introducer sheath is "a score line defined in said hemostatic valve and introducer sheath along which said hemostatic valve and introducer sheath may be separated." '904 patent, col. 7, ll. 21-23. Claims 5-8 are dependent on claim 4. In a preferred embodiment, the specification describes a pair of diametrically opposed longitudinal score lines **34** and **36** extending down the axial length of the introducer sheath and the hemostatic valve. The introducer sheath's score line is aligned with the hemostatic valve's score line. *See* col. 3, ll.12-22; col. 5, l. 67-col. 6, l. 4; Fig. 3. The preferred embodiment also leaves open the possibility that the score lines are not entirely longitudinal. col. 6, ll. 28-31 ("it is entirely possible that score lines **34** and **46** will be continued through flanges **38** and **40** to provide deep scores instead of open slots **44** and **46**").

It is axiomatic that courts should avoid importing limitations from the specification into the claim terms, absent a clear disclaimer of claim scope. *Phillips v. AWH Corp.* 415 F.3d 1303, 1323 (Fed.Cir.2005); *Gillette Co. v. Energizer Holdings, Inc.*, 405 F.3d 1367, 1375 (Fed.Cir.2005). At the same time, where the specification uses language of requirement, rather than preference, the specification describes an essential step or element of the claim rather than merely a preferred embodiment. *See Andersen Corp. v. Fiber Composites, Inc.*, 474 F.3d 1361, 1372-73 (Fed.Cir.2007), *Honeywell Int'l v. ITT Indus., Inc.*, 452 F.3d 1312, 1318 (Fed.Cir.2006).

Pressure Products argues that Enpath's proposed construction improperly imports limitations from the specification, namely the description of the preferred embodiment, into the claims. Enpath responds that during reexamination of the '904 patent, the applicant stated that he invented a "splittable hemostatic valve in combination with [a] splittable sheath." Statement of 11/3/95, Def. Resp. Cl. Const. Br., Ex. 1 at 17 [Doc. # 49]. The applicant goes on to state that "the elements which permit the function of removal by splitting are specifically described in connection with the illustration of Figure 3 beginning at column 5, line 67 through column 6, line 32 [a preferred embodiment]." *Id.* Enpath therefore argues that the applicant clearly disclaimed any means for splitting other than through use of a device with these particular score lines.

The court does not think applicant's statement during prosecution is as clear as Enpath suggests. The applicant merely points to a portion in the specification that describes a means of performing the function of removal by splitting; it does not follow that applicant was disclaiming all other elements used to accomplish removal by splitting other than the ones specifically described.

Both parties argue that something other than "line" should be used in the court's construction of this term: Pressure Products suggests "notch, incision, or partial cut" while Enpath proposes "groove or recess." However, neither side points to any place in the specification or claims of the '904 patent in which any of these words or phrases are actually used to describe the score line. However, a "score" has been defined to mean "any scratch, line, or groove" that is formed by the scoring process." *See, e.g., Academic Press: Dictionary of Science and Technology (1992)*. Therefore, "a score line" should be limited to a line. Claim 4, with reference to claim 1, clearly states that the purpose of the score line is to permit removal of the hemostatic valve and introducer sheath from the lead or catheter without requiring that the introducer sheath and valve be removed from the end of the catheter. *See also* col. 2, ll. 58-62. Finally, claim 4 of the '904 patent recites "a score line." As a general rule, the use of the word "a" means "one or more than one." *Norian Corp. v. Stryker Corp.*, 432 F.3d 1356, 1359 (Fed.Cir.2005). This is consistent with Pressure Products' proposed construction of "one or more." The court will therefore define this term as follows:

"A score line defined in said hemostatic valve and introducer sheath" is "one or more line(s) defined in the hemostatic valve and introducer sheath."

5. "Integrally formed." Used in '904 patent, claim 9.

Pressure Products proposes "connected together so as to make up a piece or unit." Enpath argues that this term means "a single body or structure, molded or cast, which includes two or more functional parts."

Claim 9 of the '904 patent (as amended) recites a sheath assembly where the introducer sheath and the hemostatic valve are "integrally formed." '904 patent, Reexamination Cert., col. 1, ll. 33-34. The parties refer to this term in two different manners. Pressure Products refers to component parts which are connected to make a whole, while Enpath refers to a single piece which includes two or more component parts. Both positions are consistent with common usage of the word. *See Oxford English Dictionary*^{FN4} (integral means "whole, entire, complete" and it also means "of or pertaining to a whole."); *Hazani v. United States ITC*, 126 F.3d 1473, 1480 (Fed.Cir.1997) ("integral" means complete or entire).

FN4. Available at <http://dictionary.oed.com>

Enpath's proposed construction is too restrictive. At the claim construction hearing, Enpath took the position that, "integrally formed" required that, during the manufacturing process, the components be cast or molded together from inception. Tr. at p. 110, ll. 2-6. However, the specification states that the construction of the assembly is not critical,

at least to the extent of whether sheath **12** and valve assembly **10** must be separate or integral parts or how they may be connected with each other ... For example, sheath **12** may be integrally molded or cast with valve assembly, may be adhesively affixed thereto, may be compression fitted, slip fit, threaded, or connected in any manner desired to valve assembly **14** ...

'904 patent, col. 5, ll. 41-55. The specification, therefore, contemplates situations in which the valve assembly and sheath may be created as separate entities and later connected to form a unit. Enpath's construction of "integrally formed" is contrary to the specification. *See also* In re Morris, 127 F.3d 1048, 1055-56 (Fed.Cir.1997) ("integral" can be interpreted to mean more than a "unitary construction."). The court will define this term as follows:

"Integrally formed" means "connected together so as to make up a piece or unit."

6. "Permits removal of said valve and sheath as an integral body." Used in '904 patent, claim 9.

Pressure Products proposes "permits removal of the separated portions of the valve and sheath as a connected body." Enpath argues that the term should be construed as "the end result of using an apparatus which includes a valve and sheath that can be removed from a lead or catheter without separating the valve and sheath from each other."

As already discussed, the commonly understood meaning of the word "integral" is "whole, entire, complete" or "of or pertaining to a whole." Neither party disputes that the valve and sheath must be removed together, be it is "as a connected body" (Pressure Products) or "without separating the valve and sheath from each other" (Enpath). Both sides agreed at the claim construction hearing that when the valve and sheath are removed from the lead or catheter, the end product is two separate pieces, each of which contains part of the valve and part of the sheath. Tr. at p. 117, ll. 15-25, p. 118, l. 25-p. 119, l. 4.

Both parties' proposed constructions are potentially confusing to a jury, Enpath's because it is redundant when read in the context of Claim 9, and Pressure Products' because it, correctly yet confusingly, describes the valve and sheath as simultaneously separated and connected. Therefore, the Court will construe this term as follows:

"Permits removal of said valve and sheath as an integral body" means "permits removal of the valve and sheath in two pieces, with each piece containing a portion of the valve and a portion of the sheath still connected together."

7. "Disposing an introducer sheath and hemostatic valve coupled to said introducer sheath in a body lumen." Used in '904 patent, claims 13-17; '355 patent, claims 14-18.

Pressure Products suggests "placing an introducer sheath, having a hemostatic valve coupled thereto, in a body lumen." Enpath proposes "placing an introducer sheath and an attached hemostatic valve inside a body opening or conduit." At the claim construction hearing, Pressure Products clarified that it actually meant "into a body lumen." Tr. at p. 120, ll. 20-21.

Pressure Products agreed at the claim construction hearing that "lumen" simply means "body opening." Tr. at p. 119, ll. 20-23. Both parties agree that the introducer sheath and hemostatic valve are somehow connected; they differ only on whether the sheath and valve are "coupled" (Pressure Products) or "attached" (Enpath). The specification and Claim 13 of the '904 patent, as well as claim 14 of the '355 patent, all use the word "coupled." *See* '904 patent, col. 3, ll. 40-44 and col. 8, ll. 7-8; '355 patent, col. ll. 31-33.

The parties' major disagreement over this term involves whether the introducer sheath and hemostatic valve are placed "into" the body opening (Pressure Products) or "inside" the body opening (Enpath). Pressure Products argues that a person of ordinary skill in the art would understand that while the device as a whole is placed into the body opening, the valve itself remains outside. In addition, while claim 13 of the '904 patent uses the phrase "in a body lumen," both the specification of the '904 patent and claim 14 of the '355 patent use the phrase "into a body lumen." '904 patent, col. 3, ll. 43-44, '355 patent, col. 11, ll. 32-33. In light of the specification and claim language, the court will therefore construe this term as follows:

"Disposing an introducer sheath and hemostatic valve coupled to said introducer sheath in a body lumen" means "placing an introducer sheath coupled to a hemostatic valve into a body opening."

8. "Releasable membrane." Used in '355 patent, claim 21.

Pressure Products proposes "resealable membrane," on the theory that the patentee erroneously wrote "releasable" when he actually meant "resealable." Enpath suggests "releasable membrane," and further argues that the court should find it invalid.

Pressure Products argues that claim 21 of the '355 patent is identical to claim 2 of the '355 patent, the only difference being that they are dependent from two different claims. Rather than "releasable," claim 2 uses "resealable." The specification of the '355 patent discloses that the "hemostatic valve comprises a resealable membrane." Col. 4, ll. 35-39. As Enpath points out, there is no support in the specification for a releasable membrane.

Enpath's only argument is that "courts do not redraft claims." *See* Quantum Corp. v. Rodime, PLC, 65 F.3d 1577, 1584 (Fed.Cir.1995). While Enpath is, of course, correct, a court may act to correct an error in the patent where no certificate of correction has been issued where "(1) the correction is not subject to reasonable debate based on consideration of the claim language and the specification and (2) the prosecution history does not suggest a different interpretation of the claims." *Novo Indus. L.P. v. Micro Molds Corp.*, 350 F.3d 1348, 1354 (Fed.Cir.2003). The specification discusses a hemostatic valve comprising a resealable membrane, as does claim 2. The only difference between claim 1, from which claim 2 is dependent, and claim 19, from which claim 21 is dependent, is that claim 19 includes the number of body parts the hemostatic valve is comprised of. The only reasonable interpretation, supported by the specification and claims, is that "releasable" in claim 21 is a typographical error. Enpath has pointed to nothing in the prosecution history that refutes this conclusion. The court will construe this term as follows:

"Releasable membrane" means "resealable membrane."

9. "Removing said hemostatic valve and introducer sheath while leaving said lead or catheter in place within said body lumen without sliding either said introducer sheath or hemostatic valve over an end of said lead or catheter." Used in '904 patent, claims 13-17; '355 patent, claims 14-18.

Pressure Products suggests that this term does not need to be construed by the court. In the alternative, it proposes "removing the hemostatic valve and introducer sheath while leaving the lead or catheter in place within the body lumen without sliding either the introducer sheath or hemostatic valve over an end of the lead or catheter." Enpath's proposed construction is:

the step of removing a hemostatic valve and introducer sheath while leaving a lead or catheter in place within a body lumen, without sliding either said introducer sheath or hemostatic valve over an end of the lead or catheter must be performed by using the structure disclosed for performing the function of removing the hemostatic valve and sheath."

The key dispute between the parties is whether the claims should be analyzed under 35 U.S.C. s. 112, para. 6. Pressure Products argues that these are method claims, not drafted in means-plus-function or step-plus-function form, which recite a series of steps without also reciting a function. Enpath's position is that the claims recite a step ("removing said hemostatic valve and introducer sheath") without reciting any supporting act for performing that step, but that the corresponding act is found in the specification (splitting or tearing the valve and sheath along a score line). *See* '904 patent, col. 3, l. 58-col. 4, l. 6.

Section 112 para. 6 is implicated only when steps plus function, without corresponding acts, are present in a claim. *O.I. Corp. v. Tekmar*, 115 F.3d 1576, 1583 (Fed.Cir.1997). Here, the independent claims (claim 13 of the '904 patent and claim 14 of the '355 patent) recite a "method of percutaneous sheath lead or catheterization" (claim 13) or a "method of percutaneous catheterization" (claim 14) which comprise certain "steps," including the term to be construed. Merely claiming a step by itself, or even a series of steps, does not implicate Section 112 para. 6, and a preamble statement of purpose does not necessarily provide a function. *Id.*; *see also* *Epcon Gas Sys. Inc. v. Bauer Compressors, Inc.*, 279 F.3d 1022, 1028 (Fed.Cir.2002).

Here, the claims merely recite a series of steps without a corresponding function. As such, it is a method, rather than a step- or means-plus-function, claim and will not be subject to Section 112 para. 6.FN5 The parties' proposed constructions do not seem to dispute the meaning of the term beyond this. The court will define "body lumen" as "body opening," *see supra*, Part IV(7), but will not further construe this term:

FN5. While Enpath argues that these claims should be treated as means- or step-plus-function claims because language similar to the recited step follows "means for" language in the device claims (*see, e.g.*, '904 patent, claim 12 [col. 7, ll. 55-59]), the Federal Circuit rejected a similar argument in *O.I. Corp.* There, the court emphasized that "[e]ach claim must be independently reviewed in order to determine if it is subject to the requirements of section 112, [para.] 6. Interpretation of claims would be confusing indeed if claims that are not means- or step-plus-function claims were to be interpreted as if they were, only because they use language similar to that used in other claims that are subject to this provision." *O.I. Corp.*, 115 F.3d at 1583-84.

"Removing said hemostatic valve and introducer sheath while leaving said lead or catheter in place within said body lumen without sliding either said introducer sheath or hemostatic valve over an end of the lead or catheter" means "Removing said hemostatic valve and introducer sheath while leaving said lead or catheter in place within said body opening without sliding either said introducer sheath or hemostatic valve over an end of the lead or catheter."

10. (A) "Means for permitting removal of said hemostatic valve and introducer sheath from said lead

or catheter disposed therethrough." Used in '904 patent, claims 1-11; '355 patent, claims 1-2, 4-5, 7, 11, 19-21, 23-25, 29.

(B) "Means for splitting said introducer sheath and hemostatic valve away from said lead or catheter which is disposed therethrough." Used in '904 patent, claim 2.

(C) "Means for peeling away said introducer sheath and hemostatic valve from said lead or catheter which is disposed therethrough." Used in '904 patent, claim 3.

The parties agree, and the court finds, that these terms are governed by 35 U.S.C. s. 112, para. 6. The parties dispute both the functions and the corresponding structures.

There is very little disagreement between the parties as to function. *See* Tr. at p. 129, ll. 6-19. For example, Pressure Products' proposed function for (A) ("means for permitting removal ...") is "permitting removal of the hemostatic valve and introducer sheath" while Enpath suggests "permitting removal of both the hemostatic valve and its attached introducer sheath from the lead or catheter." FN6 The claim clearly states that the function is permitting removal of the hemostatic valve and introducer sheath from the lead or catheter, and neither party has put forth an argument as to why its modifications should be incorporated. Enpath's construction would seem to require that the hemostatic valve and introducer sheath be removed from the catheter in one piece, when the claims and specification clearly state that the valve and sheath are splittable. Notably, both parties agree that the functions involved include removing, splitting, or peeling *both* the hemostatic valve and the introducer sheath.

FN6. The parties' disputes over the structure of (B) ("means for splitting ...") and (C) ("means for peeling ...") are similarly minor. For (B), Pressure Products proposes "splitting the introducer sheath and hemostatic valve away from the lead or catheter" and Enpath suggests "splitting both the hemostatic valve and its attached introducer sheath away from the lead or catheter." With respect to (c), Pressure Products suggests "peeling away the introducer sheath and hemostatic valve from the lead or catheter" and Enpath proposes "peeling away both the hemostatic valve and its attached introducer sheath from the lead or catheter."

Pressure Products proposes the same structure for all three terms: "valve, sheath, and structural equivalents thereof." Pressure Products contends that the patents disclose at least three structures (splitting, peeling, and score lines), which permit removal. This court questions how "splitting", or "peeling" can be a "structure" and how the valve and sheath could be the particular structure which removes, splits, or peels away itself. Pressure Products subsequently argued that the numerous structures (perforations, slots, precuts, PTFE, holes, notches, cutting blades, etc.) set forth in numerous prior art references cited within the '904 and '355 patents constitute the requisite structure. Pressure Products notes that the patents disclose that "any method now known or later devised by which such sheaths **12** and valve assemblies **14** may be split or separated may be employed and are contemplated as being within the scope of the invention." '904 patent, col. 5, ll. 59-66; ' 355 patent, col. 7, ll. 37-44.

Enpath also suggests the same structure for all three, "score lines through both the hemostatic valve and sheath." Enpath's position for all three terms is that the specifications disclose only one corresponding structure for performing the claimed functions (score lines). *See* '355 patent, col. 3, ll. 18-26, '904 patent, col. 3, ll. 10-26. Enpath also argues that disclaimers made by the applicant during prosecution prevent the

inclusion of any equivalents.

As stated above, Pressure Products argues that the specification discloses the structure for removing the valve and catheter as valve **16** and sheath **12**, and structural equivalents thereof. According to Pressure Products, the patents-in-suit disclose at least three ways in which removal can be accomplished: splitting, peeling, and/or score lines. The structure for removal by splitting and peeling, it argues, is disclosed by the patentee's reference to numerous publications and patents that describe splittable or peel away sheaths. '904 patent, col. 1, ll. 41-61. Therefore, they argue, in addition to the score lines disclosed in the specification itself, the structure for all three means-plus-function terms is disclosed by these references.

There is support for this position. *See, e.g.,* Clearstream Wastewater Sys., Inc. v. Hydro-Action, Inc., 206 F.3d 1440 (Fed.Cir.2000) (the structure disclosed in the prior art could be used to show structure in a means-plus-function claim where the prior art did not teach away from using this structure, the means-plus-function element was not the only point of novelty in the claim, and the prosecution history supported such a reading); Atmel Corp. v. Info. Storage Devices, Inc., 198 F.3d 1374 (Fed.Cir.1999) (where the statement of patentee that techniques to perform the recited function were well-known in the art and the full title of the article was sufficient to disclose the structure to one skilled in the art, the structure disclosed in the prior art could be used for the means-plusfunction claim).

The doctrine of claim differentiation would normally lead the court to the conclusion that something more than score lines would accomplish the function of the claim limitations. However, the function in this case, as agreed by the parties, is removal of both the valve and introducer sheath. Since the function is dual (removal of both elements), the structure must be able to accomplish both functions. *See* Cardiac Pacemakers, Inc. v. St. Jude Medical, Inc., 296 F.3d 1106, 1114 (Fed.Cir.2002). Despite the lengthy recitation of structures in the prior art incorporated into the specifications provided by Pressure Products, all of these structures are only "suitable and effective for permitting removal of the introducer device." Pl's Supp. Cl. Const. Br. at p. 2 [Doc. # 55]. The patent specifications characterize the prior art as describing "a number of splittable or peel away sheaths," '904 patent, col. 1, ll. 41-42, while the novelty of the claimed inventions is the combination of a valve and introducer sheath that can be split for removal. '904 patent, col. 2, ll. 52-64. Because the incorporated prior art references do not disclose structure to perform both functions, score lines are the only structure disclosed in the patent specifications.

There is an argument that the patentee disclosed references to the prior art splittable or peelable sheaths and a person skilled in the art would recognize that these methods could be used to split and peel the sheath and the valve, as opposed to just the sheath. In fact, there is nothing in the specifications of the '904 patent which indicates that structures contained in the prior references cannot perform the function of splitting or peeling away the sheath and the valve. However, the court must look at the specifications to determine if the structures contained in the prior art references were adequately disclosed. The '904 patent does state that "any method now known or later devised by which such sheaths **12** and valve assemblies **14** may be split or separated may be employed and are contemplated as being within the scope of the invention." '904 patent, col. 5, ll. 62-66. However, a bare statement that known techniques or methods can be used does not disclose structure. *Biomedino, LLC v. Waters Technologies Corporation*, 490 F.3d 946, 953 (Fed.Cir.2007). The only question remaining is whether the disclosure of the prior art references disclose corresponding structure. In *Atmel*, the specifications stated that known circuit techniques were used to implement the function and then referred the reader to a particular scientific article. *Atmel*, 198 F.3d at 1382. The unrebutted testimony of an expert established that the title alone was sufficient to indicate to one skilled in the art the precise of the structure.FN7 *Id.*

FN7. Chief Judge Mayer, in his dissent, disagreed with the majority for "limiting inquiry to the structure that the mere title of the incorporated article would suggest to one skilled in the art". *Atmel*, 198 F.3d at 1383.

In this case, Pressure Products fails to present this court with evidence that a person skilled in the art could somehow glean sufficient structure from the titles disclosed (tears, slits, perforations, PTFE, etc.) which could perform the claimed function. A close examination of the titles of the references fails to indicate any such structure. Therefore, even if this court felt that structures contained within such splittable or peelable sheaths are clearly linked to the function of removing, splitting, or peeling away the valve, said structure has not been disclosed adequately under *Atmel*. FN8

FN8. It should also be noted that during the re-examination of the '904 patent, it was stated that the elements which permit the function of removal by "splitting" or "peeling apart" are score lines. *See Statement of Patentee*, p. 17.

However, it should be noted that the '355 patent specifications do disclose two elements (other than score lines) for "permitting removal of the hemostatic valve and introducer sheath." *See* '355 patent, col. 4, ll. 28-39. This language is not included in the '904 patent. The first disclosed element is a "two-part body comprising the hemostatic valve"; the second is "a cut in the resealable membrane to facilitate parting of the membrane wherein the body portions are pulled apart." FN9 Therefore the court will include these specific structures when construing the means-plus-function claims in the '355 patent.

FN9. Neither party argued in their respective briefing or at the hearing that these structures should be included. However, the language of the '355 patent seems clear in this regard.

Enpath argues that during re-examination of the '904 patent, the patentee distinguished his invention over German Patent No. 3,834,600 ("the Haindl reference"), which disclosed a splittable valve and sheath combination, by arguing that Haindl was not enabled because no "preformed line of separation" was disclosed. According to Enpath, the patentee's remarks stand for the proposition that he clearly and specifically limited the scope of "means for permitting removal" to the embodiment shown in Figure 3 (i.e., with score lines). *See* Statement of 11/3/95, Def. Claim Const. Br., Ex. 1 [Doc. # 49]. In support of this position, Enpath cites patentee's statement that "under the statutory definition of Section 112, the means for permitting removal of the hemostatic valve and introducer sheath comprises score lines through the valve body and sheath that permit it to be 'peeled apart' and not shattered, splintered, or explosively fractured as taught by Haindl." *Id.* at 12.

The court does not think that such a clear disavowal occurred in this case. The Federal Circuit has stated that prosecution disclaimer must be "both clear and unmistakable to one of ordinary skill in the art." *Elbex Video, Ltd. v. Sensormatic Elec. Corp.*, 508 F.3d 1366, 1371-72 (Fed.Cir.2007) (citing cases in which no clear disclaimer was present). Where the patentee intended to disclaim subject material, he did so explicitly (the claims did not encompass a removal method that "shattered, splintered, or explosively fractured as taught by Haindl"). The statement Enpath points to is not supported by the specification, which describes removal along score lines as a preferred embodiment and references "a number of splittable or peel away

sheaths" known in the prior art. *See* '904 Patent, Col. 1, ll. 41-61. The Court will therefore construe these terms as follows:

(A) **"Means for permitting removal of said hemostatic valve and introducer sheath from said lead or catheter disposed therethrough."** The function for this in both patents is "permitting removal of the hemostatic valve and introducer sheath from the lead or catheter," and the corresponding structure disclosed in the '904 patent is "score lines defined in the hemostatic valve and introducer sheath, and equivalents thereof." The corresponding structure in the '355 patent is "(1) score lines defined in the hemostatic valve and introducer sheath; (2) a two-part body comprising the hemostatic valve; (3) a cut in the resealable membrane; and (4) equivalents thereof."

(B) **"Means for splitting said introducer sheath and hemostatic valve away from said lead or catheter which is disposed therethrough."** The function of this term is "splitting the introducer sheath and hemostatic valve away from the lead or catheter," and the structure is "score lines defined in the hemostatic valve and introducer sheath, and equivalents thereof."

(C) **"Means for peeling away said introducer sheath and hemostatic valve from said lead or catheter disposable therethrough."** The function of this term is "peeling away the introducer sheath and hemostatic valve from the lead or catheter," and the structure is "score lines defined in the hemostatic valve and introducer sheath, and equivalents thereof."

11. "Means for permitting removal of said valve subassembly and introducer sheath from said lead or catheter disposed therethrough." Used in '904 patent, claims 20-26.

The parties agree, and the court finds, that this term is governed by 35 U.S.C. s. 112, para. 6. The parties dispute both the function and the corresponding structure. Pressure Products argues that the function is "permitting removal of the hemostatic valve subassembly and introducer sheath from the lead or catheter," and the structure is "valve, sheath, and structural equivalents thereof." Enpath suggests that the function is "permitting removal of both the hemostatic valve subassembly and the introducer sheath from the lead or catheter," and the structure is "score lines through both the hemostatic valve subassembly and sheath to allow the hemostatic valve subassembly to be peeled away, or split into two pieces."

For the reasons discussed in Part IV(10) *supra*, namely that neither party has given the court a good reason to modify the plain language of the claim, the function of this term will be "permitting removal of the hemostatic valve subassembly and introducer sheath from the lead or catheter."

"Hemostatic valve subassembly" has been construed to mean "the hemostatic valve component that is coupled to the introducer sheath component of the assembly." *See* Part IV(3). For the reasons discussed in Part IV(10) *supra*, the structure of this term will be "score lines defined in the hemostatic valve and introducer sheath, and equivalents thereof."

12. "Means for sealing said body portions together." Used in '355 patent, claims 1-2, 4-5, 7, 11, 19-21, and 29.FN10

FN10. The parties agreed at the *Markman* hearing that Claim 23 recited sufficient structure such that it would not be subject to Section 112 para. 6, and that ordinary meaning would apply. Tr. at p. 167, ll. 3-23.

The parties agree, and the court finds, that this term is governed by 35 U.S.C. s. 112, para. 6, and that the function is "sealing the body portions together." The parties dispute the corresponding structure. Pressure Products proposes "sealing lips and structural equivalents thereof." Enpath suggests that there are two structures disclosed in the specification: "circumferential sealing lips on each body portion and circumferential tape wound around the two body portions," or "tight snap-fit between the two body portions."

The specification states that the "element for sealing the body portions together comprises a circumferential sealing lip on each of the body portions, with at least one band of circumferential tape wound around the two body portions, in order to "maintain the ... sealing lips in a sealed configuration." '355 patent, col. 4, ll. 47-49, 58-62.

The '355 patent then addresses the sealing lips in detail. Figures 7a and 7b depict an interior circumferential lip **58a** which slip-fits into an exterior circumferential lip **58b** held together with tape **56**. '355 patent, col. 8, ll. 58-68. Figure 8 depicts another embodiment which consists of an outer circumferential seal **60a** and an inner circumferential seal **60b**. '355 patent, col. 9, ll. 1-12. The figure and specifications do not denote the use of tape in this embodiment.

Figures 9a and 9b show an embodiment where the two portions of the valve join together in an "interior tongue and groove snap-fit seal". '355 patent, col. 9, ll. 13-17. This embodiment utilizes groove **62a** and mating tongue **62b**. The patent then explains that "it is contemplated that at least in the embodiment of FIGS. 9a and 9b, if not other ones of the embodiment shown, that the need for tape **56** will be unnecessary in that the body portions will fit tightly together by virtue of their snap fit". '355 patent, col. 9, ll. 26-29. Therefore, it appears that tape is not necessary structure when snapfitted together.

Figure 10 illustrates another embodiment which utilizes a knife edge seal **68**, conforming groove **70**. The portions may be held together by tape **56** or have a snapfit facilitated by an expanded head **72** below knife edge **68** which is accompanied by a snap-fit conforming interior shape of groove **70**.

Finally, the '355 patent provides that there are other embodiments which may be devised in which the portions may be joined with or without the aid of tape, friable spots of adhesive, or various compression seals as shown in the embodiments. Further, the patent states that "all equivalent elements for performing substantially the same function in substantially the same way to obtain substantially the same result" are contemplated by the invention. '355 patent, col. 9, l. 64-col. 10, l. 2.

The structure for "**means for sealing said body portions together**" will therefore be "(1) a circumferential sealing lip on each of the body portions, with at least one band of circumferential tape wound around the two body portions; (2) interior circumferential lip **58a** which slip fits into an exterior circumferential lip **58b** held together with tape **56**; (3) outer circumferential seal **60a** and an inner circumferential seal **60b**; (4) groove **62a** and mating tongue **62b**; (5) knife edge seal **68**, conforming groove **70**, which may be held together by tape **56** or have a snapfit facilitated by an expanded head **72** below knife edge **68** which is accompanied by a snap-fit conforming interior shape of groove **70**; and (6) equivalents thereof.

V. CONCLUSION

The jury shall be instructed in accordance with the court's interpretation of the disputed claim terms in the '904 and '355 patents.

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Pressure Products Medical Supplies, Inc. v. Enpath Medical, Inc.

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