IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

LIFEPORT SCIENCES LLC, Plaintiff,)))
v.) Civil Action No. 12-1791-GMS
ENDOLOGIX, INC.,)
Defendant.))

ORDER CONSTRUING THE TERMS OF U.S. PATENT NOS. 5,489,295; 5,993,481; 6,302,906; 5,676,696

The court having considered the submissions of the parties and having heard oral argument on the matter—IT IS HEREBY ORDERED, ADJUDGED, and DECREED that, as used in the asserted claims of U.S. Patent Nos. 5,489,295 ("the '295 Patent"); 5,993,481 ("the '481 Patent"); 6,302,906 ("the '906 Patent"); and 5,676,696 ("the '696 Patent"):

The '295 Patent

1. The term "first expandable attachment means" is construed as a means-plus-function claim. The claimed function is: "anchoring the main body in the aorta." The corresponding structure is: "a plurality of vees with the apices being formed with helical coil springs, with hook-like elements bonded to the legs of the vees."

^{1 &}quot;An 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 . . . and such claim shall be construed to cover the corresponding structure . . . described in the specification and equivalents thereof." 35 U.S.C. § 112(f). In practice, "[t]he statute does not permit limitation of a means-plus-function claim by adopting a function different from that explicitly recited in the claim. Nor does the statute permit incorporation of structure from the written description beyond that necessary to perform the claimed function." *Micro Chem., Inc. v. Great Plains Chem. Co.*, 194 F.3d 1250, 1258 (Fed. Cir. 1999).

The claimed function comes directly from claim 1: "first expandable attachment means for anchoring said main body... such that said main body can be anchored by said first attachment means in said aorta..." '295 Patent, claim 1. The parties do no meaningfully dispute the claimed function.

2. The term "second expandable attachment means" is construed as a means-plus-function claim. The claimed function is: "anchoring the first tubular leg in the first iliac artery."

Instead, the dispute focuses on the corresponding structure disclosed in the specification. "A corresponding structure must be clearly linked to the claimed function." *Omega Eng'g, Inc, v. Raytek Corp.*, 334 F.3d 1314, 1328 (Fed. Cir. 2003). The court agrees with the defendant that a more detailed structure than that put forth by the plaintiff is necessary. The plaintiff proposes a generic "self-expandable spring" as adequate structure. But the specification does not teach that *any* expandable spring can perform the claimed attaching function. Rather, the patent teaches a very specific embodiment:

Expandable spring attachment means 126 is secured to the expandable main body adjacent the opening 113. Also expandable spring attachment means 127 is secured to the first leg 116 adjacent the opening 118. These expandable spring attachment means 126 and 127 serve as anchoring means for securing the graft 20 to vessel wall in which the graft 20 is disposed. [T]he expandable spring attachment means 126 and 127 are formed of a plurality of vees 131 with the apices 132 being formed with helical coil springs. . . . Hook-like elements 141 are provided at the apices 132 The hook-like elements 141 are bonded to the legs 136 of the vees 131 by suitable means such as welding.

'295 Patent, col. 5 ll. 29–63 (emphasis added). Thus, there is a "clear[] link[]" between the defendants' proposed structure and the claimed function—it is taken almost verbatim from the specification. See Omega Eng'g, 334 F.3d at 1328. The plaintiff isolates "expandable spring" and ignores all the additional context explaining the features of the mechanism that actually allow it to perform the claimed function.

The court's ruling is consistent with *Mettler-Toledo, Inc. v. B-Tek Scales, LLC*, 671 F.3d 1291 (Fed. Cir. 2012), despite the plaintiff's contention that the case supports its construction. The references to generic expandable springs in the Abstract and specification serve merely for identification purposes. *See id.* at 1296 ("[E]very mention of a converter in the specification refers back to [a] specific type of converter."). The patent does not teach that a generic expandable spring can perform the claimed function. Only a single embodiment—*i.e.*, a particular type of expandable spring—is clearly linked to performing function. "If a patentee chooses to disclose a single embodiment, then any means-plus-function claim limitation will be limited to the single disclosed structure and equivalents thereof." *See id.* at 1296; *see also id.* ("Although generic A/D converters were known in the art, the patentee chose to use means-plus-function language which limits it to the disclosed embodiments and equivalents. . . . We are not persuaded that the single statement in the Abstract regarding an 'A/D converter' requires a different result. . . . The district court correctly held that the multiple slope integrating A/D converter was the only converter disclosed by the [patent] and linked to the claimed functions.").

The plaintiff's claim differentiation argument—that dependent claims add the limitations found in the defendants' proposed structure—has been rejected by Federal Circuit precedent. See Laitram Corp. v. Rexnord, Inc., 939 F.2d 1533, 1538 (Fed. Cir. 1991) ("[T]he judicially developed guide to claim interpretation known as 'claim differentiation' cannot override [§ 112(f)]. A means-plus-function limitation is not made open-ended by the presence of another claim specifically claiming the disclosed structure which underlies the means clause or an equivalent of that structure.").

The corresponding structure is: "a plurality of vees with the apices being formed with helical coil springs, with hook-like elements bonded to the legs of the vees."²

The '481 Patent

3. The term "dividing means" is construed as a means-plus-function term. The claimed function is "forming first and second passageways communicating between said proximal and distal ends." The corresponding structure is: "(1) a line of stitching joining one surface of the base member to an opposite surface of the base member, or (2) a web of material arranged longitudinally inside the base member and defining a first substantially round aperture adjacent the distal end of the base member and a second substantially round aperture at a spaced distance from the distal end of the base member."³

² The court's construction mirrors that from note 1, *supra*. The "second expandable attachment means" serves the slightly different function than that of the first: "second expandable attachment means for anchoring said *first tubular leg*... such that... said first tubular leg can be anchored by said second attachment means in said *first iliac artery*..." '295 Patent, claim 1. Aside from the location of anchoring, the claimed function is not in dispute.

The court's analysis for the "first expandable attachment means" guides its determination of the

The court's analysis for the "first expandable attachment means" guides its determination of the corresponding structure of the instant term as well. See supra note 1; see also '295 Patent, col. 5 ll. 29-63.

³ The parties' only dispute is over the corresponding structure for this means-plus-function claim term. As quoted above, § 112(f) does not "permit incorporation of structure from the written description beyond that *necessary to perform the claimed function.*" *Micro Chem.*, 194 F.3d at 1258 (emphasis added). "A corresponding structure must be clearly linked to the claimed function." *Omega Eng'g*, 334 F.3d at 1328.

The court adopts the defendant's proposed structure, which comes straight from the specification:

[[]T]he base member may include dividing means for forming first and second passageways communicating between the proximal and distal ends of the base member. The dividing means may include a line of stitching joining one surface of the base member to an opposite surface of the base member. Alternatively, the dividing means may include a web of material arranged longitudinally inside the base member and defining a first substantially round aperture adjacent the distal end of the base member and a second substantially round aperture at a spaced distance from the distal end of the base member.

^{&#}x27;481 Patent, col. 3 ll. 4–14. Thus, there can be little doubt that these two structural embodiments are "clearly linked" to the claimed function of *forming* first and second passageways. See Omega Eng'g, 334 F.3d at 1328. The plaintiff contends that the defendant's two structural embodiments are too narrow, but the language comes straight from the written description. The plaintiff will be free to argue other equivalents fall within the scope of the claim. See 35 U.S.C. § 112(f) ("[A means-plus-function claim] shall be construed to cover the corresponding structure . . . described in the specification and equivalents thereof." (emphasis added)); Mettler-Toledo, 671 F.3d at 1296 ("Our case law is clear that a means-plus-function claim limitation is limited to the structures disclosed in the specification and

4. The term "joining means" is construed as a means-plus-function term. The claimed function is: "intraluminally joining the distal end of the primary limb to the proximal end of the base member." The corresponding structure is: "a stent formed from wire or the like which has been bent back and forth in a curved pattern in the longitudinal direction of the graft and then wrapped in a circumferential direction transverse to the longitudinal direction, or barbs or sutures."

[First leg] may then be created by sewing upwardly from the enlarged end of the tapered portion and parallel to the wall thereof with an overlapping edge stitch. The stitch may then be continued to form the crotch area of base member 112 and then downwardly toward the enlarged end of the tapered portion and away from the wall thereof to form [second leg]. Subsequently, any excess material between [the legs] may be cut away.

Moreover, the plaintiff's "two tubes" proposal must fail because it also does not account for the specific claimed function. The corresponding structure must be clearly linked to "forming first and second passageways communicating between the proximal and distal ends of the base member." The plaintiff completely ignores the fact that the proximal end of the base member is a single inlet. See '481 Patent, claim 1. Two tubes cannot form the passageways—rather, the tubes are themselves the two passageways, the result.

⁴ Again, the parties' only dispute is over the corresponding structure for this means-plus-function claim term—whether the corresponding structure should be limited to a generic expandable stent or a particular preferred embodiment disclosed in the specification. And, again, the court rejects the plaintiff's generic structure.

The specification discloses:

Each of grafts 110, 114 and 116 preferably consists of a flexible outer layer 152 which is supported internally along substantially its entire length by an expandable stent 154 which assumes a generally cylindrical or tapered configuration in the expanded condition, depending upon the configuration it is given when initially formed, and which provides the graft with sufficient structural strength to permit the components of modular system 10 to be assembled to one another in situ.

'481 Patent, col. 11 ll. 60–67 – col 12 l. 1 (emphasis added). Thus, expandable stent 154 provides structural support and allows the components to be assembled. The parties appear in agreement that this is, in essence, the claimed joining function. Stent 154 is described subsequently:

Stent 154 may be formed from a wire or the like of a low shape-memory material which has been bent back and forth in a curved pattern in the longitudinal direction of the graft and then wrapped in a circumferential direction transverse to the longitudinal direction to form one or more loops of a predetermined circumference.

Id. col. 13 Il. 44-49.

equivalents. A court must look to the specification to determine the structures that correspond to the claimed function." (internal citation omitted)).

The plaintiff's additional proposed structures go beyond what is necessary to perform this specific function. For instance, the specification teaches that the crotch structure put forth by the plaintiff is actually the result of the stitching:

^{&#}x27;481 Patent, col. 3 ll. 4–14. Thus, the crotch is a byproduct of the stitching itself—it cannot be considered "necessary." *See Micro Chem.*, 194 F.3d at 1258. The stitching is the structure that actually *forms* the two legs, the first and second passageways.

- 5. The term "connecting means" is construed as a means-plus-function term. The claimed function is: "connecting the proximal end of the secondary limb to the distal end of the base member." The corresponding structure is: "a stent formed from wire or the like which has been bent back and forth in a curved pattern in the longitudinal direction of the graft and then wrapped in a circumferential direction transverse to the longitudinal direction, or barbs or sutures."
- 6. The term "attaching means" is construed as a means-plus-function term. The claimed function is: "attaching the proximal end of another secondary limb to the distal end of the base member." The corresponding structure is: "a stent formed from wire or the like which has been bent back and forth in a curved pattern in the longitudinal direction of the graft and then wrapped in a circumferential direction transverse to the longitudinal direction, or barbs or sutures."

The '906 Patent

7. The term "to contain" is construed to mean "to enclose."

The patent does not teach that any expandable stent will work. The plaintiff points to a passage in the Summary of the Invention: "The base member and the primary limb may both consist of a flexible layer which is radially supported along substantially its entire length by an expandable stent." *Id.* col. 2 ll. 64–66. But the above-quoted portion of the specification makes clear that only expandable stent 154 possesses "sufficient structural strength." *Id.* col. 11 ll. 66. In other words, some expandable stents—with other configurations—will not provide *sufficient* strength. The plaintiff attempts to argue those stents not possessing sufficient strength would not perform the claimed function and therefore would not infringe. (D.I. 74 at 74–75.) This argument turns the means-plus-function doctrine on its head. The identified corresponding structure must be capable of performing the claimed function. And the plaintiff's argument that "the portion of the specification on which we are relying here does state that the expandable stent provides the graft with sufficient structural strength" is incorrect. (*Id.* at 75.) The specification only teaches a single embodiment having sufficient structural strength: stent 154. *See Mettler-Toledo*, 671 F.3d at 1296.

⁵ The parties' collapse their discussion of this term together with "joining means." See supra note 4.

⁶ The parties' collapse their discussion of this term together with "joining means." See supra note 4.

⁷ The relevant portion of the claims is: "an outer sheath configured to contain said bifurcated endoluminal prosthesis." *See, e.g.*, '906 Patent, claim 1. The parties present two different plain-and-ordinary-meaning definitions of "contain": "enclose" versus "restrain (radially)." As such, the court must construe the term. *See O2 Micro Int'l Ltd. v. Beyond Innovation Tech. Co.*, 521 F.3d 1351, 1361 (Fed. Cir. 2008) ("A determination that a claim term 'needs

8. The term "first introducer" is construed as a means-plus-function term. The claimed function is "introducing a first prosthesis into the vessel." The corresponding structure is "a tubular outer sheath, a proximal portion pusher, and a distal portion pusher."

no construction' or has the 'plain and ordinary meaning' may be inadequate when a term has more than one 'ordinary' meaning or when reliance on a term's 'ordinary' meaning does not resolve the parties' dispute.").

The court adopts the broader definition of "to enclose." This definition is consistent with the patentees' usage of "contain" throughout the rest of the specification. See, e.g., '906 Patent, col. 6 ll. 50–51 ("first introducer containing the stent or prosthesis"); col. 7 ll. 1–2 ("an introducer containing the prosthesis"); col 13 ll. 6–7 ("cylindrical tube slidably contained within distal portion pusher"). The defendant does not argue that "contain" has the more restricted definition when used in these contexts.

The defendant's primary support for its proposal comes from the specific discussion in the specification of the interaction of the sheath and the prosthesis: "[T]he prosthesis is inserted such that the outer surface of proximal portion 12 contacts and is radially restrained by outer sheath 101, and the outer surface of distal portion 16 contacts and is radially restrained by proximal portion pusher 102." Id. col. 14 ll. 30–34. Thus, the defendant contends there is a direct parallel between the claimed interaction and that described in the specification. But importantly, the quoted passage makes clear that the outer sheath only radially restrains a portion of the prosthesis—specifically, "the outer surface of proximal portion 12." Id. But a different element—the proximal portion pusher—restrains the distal portion of the prosthesis. Id. The court therefore cannot say that the more narrow definition is being used in the claim, which says—without qualification—that the outer sheath contains the prosthesis. At the very least, the broader definition unquestionably applies.

In light of the specification's consistent use of "contain" to mean "enclose" and the questions surrounding the defendant's narrower construction, the court is satisfied that the broader definition is the appropriate construction.

⁸ The parties dispute whether the claim term should be construed as a means-plus-function claim. The Federal Circuit recently clarified the doctrine of means-plus-function claiming:

The standard is whether the words of the claim are understood by persons of ordinary skill in the art to have a sufficiently definite meaning as the name for structure. When a claim term lacks the word "means," the presumption can be overcome and § 112[(f)] will apply if the challenger demonstrates that the claim term fails to recite sufficiently definite structure or else recites function without reciting sufficient structure for performing that function. The converse presumption remains unaffected: use of the word "means" creates a presumption that § 112[(f)] applies.

Williamson v. Citrix Online, LLC, No. 2013-1130, 2015 WL 3687459, at *7 (Fed. Cir. June 16, 2015) (internal citations and quotation marks omitted). The court finds that the defendant has adequately rebutted the presumption.

Claim 11 claims in relevant part: "A system for introducing endoluminal prostheses into a vessel to define a continuous lumen, said system comprising: a first introducer for introducing a first prosthesis into the vessel" '906 Patent, claim 11. In the court's view, this is quintessential functional claiming: an introducer for introducing. Although the Federal Circuit abandoned the standard that a means-plus-function claim must "essentially [be] devoid of anything that can be construed as structure," the court finds the characterization appropriate in this instance. See Williamson, 2015 WL 3687459, at *6–7 ("We also overrule the strict requirement of 'a showing that the limitation essentially is devoid of anything that can be construed as structure." (quoting Flo Healthcare Solutions, LLC v. Kappos, 697 F.3d 1367, 1374 (Fed. Cir. 2012))).

An introducer is merely something that introduces. It "does not provide any indication of structure because it sets forth the same black box recitation of structure for providing the same specified function as if the term 'means' had been used." See Williamson, 2015 WL 3687459, at *8. And the fact that there is both a first introducer and a second introducer also fails to connote structure.

The plaintiff argues that the specification imparts structure to the term "introducer." See '906 Patent, col. 6 ll. 20–30. But a description of structure in the specification is not enough to avoid application of § 112(f). Indeed, all means-plus-function claims require a recitation of corresponding structure in the written description to avoid being

9. The term "second introducer" is construed as a means-plus-function term. The claimed function is "introducing a second prosthesis in a radially compressed state into the vessel, and deploying the second prosthesis to connect to the portion of said first prosthesis." The corresponding structure is "a cylindrical outer sheath and female Luer lock assembly."

The '696 Patent

found indefinite. Ergo Licensing, LLC v. CareFusion 303, Inc., 673 F.3d 1361, 1363 (Fed. Cir. 2012) ("Failure to specify the corresponding structure in the specification amounts to impermissible pure functional claiming. . . . If an applicant does not disclose structure for a means-plus-function term, the claim is indefinite."). To avoid application of § 112(f) when the claims fail to recite structure, the specification must make clear that the term itself has particular structural significance. Here, the specification fails to do so. See Williamson, 2015 WL 3687459, at *8 ("Although the 'distributed learning control module' is described in a certain level of detail in the written description, the written description fails to impart any structural significance to the term. At bottom, we find nothing in the specification or prosecution history that might lead us to construe that expression as the name of a sufficiently definite structure as to take the overall claim limitation out of the ambit of § 112[(f)].").

The court is not persuaded by the plaintiff's expert declaration of Dr. James Moore. (D.I. 62.) Dr. Moore opines that "[o]ne of skill in the art would understand that the term 'introducer' refers to a system commonly used in the field to introduce an endoluminal prosthesis in to the vasculature." (Id. ¶ 58.) But he acknowledges that "an introducer can be designed in any number of ways"—in other words, the term itself has no structural significance. (Id.).

Moreover, as discussed above, *supra* note 1, claim differentiation has little force in the context of mean-plus-function claim construction. *See Laitram Corp.*, 939 F.2d at 1538 ("[T]he judicially developed guide to claim interpretation known as 'claim differentiation' cannot override [§ 112(f)].").

Thus, the claim term is a means-plus-function term. The claimed function comes straight from the claim language: a first introducer for introducing a first prosthesis into the vessel. '906 Patent, claim 11 (emphasis added). The corresponding structure is disclosed in the specification: "The introducer comprises a tubular outer sheath, a proximal portion pusher disposed at least partially within the outer sheath, and a distal portion pusher disposed at least partially within the proximal portion pusher." *Id.* col. 6 ll. 26–30. The defendant seeks to also include a balloon catheter as an element of the corresponding structure, but not all descriptions of the introducer include a balloon catheter (as demonstrated in the above-quoted text). Thus, the court cannot consider it "necessary" to perform the claimed function. *See Micro Chem.*, 194 F.3d at 1258.

⁹ The court's reasoning mirrors that of "first introducer," supra note 8. The claimed function comes directly from the claims: "a second introducer for (a) introducing a second prosthesis in a radially compressed state into the vessel and into said portion of said first prosthesis, and (b) deploying said second prosthesis to connect to said portion of said first prosthesis" '906 Patent, claim 11. The corresponding structure is found in the specification: "FIG. 21(a) illustrates an exemplary second introducer 300 used for deploying second distal part 44. Second introducer 300 of the illustrated embodiment comprises cylindrical outer sheath 301 and female Luer lock assembly 310." Id. col. 15 ll. 44–46 (emphasis added).

10. The term "engages and becomes secured within" is construed to have its plain and ordinary meaning. 10

The court is satisfied that there was no redefinition of the claim term in the specification.

To act as its own lexicographer, a patentee must "clearly set forth a definition of the disputed claim term" other than its plain and ordinary meaning. It is not enough for a patentee to simply disclose a single embodiment or use a word in the same manner in all embodiments, the patentee must "clearly express an intent" to redefine the term.

Thorner, 669 F.3d at 1365 (internal citation omitted) (quoting CCS Fitness, Inc. v. Brunswick Corp., 288 F.3d 1359, 1366 (Fed.Cir.2002); Helmsderfer v. Bobrick Washroom Equip., Inc., 527 F.3d 1379, 1381 (Fed.Cir.2008)). The court cannot discern any intent of the patentee to refine the scope of the claim term. It certainly was not "clearly express[ed]." See id.

of ordinary skill in the art when read in the context of the specification and prosecution history. There are only two exceptions to this general rule: 1) when a patentee sets out a definition and acts as his own lexicographer, or 2) when the patentee disavows the full scope of a claim term either in the specification or during prosecution." Thorner v. Sony Computer Entm't Am. LLC, 669 F.3d 1362, 1365 (Fed. Cir. 2012) (internal citation omitted).

The defendant has not established that either exception applies to this term. The primary dispute is whether "becom[ing] secure" requires the aid of mechanical structures, such as barbs, sutures, and the like. The specification explains that such mechanical structures are optional. See '696 Patent, col. 12 ll. 1–5 ("In the case of primary graft 110, stent 154 may . . . include one or more barbs 156 for anchoring graft 110 to the wall of aorta 200 to assist in holding modular assembly 100 in place."). And while the Summary of the Invention consistently uses the exact claim term—"engages and becomes secured with"—the Detailed Description of the Preferred Embodiments never uses this term and instead alternates among other word formulations. See, e.g., id. col. 14 ll. 23–27 ("Once properly located, the component is deployed from the catheter and radially expanded until its circumference firmly contacts the interior wall of either the artery in which it is situated or the component to which it is being connected to hold the graft in this implanted location." (emphasis added)); col. 16 ll. 41–43 ("This radial expansion will continue until the outer layer 152 of graft 114 firmly engages the interior wall of iliac 206 to hold graft 114 in this implanted location." (emphasis added)); col 17 ll. 1–3 ("[B]ase member 112 will expand radially until the free end of leg 132 contacts and firmly engages the interior wall" (emphasis added)). Thus the court cannot draw a direct parallel between the claim term and the defendant's proposed construction.