IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

VOLCANO CORPORATION, Plaintiff and Counterclaim Defendant, v. ST. JUDE MEDICAL, CARDIOVASCULAR AND ABLATION TECHNOLOGIES DIVISION, INC., ST. JUDE MEDICAL, CARDIOLOGY DIVISION, INC., ST. JUDE MEDICAL, U.S. DIVISION, ST. JUDE MEDICAL S.C., INC., and ST. JUDE MEDICAL SYSTEMS AB, Defendants and Counterclaim Plaintiffs.	Civil Action No. 13-687-RGA

MEMORANDUM OPINION

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ANDREWS, U.S. DISTRICT JUDGE:

Pending before this Court is the issue of claim construction of one disputed term found in U.S. Patent Nos. 8,419,647 ("'647 patent") and 8,419,648 ("'648 patent").[1]

I. BACKGROUND

On April 16, 2013, Volcano filed a patent infringement action against St. Jude Medical, Cardiovascular and Ablation Technologies Division, Inc., St. Jude Medical, Cardiology Division, Inc., St. Jude Medical, U.S. Division, St. Jude Medical S.C., Inc. and St. Jude Medical Systems AB. (D.I. 1). St. Jude convinced the Court that construction of a single term could be dispositive of Volcano's literal infringement case (D.I. 16 at 7-10), and the Court, relying on this representation, granted an early claim construction hearing for that lone term. (D.I. 27). The Court has considered the Parties' Joint Claim Construction Brief (D.I. 51), appendix (D.I. 52), and oral argument on November 18, 2013. (D.I. 53).

II. LEGAL STANDARD

"It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) (internal quotation marks omitted). "'[T]here is no magic formula or catechism for conducting claim construction.' Instead, the court is free to attach the appropriate weight to appropriate sources 'in light of the statutes and policies that inform patent law.'" *SoftView LLC v. Apple Inc.*, 2013 WL 4758195, at *1 (D. Del. Sept. 4, 2013) (quoting *Phillips*, 415 F.3d at 1324). When construing patent claims, a matter of law, a court considers the literal language of the claim, the patent specification, and the prosecution history. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 977-80 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370

[1] The '647 and '648 patents share a common specification. The disputed term is construed identically in both patents.

(1996). Of these sources, "the 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 (internal quotations and citations omitted).

Furthermore, "the words of a claim are generally given their ordinary and customary meaning . . . [which is] the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application." *Phillips*, 415 F.3d at 1312-13 (internal citations and quotation marks omitted). "[T]he ordinary meaning of a claim term is its meaning to [an] ordinary artisan after reading the entire patent." *Id.* at 1321 (internal quotation marks omitted). "In some cases, the 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." *Id.* at 1314 (internal citations omitted).

A court may consider extrinsic evidence, which "consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises," in order to assist the court in understanding the underlying technology, the meaning of terms to one skilled in the art and how the invention works. *Id.* at 1317-19 (internal quotation marks and citations omitted). However, extrinsic evidence is less reliable and less useful in claim construction than the patent and its prosecution history. *Id.*

Finally, "[a] claim construction is persuasive, not because it follows a certain rule, but because it defines terms in the context of the whole patent." *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998). It follows that "a claim interpretation that would exclude the inventor's device is rarely the correct interpretation." *Osram GmbH v. Int'l*

Trade Comm'n, 505 F.3d 1351, 1358 (Fed. Cir. 2007) (internal quotation marks and citation omitted).

III. CONSTRUCTION OF DISPUTED TERMS

A. U.S. Patent Nos. 8,419,647 & 8,419,648

1. "flexible element"

Plaintiff's proposed construction: The term does not require construction, but if the Court chooses to construe the term, the Court should construe it to have its full ordinary and customary meaning.

Defendant's proposed construction: This is a means plus function limitation where the function is "providing flexibility" and the structure is a "coil spring."

Court's construction: "A coil."

Volcano contends that "flexible element" should be entitled to its full ordinary and customary meaning. The full ordinary and customary meaning, according to Volcano, encompasses hypotubes, coils, and balloons, as found in claims 16-18, respectively. In the alternative, Volcano proposes: "structure that is easily bent." St. Jude, on the other hand, asserts several arguments that seek to narrow the term's scope. These limiting arguments will be addressed in turn.

a. "Flexible Element" Is Not Subject to Means-Plus-Function

The term "flexible element" is not properly construed as a means-plus-function limitation. A claim term that does not contain the word "means" is presumptively not subject to § 112 ¶ 6 (now § 112(f)). *See CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1369 (Fed. Cir. 2002). The presumption "can be overcome if it is demonstrated that 'the claim term fails to recite sufficiently definite structure or else recites function without reciting sufficient structure

for performing that function.'" *Lighting World, Inc. v. Birchwood Lighting, Inc.*, 382 F.3d 1354, 1358 (Fed. Cir. 2004) (quoting *CCS Fitness*, 288 F.3d at 1369); *Mass. Inst. of Tech. & Elecs. for Imaging, Inc. v. Abacus Software*, 462 F.3d 1344, 1354 (Fed. Cir. 2006) ("*MIT*") ("Claim language that further defines a generic term like 'mechanism' can sometimes add sufficient structure to avoid 112 ¶ 6."). This presumption "is a strong one that is not readily overcome." *Lighting World*, 382 F.3d at 1358. Even though a term might not bring a particular structure to mind, that is not dispositive and the court can look to the dictionary to see if the term is one that is "understood to describe structure, as opposed to a term that is simply a nonce word or a verbal construct that is not recognized as the name of structure and is simply a substitute for the term 'means for.'"[2] *Id.* at 1360; *MIT*, 462 F.3d at 1354.

In *MIT*, for example, the Federal Circuit found that the term "colorant selection mechanism" is subject to § 112 ¶ 6. *See MIT*, 462 F.3d at 1354 (noting that patentee used "mechanism" and "means" as synonyms and that "[a]t least one dictionary definition equates mechanism with means"). Moreover, "colorant selection" was not defined in the specification, did not have a dictionary definition, and there was no showing that "colorant selection mechanism" would "connote sufficient structure" to one of ordinary skill in the art. *Id.* The Federal Circuit later relied on *MIT* in holding that a claim reciting a "mechanism for moving said finger" was subject to § 112 ¶ 6. *Welker Bearing Co. v. PHD, Inc.*, 550 F.3d 1090, 1095-97 (Fed. Cir. 2008). In addition to a dearth of structural context in the claim language, the "mechanism for moving said finger" also lacks an adjective that "endows the claimed 'mechanism' with a physical or structural component." *Id.* at 1096. Recognizing that the person having ordinary skill in the art ("PHOSITA") "would have no recourse but to turn to the []

[2] According to my dictionary, a "nonce word" is "a word coined and used for a single occasion."

patent's specification to derive a structural connotation for the generically claimed 'mechanism for moving said finger,'" the court applied § 112 ¶ 6. *Id.* (hinting that inclusion of "a 'finger displacement mechanism,' a 'lateral projection/retraction mechanism,' or even a 'clamping finger actuator,'" in the patent would have provided sufficient structural support to permit the court to delve into the PHOSITA's understanding of the term). In contrast, the Federal Circuit held that "detent mechanism" was not subject to § 112 ¶ 6 because "the noun 'detent' denotes a type of device with a generally understood meaning in the mechanical arts, even though the definitions are expressed in functional terms." *Greenberg v. Ethicon Endo-Surgery, Inc.*, 91 F.3d 1580, 1583 (Fed. Cir. 1996).

As recognized above, there is a strong presumption against applying § 112 ¶ 6 to "flexible element" because the word "means" is not used in the claim language. Here, unlike in *MIT* and *Welker Bearing*, that presumption cannot be overcome because the claim language itself connotes sufficient structure to the PHOSITA. Claim 1 involves:

> [A] first flexible element, disposed near a distal portion of the long proximal hypotube, with an outer diameter of 0.018" or less and an increased flexibility relative to the long proximal hypotube; a short hypotube sensor housing disposed near a distal extremity of the first flexible element . . . .

'648 patent, claim 1. This tells the PHOSITA where the flexible element is located in the invention (between the long proximal hypotube and a short hypotube sensor housing), the size of the flexible element (diameter of 0.018" or less), and describes its physical properties (the flexible element is more flexible than the long hypotube).

Other courts have construed "flexible element," although § 112(f) was not at issue. In *ICU Medical*, the Northern District of California construed "flexible element" to mean "a portion

of the valve that is capable of being bent, usually without breaking." *ICU Med., Inc. v. B. Braun Med., Inc.*, 2005 WL 588341, at *2 (N.D. Cal. Mar. 14, 2005). There, the claim recited:

> [A] flexible element positioned in said cavity movable between an uncompressed position . . . and a compressed position . . . said flexible element comprising a wall . . . an end fitting against a ring shaped support . . . a first external diameter . . . , a second external diameter in said main portion, said second diameter being smaller than said first diameter and said third diameter, and at least a portion of the outer surface of the wall of the flexible element . . . being tapered.

Id. Although § 112 ¶ 6 was not at issue in *ICU Medical*, St. Jude suggests that neither party advanced a means-plus-function argument because the claim language provided sufficient structure to avoid such a construction. (D.I. 51 at 18-19 ("The flexible element in *ICU* has structure because the '[c]laim language . . . further defines' the made-up term, 'add[ing] sufficient structure to avoid 112 ¶ 6.' Accordingly, neither party argued that 'flexible element' should be treated under § 112 ¶ 6 . . . .") (internal citation omitted)). Admittedly, the claim language at issue here does not contain as much structure, but the claim in *ICU Medical* likely provided more than enough structure because § 112 ¶ 6 was not even raised. Moreover, several key elements are present in both claims: location of the claimed element in the invention, relative dimensions of the claimed element, and a description of the claimed element's physical properties. *Compare* '648 patent, claim 1, *with ICU Med., Inc.*, 2005 WL 588341, at *2.

Additionally, although it might escape precise definition, an element that is flexible does connote structure. Random House Unabridged Dictionary defines "flexible" as "capable of being bent, usually without breaking; easily bent," "willing or disposed to yield; pliable," or "a flexible substance or material." RANDOM HOUSE UNABRIDGED DICTIONARY 733 (2d ed. 1987); *see also ICU Med., Inc. v. B Braun Med., Inc.*, 344 F. Supp. 2d 663, 668 (N.D. Cal. 2004). This alone is enough to distinguish the current case from *Welker Bearing* where no adjective

conveying any "physical or structural component" was present. St. Jude's contention that being flexible is the function of the element, not the definition, is not dispositive of Volcano's position. *See Greenberg*, 91 F.3d at 1583 ("[T]he fact that a particular mechanism—here 'detent mechanism'—is defined in functional terms is not sufficient to convert a claim element containing that term into a 'means for performing a specified function' within the meaning of section 112(6). Many devices take their names from the functions they perform."). Because "flexible element" does not contain the word "means" and the term connotes sufficient structure to a PHOSITA, the Defendants fail to overcome the presumption that "flexible element" is not a means-plus-function term. Accordingly, § 112 ¶ 6 does not apply.

b. The Specification Limits "Flexible Element" to a Coil

Although the term "flexible element" does not fall within the ambit of § 112 ¶ 6 because it is not simply a nonce word that conveys no structure, the exact structure intended by the patentee would likely not be clear to the PHOSITA without consulting the specification. When the '648 patent specification discusses flexibility, it is always in reference to a coil. Because the Court believes that the patentees' invention was limited to the use of a coil, the term "flexible element" is construed accordingly.

It is a well understood canon of patent law that limitations from the specification generally should not be imported into the claim language, but "if a disputed term has 'no previous meaning to those of ordinary skill in the prior art[,] its meaning, then, must be found [elsewhere] in the patent.'" *Irdeto Access, Inc. v. Echostar Satellite Corp.*, 383 F.3d 1295, 1300 (Fed. Cir. 2004) (alterations in original); *see also E.I. du Pont de Nemours & Co. v. Phillips Petroleum Co.*, 849 F.2d 1430, 1433 (Fed. Cir. 1988) ("It is entirely proper to use the specification to interpret what the patentee meant by a word or phrase in the claim."). According

to the Federal Circuit, the "construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction." *Renishaw PLC*, 158 F.3d at 1250 ("Ultimately, the interpretation to be given a term can only be determined and confirmed with a full understanding of what the inventors actually invented and intended to envelop with the claim.").

Flexible element does not have a previous meaning in the art to one of ordinary skill. To support its contention that "flexible element" has a well understood meaning in the art, Volcano points to dictionary definitions, other cases where the courts have construed the term, St. Jude's own patents, other issued patents that use the term, and a Google search. (D.I. 51 at 29). The dictionary definitions, other courts' constructions, previously issued patents and the Google search are not persuasive because many of these examples do not relate to the field of art at issue in this case—pressure-sensing guide wires. St. Jude's use of "flexible element" in its patents is similarly unavailing because those patents recite an "elongate flexible element" or "elongated flexible member." Both of these terms are understood to be a hypotube, which is distinct from the "flexible element" at issue here. *See* '648 patent, 3:50-56.

The term "flexible element" does not appear in the specification itself. This is because the specification is common to a family of related patents that date back to 1994, whereas the '647 and '648 patents introduced the term into the claim language when those patents issued in 2013.[3] At least one of the earlier patents that shares this specification claims a "coil" instead of a

[3] The parties in this case have been wielding their patent portfolios against one another in active litigation since the middle of 2010. (1:10-cv-631-RGA; 1:12-cv-441-RGA). Given the extensive litigation over the devices at issue, a claim differentiation argument regarding claims 16-18 of the '648 patent—dependent claims that cover a hypotube, coil, and balloon as further limitations to "flexible element"—is not persuasive. Claim differentiation "is not a rigid rule but rather is one of several claim construction tools." *ICU Med., Inc. v. Alaris Med. Sys., Inc.*, 558 F.3d 1368, 1376 (Fed. Cir. 2009). This is especially true when the patentee seeks to use claim differentiation to expand the claim scope years after the patent was originally filed. *See id.* (rejecting claim differentiation argument advanced by patentee where dependent claim "was only added to the [] patent in 2001, years after the filing date of the original

"flexible element." *See, e.g.*, U.S. Pat. No. 6,976,965, claim 1 ("A pressure sensor apparatus comprising: a guidewire; . . . a *first coil* disposed proximally from the sensor housing . . . .") (emphasis added). This suggests that a coil was understood to provide the claimed flexibility.

The specification does reference a "flexible elongate element 41," or a "flexible elongate member 41," and a "flexible elongate tubular member 173." *See* '648 patent, 3:51, 4:2-3, and 10:30. It also discusses flexibility, but only in the context of a coil or pair of coils. For example, the specification states: "The use of two coils 46 and 54 on opposite ends of the housing 61 provides a very flexible floppy tip for the guide wire . . . ." *Id.* at 4:17-19. Indeed the claim language requires a "flexible floppy tip" that comprises a short hypotube sensor housing sandwiched between a first flexible element and second flexible element. *Id.* at claim 1. In other words, the sensor housing and the two flexible elements comprise the flexible floppy tip. The flexible floppy tip is located distal to the hypotube and therefore was not intended to include the hypotube itself. *Id.* The figures and accompanying description reinforce that the flexible element must be limited to a coil. Figures 2 and 3 depict both a "flexible elongate element 41," which the specification notes is "conventionally called a 'hypotube,'" as well as two coil springs affixed to the distal portion of the elongate flexible element, thereby forming the flexible floppy tip. *Id.* at 3:55-56. When the claim states a "first flexible element, *disposed near a distal portion of the long proximal hypotube*," it is clearly informing the PHOSITA that it is not claiming the hypotube itself as the first flexible element, but rather a structure that is distal to the "flexible elongate member 41." *Id.* at claim 1 (emphasis added). That structure is the coil that forms a part of the flexible floppy tip. When read in this light, the claim term "flexible element" cannot be understood to be anything other than a coil. *See Renishaw PLC*, 158 F.3d at 1250 (relying on

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patents . . . and the introduction of the allegedly infringing Alaris products"). Here, "flexible element" was added almost twenty years after the specification was drafted.

"full understanding of what the inventors actually invented and intended to envelop with the claim").

It is also difficult to believe, as Volcano argues, that a balloon can act as a flexible element within the meaning of the patents. Whenever the word balloon appears in the specification, it is described as being used to dilate a stenosis. *See, e.g.*, '648 patent, 8:8-11 ("[A]n angioplasty catheter having a balloon thereon (not shown) can be advanced over the guide wire 21 and advanced into the stenosis to dilate the stenosis."); *id.* at 10:26-29 (discussing "another embodiment of a guide wire" which carries "an integral balloon"); *id.* at 10:41-61 ("The balloon 176 is provided with a distal extremity which is closed and which is secured to the proximal extremity of a coil spring . . . . The flexible elongate tubular member 172 is provided with a balloon inflation lumen 187 which can be used for inflating and deflating the balloon 176."); *id.* at 11:32-37 ("[W]here desired, the guide wire can be provided with an integrally mounted balloon on its distal extremity so that the guide wire can be utilized for performing an angioplasty . . . ."). One of the older patents in the patent family even claims the balloon as a dilation tool. *See* U.S. Pat. No. 6,767,327, claim 8 ("The method of claim 1 further comprising the steps of: advancing an angioplasty catheter having a balloon thereon over the guide wire to the location of the stenosis, and dilating the stenosis with the balloon."). There is no mention of any other use for the balloon in the specification, let alone any statements suggesting that its inflatability makes it "more flexible than the elongate tubular member, which is not inflatable." (D.I. 51 at 37-38). Therefore, the claimed "flexible element" does not include a balloon and is limited to a coil.

IV. CONCLUSION

Within five days the parties shall submit a proposed order consistent with this Memorandum Opinion suitable for submission to the jury.