IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ABBOTT CARDIOVASCULAR SYSTEMS, INC. and EVALVE, INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. 19-149 (MN)
EDWARDS LIFESCIENCES CORP. and EDWARDS LIFESCIENCES, LLC,	)	
Defendants.	)	

MEMORANDUM ORDER

At Wilmington this 22nd day of October 2019:

IT IS HEREBY ORDERED that the claim terms of U.S. Patent Nos. 7,288,097 ("the '097 patent"), 6,752,813 ("the '813 patent"), 7,563,267 ("the '267 patent"), 7,736,388 ("the '388 patent") and 8,057,493 ("the '493 patent") with agreed-upon constructions are construed as follows (*see* D.I. 293 at 1-2):

1. "proximal" means "the direction toward the end of the device to be manipulated by the user outside the patient's body" ('813 and '388 Patents)

2. "distal" means "the direction toward the working end of the device that is positioned at the treatment site and away from the user" ('813 Patent)

3. "downstream surface of at least one leaflet" means "a surface of the heart valve leaflet facing downstream in relation to the flow of blood, *e.g.*, the ventricular surface of a mitral valve leaflet" ('813 Patent)

4. "atraumatically" means "without causing any significant clinical impairment of the tissue; minor penetration or denting permitted" ('388 Patent)

5. "may be left to attach the free edges of the leaflets together" shall be given its plain and ordinary meaning, which does not require direct contact between the leaflet free edges ('097 Patent)[1]

6. "wherein the distal element is protrudable radially outward" means "wherein the distal element is capable of being protruded radially outward from the longitudinal axis of the interventional catheter, which axis may extend below the catheter" ('813 and '388 Patents)[2]

Further, as announced at the hearing on October 17, 2019, IT IS HEREBY ORDERED that the disputed claim terms of the '097, '813, '267, '388 and '493 Patents are construed as follows:

1. "a first pair of elements adapted to be brought up beneath a pair of valve leaflets from the ventricular side and a second pair of elements adapted to be brought down over the pair of valve leaflets from the atrial side, wherein the first pair of elements engages the ventricular side of both leaflets and the second pair of element engages the atrial side of both the leaflets to capture both leaflets" is not a means-plus-function limitation subject to 35 U.S.C. § 112(6) and the term shall be given its plain and ordinary meaning ('097 Patent, claim 1)

2. "free end" means "an end not attached to the other free end or the coupling member" ('267 Patent, claims 2, 5, 7 & 12; '388 Patent, claims 6, 11, 14, 16, 17, 22, 28, 31, 33 & 34; '493 Patent, claims 2, 5, 7, 15, 21, 24, 26 & 34)

3. "coupled to" shall be given its plain and ordinary meaning, which permits indirect coupling[3]

4. "pivotably coupled" means "coupled so as to rotate around a fixed point" ('388 Patent, claims 6, 11, 14, 16, 17, 22, 28, 31, 33 & 34)

5. "an inverted position wherein the engagement surfaces face away from each other" means "a position where the free ends of the fixation elements point in a distal direction and where the engagement surfaces face away from each other" ('267 Patent, claims 2, 5, 7 & 12; '493 Patent, claims 21, 24, 26 & 34)

6. "adapted to move the fixation elements between the closed position and the first open position" means "adapted to move the fixation elements from a

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[1] This term was discussed at length and construed according to its plain and ordinary meaning in the Court's preliminary injunction opinion. (*See* D.I. 164 at 9-15).

[2] The parties reached agreement on this construction at the hearing. (*See* D.I. 296 at 108:25-109:12).

[3] As stated at the hearing, this construction applies to all instances of "coupled to" in the asserted patents unless otherwise construed by the Court. (*See* D.I. 296 at 119:7-11).

closed position to a first open position and also from a first open position to a closed position, *i.e.*, it allows a back-and-forth movement" ('388 Patent, claim 11; '493 Patent, claims 2, 5, 7 & 15)

7. "the fixation elements are moveable between a closed position wherein the engagement surfaces face each other to a first open position wherein the engagement surfaces are positioned away from each other" means "the fixation elements are moveable from a closed position wherein the engagement surfaces face each other to a first open position wherein the engagement surfaces are positioned away from each other" ('493 Patent, claims 2, 5, 7 & 12)

8. "guide conduit" shall be given its plain and ordinary meaning, which is "a channel that you can bring things towards and away from a location" ('813 Patent, claims 119 & 123)

9. "interventional tool" means "interventional catheter" ('813 Patent, claim 123)

The parties briefed the issues (*see* D.I. 215) and submitted an appendix containing both intrinsic and extrinsic evidence (*see* D.I. 216, 242 & 243; *see also* D.I. 185 & 186). Neither side provided a tutorial describing the relevant technology. The Court carefully reviewed all submissions in connection with the parties' contentions regarding the disputed claim terms, heard oral argument (*see* D.I. 296) and applied the following legal standards in reaching its decision:

I. LEGAL STANDARD

A. Claim Construction

"[T]he ultimate question of the proper construction of the patent [is] a question of law," although subsidiary fact-finding is sometimes necessary. *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 837-38 (2015). "[T]he 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 v. AWH Corp.*, 415 F.3d 1303, 1312-13 (Fed. Cir. 2005) (en banc) (internal citations and quotation marks omitted). Although "the claims themselves provide substantial

guidance as to the meaning of particular claim terms," the context of the surrounding words of the claim also must be considered. *Id.* at 1314. "[T]he ordinary meaning of a claim term is its meaning to the ordinary artisan after reading the entire patent." *Id.* at 1321 (internal quotation marks omitted).

The patent specification "is always highly relevant to the claim construction analysis . . . [as] it is the single best guide to the meaning of a disputed term." *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). It is also possible that "the specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess. In such cases, the inventor's lexicography governs." *Phillips*, 415 F.3d at 1316. "Even when the specification describes only a single embodiment, [however,] the claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using words or expressions of manifest exclusion or restriction." *Hill-Rom Servs., Inc. v. Stryker Corp.*, 755 F.3d 1367, 1372 (Fed. Cir. 2014) (internal quotation marks omitted) (quoting *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004)).

In addition to the specification, a court "should also consider the patent's prosecution history, if it is in evidence." *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 980 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996). The prosecution history, which is "intrinsic evidence, . . . consists of the complete record of the proceedings before the PTO [Patent and Trademark Office] and includes the prior art cited during the examination of the patent." *Phillips*, 415 F.3d at 1317. "[T]he prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." *Id.*

In some cases, courts "will need to look beyond the patent's intrinsic evidence and to consult extrinsic evidence in order to understand, for example, the background science or the meaning of a term in the relevant art during the relevant time period." *Teva*, 135 S. Ct. at 841. Extrinsic evidence "consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." *Markman*, 52 F.3d at 980. Expert testimony can be useful "to ensure that the court's understanding of the technical aspects of the patent is consistent with that of a person of skill in the art, or to establish that a particular term in the patent or the prior art has a particular meaning in the pertinent field." *Phillips*, 415 F.3d at 1318. Nonetheless, courts must not lose sight of the fact that "expert reports and testimony [are] generated at the time of and for the purpose of litigation and thus can suffer from bias that is not present in intrinsic evidence." *Id.* Overall, although extrinsic evidence "may be useful to the court," it is "less reliable" than intrinsic evidence, and its consideration "is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence." *Id.* at 1318-19. Where the intrinsic record unambiguously describes the scope of the patented invention, reliance on any extrinsic evidence is improper. *See Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1308 (Fed. Cir. 1999) (citing *Vitronics*, 90 F.3d at 1583).

B. Indefiniteness

"The primary purpose of the definiteness requirement is to ensure that the claims are written in such a way that they give notice to the public of the extent of the legal protection afforded by the patent, so that interested members of the public, *e.g.* competitors of the patent owner, can determine whether or not they infringe." *All Dental Prodx, LLC v. Advantage Dental Prods., Inc.*, 309 F.3d 774, 779-80 (Fed. Cir. 2002) (citing *Warner-Jenkinson Co. v. Hilton-Davis Chem. Co.*, 520 U.S. 17, 28-29 (1997)). Put another way, "[a] patent holder should know what he owns, and

the public should know what he does not." *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.*, 535 U.S. 722, 731 (2002).

A patent claim is indefinite if, "viewed in light of the specification and prosecution history, [it fails to] inform those skilled in the art about the scope of the invention with reasonable certainty." *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120, 2129 (2014). A claim may be indefinite if the patent does not convey with reasonable certainty how to measure a claimed feature. *See Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 789 F.3d 1335, 1341 (Fed. Cir. 2015). But "[i]f such an understanding of how to measure the claimed [feature] was within the scope of knowledge possessed by one of ordinary skill in the art, there is no requirement for the specification to identify a particular measurement technique." *Ethicon Endo–Surgery, Inc. v. Covidien, Inc.*, 796 F.3d 1312, 1319 (Fed. Cir. 2015).

Like claim construction, definiteness is a question of law, but the Court must sometimes render factual findings based on extrinsic evidence to resolve the ultimate issue of definiteness. *See, e.g., Sonix Tech. Co. v. Publications Int'l, Ltd.*, 844 F.3d 1370, 1376 (Fed. Cir. 2017); *see also Teva*, 135 S. Ct. at 842-43. "Any fact critical to a holding on indefiniteness . . . must be proven by the challenger by clear and convincing evidence." *Intel Corp. v. VIA Techs., Inc.*, 319 F.3d 1357, 1366 (Fed. Cir. 2003); *see also Tech. Licensing Corp. v. Videotek, Inc.*, 545 F.3d 1316, 1338 (Fed. Cir. 2008).

II. THE COURT'S RULING

The Court's rulings regarding the disputed claim terms of the '097, '813, '267, '388 and '493 Patents were announced from the bench at the conclusion of the hearing as follows:

> . . . So at issue we have five patents, United States Patent Numbers 7,288,097, 6,752,813, 7,563,267, 7,736,388, and 8,057,493.

There were originally ten terms in dispute, but the parties have agreed to one of those, and that's the term "wherein the distal element is protrudable radially outward." And that term will have the agreed upon construction that Mr. Hurst just read into the record.

I am prepared to rule on the remaining nine disputes. I will not be issuing a written opinion, but I will issue an order stating my rulings. I want to emphasize before I announce my decisions that while I am not issuing a written opinion, we have followed a full and thorough process before making the decisions I am about to state. I have reviewed each of the five patents, the portions of the prosecution history submitted and the joint appendix. I have also reviewed the declaration of Dr. Jensen submitted by Defendants regarding the meaning of the one disputed term of the '097 Patent. There was full briefing of each of the disputed terms and there has been argument here today. All of that has been carefully considered.

Now as to my rulings. I am not going to read into the record my understanding of claim construction law and indefiniteness. I have a legal standard section that I have used earlier, including in my relatively recent order in *OmegaFlex v. Ward Manufacturing*, Civil Action No. 18-1004. I incorporate that law and adopt it into my ruling today and I will also set it out in the order that I issue.

Additionally, with respect to the person of ordinary skill in the art in this case, Defendants offer the opinion of their expert, Dr. Morten Olgaard Jensen, that the person of ordinary skill in the art for the '097 Patent is "a medical doctor or someone who has received an advanced degree, such as a master's degree or Ph.D., in a relevant engineering discipline with at least some experience contributing to the design, testing, and/or evaluation of heart valve treatment devices, or someone who has obtained a lesser degree but has more experience contributing to the design, testing, and/or evaluation of heart valve treatment devices." Plaintiffs do not disagree and have agreed here today that the Court may use that definition for purposes of claim construction of the '097 Patent. And the parties have also agreed for purposes of these proceedings that there are no disputes as to who a person of ordinary skill in the art is that would make a difference to my constructions.

The first disputed term is "a first pair of elements adapted to be brought up beneath a pair of valve leaflets from the ventricular side and a second pair of elements adapted to be brought down over the pair of valve leaflets from the atrial side, wherein the first pair of elements engages the ventricular side of both leaflets and the

second pair of element engages the atrial side of both the leaflets to capture both leaflets," which is in claim 1 of the '097 Patent.

Plaintiffs assert that the term should have its plain and ordinary meaning – though that meaning is unstated. Plaintiffs dispute that the term is a means-plus-function under 35 U.S.C. Section 112(6). Defendants counter that the term is a means-plus-function limitation subject to Section 112(6) and, more particularly, that the "first pair of elements" and "second pair of elements" as recited in the claims use means-plus-function language.

Here, I agree with Plaintiffs and conclude that this term is not subject to Section 112(6). First, I note that there is a rebuttable presumption that Section 112(6) does not apply in situations where, as here, the word "means" is absent from the claim term at issue. *See Williamson v. Citrix Online, LLC*, 792 F.3d 1339, 1349 (Fed. Cir. 2015). That presumption may be overcome if Defendants demonstrate that the claim term fails to recite sufficiently definite structure or if they demonstrate the claim recites function without sufficient structure for performing that function. *See Diebold Nixdorf, Inc. v. ITC*, 899 F.3d 1291, 1298 (Fed. Cir. 2018). Defendants, however, have failed to make that showing.

The thrust of Defendants' argument appears to be that the recitation of "elements" in combination with what they assert is functional language renders this term a means-plus-function limitation because the Federal Circuit has commented on several occasions that "element" is a nonce word that typically does not connote sufficiently definite structure to a person of ordinary skill in the art and is therefore tantamount to reciting "means," and thus invoking Section 112(6). And I'll cite for that the *Williamson* case, 792 F.3d at 1350, and also *TEK Global, S.R.L. v. Sealant Sys. Int'l, Inc.*, 920 F.3d 777, 785 (Fed. Cir. 2019). The relevant inquiry here, however, is whether the "elements" recited in the claim of the '097 Patent connote sufficiently definite structure to a person of ordinary skill in the art. To answer that, I look to the claims, the specification and the prosecution history and, if necessary, extrinsic evidence.

Here, I find that the claim term recites sufficiently definite structure to avoid being subject to Section 112(6). As for the claim itself, the two pairs of elements are part of a clipping system with certain requirements that connote a certain level of structure – for example, the elements physically connect to and form part of a structure that can clip leaflets together, and the limitation to cardiac valve repair also imports structural limitations. Additionally, the elements must be of a certain rigidity so as to effectively function as

a clipping mechanism, and they must be of a sufficiently small size to accomplish clipping of heart valves. Dependent claims here also give insight as to the physical structure of the claimed "elements," as was the case in *TEK Global* – for example, claim 2 here provides that the elements may be prongs, which Defendants do not seem to dispute connotes sufficient structure. The specification also provides examples of physical structures for the claimed elements – for example, side prongs at column 4, lines 39 through 53. And finally, the prosecution history also provides that "the intent of the pairs of elements is to grasp and capture both of the valve leaflets on both their atrial and ventricular sides." And that was the September 21st, 2006 Response to Office Action at page 3.

This again suggests that the "elements" have a certain structure – for example, one that allows for tissue capture such as through piercing, force, et cetera. Although not dispositive, the Court also notes that the Applicants never indicated that "elements" was being used as substitute for "means" and the Examiner never raised Section 112(6) with respect to this limitation.

The Defendants submitted a declaration from Dr. Jensen, who opines that "elements" and "pair of elements" have no particular meaning to persons of ordinary skill of the art working in the field of cardiac valve repair. His opinion, however, on the issue consists largely of two conclusionary paragraphs. The Court has considered the declaration but finds that the intrinsic evidence supports the conclusion that the "elements" recited in claim 1 have sufficiently definite structure to avoid Section 112(6). Thus, the term shall be given its plain and ordinary meaning.

The second disputed term is "free end" in claims 2, 5, 7 and 12 of the '267 Patent, claims 6, 11, 14, 16, 17, 22, 28, 31, 33 and 34 of the '388 Patent, and claims 2, 5, 7, 15, 21, 24, 26 and 34 of the '493 Patent. The Court addressed the meaning of this term in the preliminary injunction opinion from June where I construed it to mean "an end not attached to another portion of the fixation device." Although that opinion addressed the "free end" term in the context of the '388 and the '493 Patents, there is no dispute that "free end" has the same meaning in the '267 Patent as in the '388 and '493 Patents. Moreover, on that point, because the '267, '388 and '493 Patents all share a common specification, when talking about those patents, I will generally cite to the '267 Patent specification in this opinion unless otherwise noted.

As to the parties' positions, Plaintiffs assert the term means "an end that is free to move relative to the device's longitudinal

axis." Defendants counter that it means "an end not attached to another portion of the fixation device."

Plaintiffs assert that the fundamental dispute is whether the "free end" connotes freedom of movement, as Plaintiffs propose, or freedom from attachment, as Defendants propose. As I noted here today, it is not clear to me what Plaintiffs mean by free to move – or how much movement is necessary. And I also note that, when asked today whether the "first end" is "free to move relative to the longitudinal axis," Plaintiffs' counsel agreed that it was not – and it was not because it was coupled to the other first end. Thus, I do not understand that the two concepts offered are necessarily unrelated.

The claim uses the language "free." This is notable because each of the asserted claims containing "free end" recites a fixation element having a "first end" and a "free end" in contrast to the "first end" – not merely "a second end opposite the first end." In contrast to the "first ends" that are coupled to each other or to the coupling member, each "free end" is not attached or coupled as the "first ends" must be.

Today, the Defendants agreed that the concept being construed – however difficult to convey in words – is that the end must be 1) an end and 2) free from attachment to the major parts of the fixation device. And that did not include attachment to peripheral parts such as a mesh cover.

Given the contrast in the claim between the "first end" and the "free end," during the proceedings today I asked both parties about a construction of "free end" to mean "an end not attached to the other free end or the coupling member." Defendants did not object but suggested I may need to include other as yet unstated parts of the device. Although stating it is not Plaintiffs' "optimal position," Plaintiffs did not appear to have a problem with the concept of the free ends not being coupled to each other.

I will thus clarify the language of my earlier construction to make clear that peripheral attachments such as in the new embodiments raised by Plaintiffs are not excluded by my construction. In doing so, I reiterate that the "free ends" are defined in the claims by contrast to the "first ends." In the '267 and '493 Patents, unlike the "first ends" that are "movably coupled together," the "free ends" are free at least because they are not moveably coupled to each other. In the '388 Patent, unlike the "first ends" that are "coupled to the coupling member," the "free ends" are "free" at least because they are not coupled to the coupling member. The

other "free end" and the "coupling member" represent the other portions of the fixation device that the Court was attempting to capture in its earlier construction. That is, to be a "free end," the end must be free from attachment to these portions of the fixation device. Indeed, there is no disclosure in the specification of any fixation device where the free end is coupled to either the other free end or the coupling member.

Therefore, I will construe "free end" to mean "an end not attached to the other free end or the coupling member." I do recognize that the "free end" is arguably attached to the coupling member and the other "free end" by way of the coupling of the "first ends," but that is not the attachment I mean to exclude. Freedom from attachment in my construction means free from attachment to the coupling member and the other free end other than through the first ends. And finally, for the sake of completeness, I note that despite this clarification, I do not intend to change any finding or conclusion rendered in the preliminary injunction decision.

Next are two terms that use the word "coupled" – "coupled to the coupling member" and "pivotably coupled" as found in claims 6, 11, 14, 16, 17, 22, 28, 31, 33 and 34 of the '388 patent.

Plaintiffs assert that "coupled to the coupling member" means "connected, directly or indirectly, to the coupling member." Defendants assert that it should have its plain and ordinary meaning.

As noted during the argument, I am not sure what dispute remains over this term. Both sides appear to agree that the coupling – however it is articulated – allows for both direct and indirect coupling. Defendants seem to have an issue with construing this phrase only in the context of the '388 Patent because "coupled to" appears in many other claims across the various asserted patents, and Defendants do not want to use "connected" in place of "coupled."

But both parties agree that whatever coupled means, it permits indirect coupling. Whether coupled is rephrased as connected, attached, joined, whatever, there is no dispute that this term includes indirect connections, attachments, joining, et cetera. The Court does not believe at this point that rephrasing the word "coupled" as "connected" as Plaintiffs propose is necessary or helpful, particularly where Defendants dispute "connected" is the right word to add clarity. In light of this, the Court will give this term its plain and ordinary meaning with the clarification that indirect

coupling is permitted. This construction applies to all instances of "coupled to" unless otherwise construed by the Court.

As to "pivotably coupled," Plaintiffs proposed to construe it as "coupled so as to allow rotational movement, including through bendable couplings, pins, living hinges or other rotational connection mechanisms." Defendants propose to construe "pivotably coupled" to mean "fastened so as to rotate around a fixed point." The dispute over this term appears to be two-fold: first, whether the rotational movement contemplated by "pivotably" requires the rotation to be around a fixed point and, second, whether "pivotably coupled" includes structures that pivot because of bending. Defendants argue that "pivotably" is a term that connotes rotational movement that occurs about a fixed point, whereas Plaintiffs' construction is not so limited. Plaintiffs also propose that "pivotably coupled" covers rotational movement that occurs from structures other than pins and hinges, a proposal that Defendants reject.

The independent claims of the '388 Patent recite that the "first ends" of the fixation elements are "pivotably coupled to the coupling member" so that the fixation elements move to various positions defined by separation angles. Both sides here agree that the movement at issue in the '388 Patent claims is rotational movement. In the Court's view, the plain meaning of pivot means to turn as if on a pivot. This suggests that the movement contemplated by the term "pivotably" is movement that occurs with respect to a fixed point.

And turning to the specification, there is no disclosure of pivot or rotational movement of the fixation elements that does not occur about a fixed point. Even in the '388 Patent embodiments where the fixation elements' rotation is achieved by elastic deformation or bending such as in column 17, lines 58 through 67, the patent provides that that bending occurs at a fixed point – *i.e.*, "at the point of connection between the elements 18 and the coupling member 19." That's at column 17, lines 64 to 65. Therefore, the rotational movement at issue in the claims of the '388 Patent is that which occurs around a fixed point.

Defendants argue that bendable couplings should be excluded by the claims because the phrase does not appear in the patent and such bendable couplings are examples of "rotatably coupled" couplings, not "pivotably coupled" ones.

The Court does not believe there is a distinction in meaning between "rotatably" and "pivotably" in the context of the '388 Patent – the specification appears to treat the two as synonymous and Defendants have not really shown otherwise. In this patent, there is no reason to conclude that examples of "rotatably coupled" fixation elements are not also examples of "pivotably coupled" ones. Construing the term to exclude bendable couplings as Defendants suggest would exclude preferred embodiments where the entire fixation device is molded as one part and the fixation elements rotate because of elastic deformation or a living hinge, such as for example at column 17, lines 56 through 67 of the '388 Patent. This suggests that Defendants' proposal is not the correct one. That being said, as noted previously, the patent provides that, even in cases where the rotational movement comes from deflection, that rotational movement still occurs about a fixed point.

Therefore, the Court will construe "pivotably coupled" to mean "coupled so as to rotate around a fixed point." By doing so, I am not excluding rotational movement of the fixation elements that results from bending or deforming at a fixed point.

The fifth disputed term is "an inverted position wherein the engagement surfaces face away from each other" which is found in claims 2, 5, 7 and 12 of the '267 Patent, and claims 21, 24, 26 and 34 of the '493 Patent.

Plaintiffs argue that the term means "a position where the engagement surfaces face away from each other." Defendants argue that it means "a position wherein the fixation elements are inverted and wherein the engagement surfaces face away from each other."

Plaintiffs in essence argue that the claims define the inverted position to mean that the engagement surfaces of the fixation element face away from each other without more. Defendants argue that more is required – that the entire fixation element has to invert – it must either turn upside down or reverse its position as compared to the closed position where the engagement surfaces face each other.

Beginning with the claims, such as claim 2 of the '267 Patent and claim 20 of the '493 Patent, it is noteworthy that the claims recite that the "fixation elements are moveable between a closed position wherein the engagement surfaces face each other to an inverted position wherein the engagement surfaces face away from each other." This suggests that movement of the fixation element itself is necessary to achieve the inverted position – that is, the

inverted position is not defined solely based on whether the engagement surfaces face away from each other, as Plaintiffs propose. The word "inverted" has some meaning for the "inverted position" apart from what follows in the claim language. That being said, Defendants' proposal does not lend clarity to what "inverted" means – they simply argue that the fixation elements have to actually invert in order to achieve the "inverted position."

The specification, however, provides guidance on what the "inverted position" means. The specification characterizes "inverted position" in terms of where the fixation element "free ends" are pointing along with the angle of separation between the engagement surfaces. The "Summary of Invention," in column 4, lines 34 through 40 of the '267 Patent, states that "for approaches from the atrial side of the mitral valve, in the inverted position, the free ends will be pointing in a generally distal direction relative to the catheter shaft and the engagement surfaces will be facing generally away from each other, usually being disposed at an angle of more than about 180 degrees, and preferably more than 270 degrees, relative to each other." For ventricular approaches, it says "in the inverted position the free ends will be pointing in a distal direction relative to the catheter shaft and the engagement surfaces will be facing generally toward each other, usually being disposed at an angle of less than about 180 degrees, and preferably less than 90 degrees, relative to each other."

At column 9, lines 1 through 6, the "inverted position" is described in terms of the "free ends" pointing distally and where the engagement surfaces face. And at column 17, lines 5 to 28, the "inverted position" is described in terms of the "free ends" pointing in a direction opposite where the "free ends" point when they are in the closed position. The "inverted position" of the claimed invention is consistently characterized by where the free ends of the fixation element are pointing as well as the angle of separation between the engagement surfaces. And there is no disclosure of an "inverted position" where the "free ends" are not pointing in a generally distal direction. In addition to what I have already cited, see also for example in the '267 Patent at column 21, lines 55 through 63, as well as Figures 3B, 8B, 12A, 12B, 17B, 35 and 42.

Therefore, consistent with the way the "inverted position" is characterized in the patents, the Court finds that the "inverted position" is properly defined in terms of the two engagement surfaces as well as the position of the free ends in order to give "inverted" meaning in the claims. The Court will construe this term to mean: "a position where the free ends of the fixation elements

point in a distal direction and where the engagement surfaces face away from each other."

The sixth disputed term is "adapted to move the fixation elements between the closed position and the first open position" in claim 11 of the '388 Patent and claims 2, 5, 7 and 15 of the '493 Patent. Plaintiffs propose the term to mean "adapted to move the fixation elements from a closed position to a first open position and also from a first open position to a closed position, i.e., it allows a back-and-forth movement." Defendants' proposal is plain and ordinary meaning, which they assert is "adapted to move the fixation elements between the closed position and the first open position." And they note that the plain and ordinary meaning does not require adaptation for a back-and-forth movement.

The crux of this dispute is whether the term requires "back and forth movement" or only movement in one direction.

Here, I agree with Plaintiffs and construe the term to mean "adapted to move the fixation elements from a closed position to a first open position and also from a first open position to a closed position, i.e., it allows a back-and-forth movement."

As an initial matter, the claim language claims moveability "between" one position and another, not just from one position "to" another. The ordinary meaning of moving "between" is moving "to and from." That's from Webster's Dictionary of American English 1997, and Illustrated Oxford Dictionary 1998, both of which were submitted by Plaintiffs in their papers. That suggests the ability to move in only one direction is not enough.

Moreover, the specification describes the fixation elements as being in a closed position to fit in the vascular delivery catheter, then moving to an open position to catch the leaflet, and then moving back to the closed position to capture the leaflets. This back-and-forth movement is illustrated in Figures 10A, 11A and 14 of the '267 Patent and described in the text of the specification referencing those Figures.

The specification of the '267 Patent at column 21, lines 46 to 48, also describes that the device can be "repeatedly manipulated to reposition" it. It states that the device can be "reopened . . . following initial placement" and then "repositioned as desired and then reclosed . . . to coapt the leaflets" at column 16, line 58 through column 17, line 4. That's where that citation was.

According to the specification, this can be used to "reapproach the valve in an attempt to achieve better "valve function" or obtain "more optimal positioning of the device." That's for example at column 2, lines 20 through 23, column 12, lines 56 through 65, and column 13, line 65 to column 14, line 8 of the '267 patent. These passages describe a device that goes from a closed to an open position, and also from an open position to a closed position. It describes back-and-forth movement.

The seventh term is "the fixation elements are moveable between a closed position wherein the engagement surfaces face each other to a first open position wherein the engagement surfaces are positioned away from each other" in claims 2, 5, 7, and 12 of the '493 Patent. The dispute here is similar to the dispute for the prior term and involves whether the fixation elements must be capable of back-and-forth movement.

Plaintiffs assert the term means "the fixation elements are moveable from a closed position wherein the engagement surfaces face each other to a first open position wherein the engagement surfaces are positioned away from each other and also moveable from a first open position wherein the engagement surfaces are positioned away from each other to a closed position wherein the engagement surfaces face each other, i.e., it allows a back-and-forth movement."

Defendants again argue for the plain and ordinary meaning, which they say is "the fixation elements are capable of being moved between a closed position wherein the engagement surfaces face each other to a first open position wherein the engagement surfaces are positioned away from each other" and does not require capability for a back-and-forth movement.

While the dispute is similar to the prior dispute, the claim language here is different from the claim language discussed above. In the prior term, the claim language referenced moving between one position and another. The language here, however, references capability of moving between a closed position to an open position. Thus, rather than encompassing to and from by using the words "between" and "and," the claim language here really references only moving from a closed position to an open position is required.

I will construe this term to mean "the fixation elements are moveable from a closed position wherein the engagement surfaces face each other to a first open position wherein the engagement surfaces are positioned away from each other."

Moreover, this construction is supported by the specification. As already discussed, the fixation elements are closed when the device is delivered to the heart in the closed position, and then moved to the open position to deploy the device to enable leaflet capture.

The eighth disputed term is "guide conduit" in claims 119 and 123 of the '813 Patent. Plaintiffs proposed this term means a "channel for guiding an object." Defendants assert that it means "a channel capable of extending and/or retracting from the shaft of the interventional catheter for guiding an object."

The Court previously addressed this element in claim 113 in connection with the preliminary injunction proceedings. The construction proposed by Defendants, however, has changed since those proceedings. The central dispute now appears to be two-fold – first, whether the "guide conduit" must be capable of extending and/or retracting, and second, whether it must be capable of doing so "from the shaft" of the interventional catheter. I find that such limitations are not supported by the intrinsic evidence.

As an initial matter, I note that it appears that all parties agree that the ordinary meaning of "guide conduit" is "a channel that you can bring things towards and away from a location."

Defendants assert, however, that the '813 Patent only describes guide conduits that are capable of extending and/or retracting from a shaft, such as those in Figures 22, 46 and 47. At column 6, lines 12 through 16, the specification provides that the "guide conduits may be adjusted to direct the penetrating device toward the desired location" and that such adjustments "may include extending or retracting the guide conduits." The use of "may" suggests the adjustments are optional, which is further confirmed by the statements that "various alternatives, modifications and equivalents may be used" and that descriptions "should not be taken as limiting" which is at column 29, line 65 through column 30, line 4 of the '813 Patent.

Similarly, claim 113 does not explicitly recite that the "guide conduit" extends or retracts at all while other dependent claims do. This suggests that while claim 113 allows for such capability, it does not require it.

Additionally, I will not read into the claims the words "from the shaft." Independent claim 113, which includes a "guide conduit" limitation, does not mention a shaft. That limitation appears in

dependent claim 114, which recites an interventional catheter that "comprises a shaft." It appears that the patentee knew how to claim a shaft when it intended to, and it did not do so in claim 113.

Defendants assert that "shaft" should nevertheless be read into the term because dependent claim 127 refers to the claim of 113 in which the "guide conduit is capable of extending angularly outward from the shaft." And thus, according to Defendants, there must be an antecedent basis for shaft in claim 113. It seems to me there are quite a number of errors in the '813 Patent. And it may be that claim 127 or others are invalid because of those. But the validity of those claims is not before me. Claim 113, as I noted before, does not recite or require a shaft.

Finally, the last disputed term is "interventional tool" in claim 123 of the '813 patent. Plaintiffs propose the construction "interventional catheter." Defendants argue the term is indefinite.

The issue appears to be whether "interventional tool" in claim 123 lacks antecedent basis. Independent claim 113 of the '813 Patent recites "a capture device on an interventional catheter." Claim 123 adds that "the capture device is detachable from the interventional tool." Because claim 123 refers to an "interventional tool" rather than an "interventional catheter," Defendants assert that "interventional tool" is indefinite.

For this term, I agree with Plaintiffs. Federal Circuit precedent makes clear that when indefiniteness is asserted because of lack of antecedent basis, the Court has to determine whether a person experienced in the field of the invention would understand the scope of the claim term lacking antecedent basis when read in light of the specification. That's the *Energizer Holdings, Inc. v. ITC case*, 435 F.3d 1366, 1371 (Fed. Cir. 2006). A claim term is not indefinite even when it lacks an antecedent basis if the claims and surrounding context "apprise one of ordinary skill in the art of its scope." *In re Downing*, F. App'x 988, 996 (Fed. Cir. 2018).

Here, Defendants have not shown by clear and convincing evidence that a skilled artisan would fail to grasp what the term "interventional tool" means after reading the specification and the prosecution history.

Indeed, [the] specification and prosecution history support Plaintiffs' proposed construction. The '813 Patent specification appears to use the terms "interventional catheter" and "interventional tool" interchangeably at times. For example, column

3, line 59 through column 4, line 9, where they first use "interventional catheter" with a capture device, and a few lines later refer to the "interventional tool." This is true in other places as well, for example, column 4, lines 55 through 60, column 5, lines 10 through 14, column 6, lines 11 through 12, and others, all referring to an interventional tool with a capture device, and places like column 6, lines 26 through 31, column 8, lines 60 through 62, referring to the interventional catheter with a capture device.

Moreover, in the prosecution history here, as in *Energizer Holdings*, the Examiner never rejected or objected to claim 123 for lack of antecedent basis. To the contrary, the Examiner appears to have used the terms interchangeably, issuing non-final rejections for claims that recited in "interventional catheter" based on prior art that disclosed an "interventional tool."

Thus, I will construe the term "interventional tool" in claim 123 to mean "interventional catheter."

Maryellen Noreika

The Honorable Maryellen Noreika
United States District Judge