IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ENDOHEART AG,	:	
	:	
Plaintiff,	:	
	:	
v.	:	C.A. No. 14-1473-LPS
	:	
EDWARDS LIFESCIENCES CORPORATION,	:	
	:	
Defendant.	:	

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MEMORANDUM OPINION

March 31, 2016
Wilmington, Delaware

STARK, U.S. District Judge:

On December 10, 2014, Plaintiff Endoheart AG ("Endoheart") filed suit against Defendant Edwards Lifesciences Corporation ("Edwards") alleging infringement of U.S. Patent No. 8,182,530 (the "'530 patent"). The patent claims a method for performing transcatheter heart valve replacement – the "transapical" approach.

The parties submitted technology tutorials (D.I. 70, 71) and claim construction briefs. (*See* D.I. 63, 65, 81, 82) The Court held a claim construction hearing on February 4, 2016. (*See* D.I. 118 ("Tr.")).

I. LEGAL STANDARDS

The ultimate question of the proper construction of a patent is a question of law. *See Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 837 (2015) (citing *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 388-91 (1996)). "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) (internal quotation marks omitted). "[T]here is no magic formula or catechism for conducting claim construction." Id. at 1324. Instead, the court is free to attach the appropriate weight to appropriate sources "in light of the statutes and policies that inform patent law." Id.

"[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." *Id.* at 1312-13 (internal citations and quotation marks omitted). "[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. Usually, it is dispositive; 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).

While "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. *Phillips*, 415 F.3d at 1314. Furthermore, "[o]ther claims of the patent in question, both asserted and unasserted, can also be valuable sources of enlightenment . . . [b]ecause claim terms are normally used consistently throughout the patent . . . ." *Id.* (internal citation omitted).

It is likewise true that "[d]ifferences among claims can also be a useful guide . . . . For example, the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim." *Id.* at 1314-15 (internal citation omitted). This "presumption is especially strong when the limitation in dispute is the only meaningful difference between an independent and dependent claim, and one party is urging that the limitation in the dependent claim should be read into the independent claim." *SunRace Roots Enter. Co., Ltd. v. SRAM Corp.*, 336 F.3d 1298, 1303 (Fed. Cir. 2003).

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. It bears emphasis that "[e]ven when the specification describes only a single embodiment, 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) (quoting *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358

F.3d 898, 906 (Fed. Cir. 2004)) (internal quotation marks omitted).

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), *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, "the district court 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. For instance, technical dictionaries can assist the court in determining the meaning of a term to those of skill in the relevant art because such dictionaries "endeavor to collect the accepted meanings of terms used in various fields of science and technology." *Phillips*, 415 F.3d at 1318. In addition, 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." *Id.* 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, while 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).

Finally, "[t]he 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 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) (quoting *Modine Mfg. Co. v. U.S. Int'l Trade Comm'n*, 75 F.3d 1545, 1550 (Fed. Cir. 1996)).

II. CONSTRUCTION OF DISPUTED TERMS

1. "configured to conform to the direction of blood flow"[1]

Endoheart Having a property or structure for adapting to the direction of blood flow.
Edwards Indefinite. Alternatively, to the extent the court requires construction: Adapted to be carried along with the antegrade flow of blood
Court No construction necessary at this time.

The parties disagree about what it means for a guidewire to be "configured to" conform to the direction of blood flow. Endoheart argues that a wire is so configured if its properties and structure are such that it does, in fact, conform. (D.I. 65 at 10-11) The parties agree that there are different types of guidewires, some of which would conform when placed in blood flow and some which would not. (D.I. 65 at 10-11; D.I. 63 at 10) Edwards argues that this variety of guidewires renders the claims indefinite because "a person of ordinary skill in the art would not know which guidewires, if any, conform to a direction of blood – not from the literature, and not from the specification of the '530 patent." (D.I. 63 at 10)

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 party who challenges the validity of a patent or claim has the burden of establishing invalidity. *Id.* at 2130 n.10 (*citing* 35 U.S.C. § 282). Invalidity must be proven by "clear and convincing

[1]This term appears in claims 1 and 6 of the '530 patent.

evidence." *Microsoft Corp. v. i4i Ltd. Partnership*, 564 S.Ct. 2238, 2242 (2011) (discussing burden of proof for invalidity defenses). Here, Edwards has not offered clear and convincing evidence that a person of ordinary skill in the art at the time of the invention would lack reasonable certainty regarding which guidewires would conform to the flow of blood if employed in the claimed method.[2] For this reason, the Court finds that Edwards has not met its burden to prove indefiniteness.

Having determined that the term is not indefinite, the Court turns to the parties' dispute about the proper construction of the words "conform to the direction of blood flow." The parties agree that the claimed guidewires are fed into the heart in the "antegrade" direction – that is, "in the direction of blood flow." (Tr. 16-17, 56) They further agree that the claims distinguish the

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[2]Edwards submitted deposition testimony of Christoph Huber, M.D., the inventor of the '530 patent, to support its argument that one of skill in the art would not know whether a particular guidewire falls within the scope of the claims. (Tr. at 42-44) Huber was asked how one could determine whether a particular guidewire was "configured to conform to the direction of blood flow." (D.I. 113-1 at 22) Huber responded that one would "use it in a transapical procedure in a patient," and observe the result. (*Id.* at 22-23) Similarly, Huber did not specify a particular commercial designation – such as "soft" or "stiff" – from which a physician could definitively determine whether a particular guidewire would be suitable to perform the transapical procedure. (D.I. 113-1 at 53)

Neither statement is an admission of indefiniteness or clear and convincing evidence of it. First, Dr. Huber's statement about testing a guidewire's suitability appears to be a description of a test for determining whether a particular wire is suitable to perform the transapical procedure, but not necessarily the only test for whether a particular guidewire is "configured to conform" within the meaning of the claims. Second, Dr. Huber's inability to state with certainty whether all "soft" guidewires would be appropriate, or all "stiff" guidewires inappropriate, indicates that the "soft"/"stiff" distinction is not the way to determine which guidewires meet the claim limitations. This does not, however, mean that a person of ordinary skill in the art would be unable to make the determination required by the claims. In fact, Dr. Huber was resolute that such a person would know from experience what kind of wire would be suitable for feeding "into the left ventricle in antegrade direction following direction of blood flow." (D.I. 113-1 at 24-25, 28-29, 46-47)

method step of "feeding" the claimed wire into the heart from the process by which the wire "conform[s]." (Tr. 15-16, 55-56) Whereas "feeding" refers to advancing the guidewire into the heart, "conforming" refers to the process by which the blood flowing through the heart moves the fed guidewire. (Tr. 27, 56)

At the claim construction hearing, the parties offered descriptions of the process by which the guidewire "conforms" to the flow of blood that were similar to one another. (Tr. 53-65) They agreed that a wire adapted to conform to the flow of blood will respond to the forces exerted by blood flow. (*Id.*) They also agreed that a wire so adapted need not be so responsive to the force of blood flow that, were the tip of the wire placed in the blood flow, the wire would then "sail through the aortic valve." (*Id.* 55, 63-64) Instead, the wire must merely be sufficiently responsive that, when placed in the blood flow, the wire bends to mirror its direction so that it ultimately traces the path of the blood flow through the heart. (*Id.* at 15-16, 55-56, 59-60)

"[W]hen the parties present a fundamental dispute regarding the scope of a claim term, it is the court's duty to resolve it." *O2 Micro Int'l Ltd. v. Beyond Innovation Tech. Co., Ltd.*, 521 F.3d 1351, 1362 (Fed. Cir. 2008). But "district courts are not (and should not be) required to construe every limitation present in a patent's asserted claims." *Id.* In light of the discussion about this claim term at the hearing, it appears that the parties have not actually articulated a fundamental disagreement about the scope of the disputed term. Rather, their dispute seems to be about the best choice of words for describing their shared understanding of claim scope. Although a court may sometimes need to construe claims in order "to clarify and when necessary to explain what the patentee covered by the claims . . . [claim construction] is not an obligatory exercise in redundancy." *U.S. Surgical Corp. v. Ethicon, Inc.*, 103 F.3d 1554, 1568 (Fed. Cir.

1997). Under the circumstances, the Court concludes that neither Endoheart nor Edwards has offered a construction that clarifies the scope or meaning of the disputed claim terms; adopting either proposed construction would not communicate to the factfinder what is essentially (in the Court's view) the agreed-upon understanding as to how a person of ordinary skill in the art would read the term in the context of the patent. Accordingly, the Court will not construe this term at this time. However, if the parties believe that construction of the term could add meaningful clarity to the language of the claims, they may (on a schedule set out in the attached Order) jointly propose a construction to the Court that is not inconsistent with their arguments at the claim construction hearing and the statements in this Opinion. (*See* Tr. 15-17, 24-27, 53-65)

2. "elongated wire configured"[3] / "elongated wire having a length along which the wire is configured"[4]

Endoheart "elongated wire configured": A long and thin guidewire having a property or structure for achieving something "elongated wire having a length along which the wire is configured": A long and thin guidewire having a length along which the guidewire has a property or structure for achieving something
Edwards "elongated wire configured": A guidewire having its entire length configured "elongated wire having a length along which the wire is configured": A guidewire having a portion of its length configured

[3]This term appears in claim 1 of the '530 patent.

[4]This term appears in claim 6 of the '530 patent.

Court
"elongated wire configured": A guidewire having a portion of its length configured "elongated wire having a length along which the wire is configured": A guidewire having a portion of its length configured

The parties' first dispute relates to the meaning of "elongated." The parties agree that the "elongated wire" of the claims is a "guidewire." Endoheart states that the claimed guidewire is a "long and thin guidewire." (D.I. 65 at 13) Edwards contends that ***all*** guidewires are long and thin, and argues that including "long and thin" in the construction of the claim term would wrongly imply that the claimed guidewire is long and thin ***for a guidewire***. (D.I. 82 at 5) Neither the specification nor the claims demonstrate that the claimed guidewires are ***particularly*** long and thin. Endoheart's proposed construction thus confuses rather than clarifies the claim term at issue, and the Court will not include the words "long and thin" in its construction.

The parties also disagree about whether the elongated wire of claim 1 differs from the elongated wire of claim 6. The guidewire of claim 1 is described as "configured" to conform to a direction of blood flow. The guidewire of claim 6 is also so configured – but only along "a length." Edwards argues that the doctrine of claim differentiation requires the Court to give meaning to this difference by construing the claims so that the guidewire of claim 1 is configured to conform along its entire length, whereas the guidewire of claim 6 is configured along only a portion of its length.

The doctrine of claim differentiation is "based on the common sense notion that different words or phrases used in separate claims are presumed to indicate that the claims have different meanings and scope." *Karlin Technology, Inc. v. Surgical Dynamics, Inc.*, 177 F.3d 968, 971-72 (Fed. Cir. 1999). Claim differentiation is generally only weak evidence of a term's proper

construction, except when the claims would be redundant but-for a differentiating construction. *Atlas IP, LLC v. Medtronic, Inc.*, 809 F.3d 599, 607 (Fed. Cir. 2015) (urging caution in "assessing the force of claim differentiation" where other differences among the claims would allow the court to "avoid[] a conclusion of superfluousness" even without assigning different constructions to the two terms).

Here, the claims have many differences besides those in the "configured" term. For this reason, Endoheart's claim differentiation argument does not override the plain and ordinary meaning of the claim terms, each of which requires only that at least a portion of the claimed guidewire be adapted to conform to the direction of blood flow. Therefore, the Court adopts Endoheart's proposal for the "length" term.

The Court understands the term "configured" as used in this claim term to have the same meaning as in the term "configured to conform to a direction of blood flow." As discussed above, the Court does not at this time believe construction of that term is necessary. If, however, the parties propose and the Court ultimately adopts a construction of the first term discussed above, the Court will apply that construction in the context of this second claim term as well.

3. "installing"[5]

Endoheart Putting into place
Edwards Anchoring in place
Court Putting into place such that further action is required to remove it

[5] This term appears in claims 1 and 6 of the '530 patent.

The parties disagree about whether "installing" an access device in the wall of the heart requires "anchoring" the device. Edwards notes that, when the patent uses the term "installing" in other contexts (e.g., the discussion of permanently placing a heart valve), the patent requires that the valve be "anchored," or implanted, and "not merely transiently placed." (D.I. 63 at 15) As the description of one preferred embodiment explains, an access device ***may*** also be "anchored." '530 patent col. 10:4-7. Because claim terms are normally used consistently throughout the patent, *Phillips*, 415 F.3d at 1314, Edwards argues that it is proper to presume that "anchoring" is required to "install" an access device.

The parties agreed at the claim construction hearing that "installing" refers to placing an access device in the body such that it remains stationary and stable throughout a transapical procedure. (Tr. 80-81, 92-93) The parties agreed that such a placement could be accomplished with or without the use of a second device (e.g., the balloons and hooks disclosed in preferred embodiments), and that the claims merely require that, however accomplished, the placement be stable enough that the access device will not slip out unless a treatment provider deliberately attempts to remove it. (Tr. 86-87, 91-93) The Court, therefore, adopts Edwards' proposed "putting into place" construction, with the added limitation that the access device remain stable such that "further action is required to remove it."

4. **"access device having means for preventing bleeding through the access device"**[6]

Endoheart Access device: a device that provides an access port The term "means for preventing bleeding through the device" is a means-plus-function term subject to 35 U.S.C. §112 ¶6. Function: preventing bleeding through the access device Means: (1) may be mechanically operable as an iris diaphragm (like the aperture of a lens), (2) may be constructed of an elastic material with a small central opening that is dilated by whatever equipment is inserted therethrough, but always maintains a fluid-tight seal with the inserted equipment, (3) may compose any fluid-tight valve structure, or (4) may be equivalent to any of those disclosed structure
Edwards Access device: catheter The term "means for preventing bleeding through the device" is a means-plus-function term subject to 35 U.S.C. §112 ¶6. Function: preventing bleeding through the access device Means: catheter that includes a valve that is mechanically operable as an iris diaphragm or constructed of an elastic material with a small central opening that is dilated by equipment inserted therethrough and always maintains a fluid-tight seal with the inserted equipment
Court Access device: a device that provides an access port The term "means for preventing bleeding through the device" is a means-plus-function term subject to 35 U.S.C. §112 ¶6. Function: preventing bleeding through the access device Means: a valve that is mechanically operable as an iris diaphragm or constructed of an elastic material with a small central opening that is dilated by equipment inserted therethrough and always maintains a fluid-tight seal with the inserted equipment

[6] This term appears in claims 1 and 6 of the '530 patent.

The parties' first dispute with respect to this term relates to the proper construction of "access device." Endoheart argues that an access device is simply a "device that provides an access port;" Edwards contends that an access device must be a catheter. However, Edwards does not identify intrinsic evidence that supports its proposed limitation. The '530 patent simply describes an access device as a device that "provide[s] an access port to the surgical site." '530 patent col. 9:55-57. The specification explains that this device "may" be a catheter, but neither explicitly states nor implicitly requires that it be one. '530 patent col. 10:1. Because this record is consistent with Endoheart's construction, the Court construes "access device" as "a device that provides an access port."

The parties agree that the remainder of this term is written in means-plus-function form. They further agree that the function disclosed is "preventing bleeding through the access device," but disagree about the proper construction of the "means" term. Section 112 ¶ 6 provides that a patentee may express an element of a claimed invention "as a means or step for performing a specified function without . . . recitin[g] the structure, material, or acts" for performing that function. "In exchange for the ability to use a generic means expression for a claim limitation, the [patentee] must indicate in the specification what structure constitutes the means." *Ergo Licensing, LLC v. CareFusion 303, Inc.*, 673 F.3d 1361, 1363 (Fed. Cir. 2012) (internal quotation marks omitted). A means term is construed to include only the means for performing the claimed function that are disclosed in the specification, and "equivalents thereof." 35 U.S.C. 112 ¶ 6.

A means-plus-function claim should be construed to "embrace [all] distinct and alternative described structures for performing the claimed function." *Creo Prods., Inc. v.*

Presstek, Inc., 305 F.3d 1337, 1346 (Fed. Cir. 2002). Each disclosed structure must be described in sufficient detail that a person of ordinary skill in the art would be able to identify the claimed class of structures. *See Linear Tech. Corp. v. Impala Linear Corp.*, 379 F.3d 1311, 1322 (Fed. Cir. 2004).

As examples of such structures, the patent lists: a valve that is "mechanically operable as an iris diaphragm (e.g., like the aperture of a lens)," a valve "constructed of an elastic material with a small central opening that is dilated by whatever equipment is inserted therethrough, but always maintains a fluid-tight seal with the inserted equipment," and "any fluid-tight valve structure." '530 patent col. at 10:10-15. Edwards argues that the Court's construction should be limited to the first two of these disclosures because the term "any fluid-tight valve structure" does not identify sufficient structure. The Court agrees that this general disclosure – in contrast to the other two examples provided – essentially just restates the function of preventing bleeding, without specifying a class of structures that would be recognizable to one of ordinary skill in the art. Thus, the Court limits its construction of the means to the two examples disclosed, and will instruct the jury that the scope of the patentee's claims includes equivalents thereof.

5. "the feeding directed by the blood flow"[7]

Endoheart The supplying of the guidewire is guided by the blood flow
Edwards The flow of blood controlling the advancement of the guidewire
Court the wire fed into the heart conforming to the direction of blood flow

[7] This term appears in claim 6 of the '530 patent.

As the Court explained above, the claims distinguish the feeding of a guidewire into the heart from the process by which the guidewire conforms to the flow of blood. *See* '530 pat. col. 22:22-28. The Court understands the present term as describing how feeding and conforming occur in the context of the claimed method: a guidewire is fed into the heart, and the fed wire conforms to the direction of blood flow, following the path of the flow. In this way, the blood flow "directs" the wire through the heart.

The Court is unpersuaded by Edwards' argument that the principle of claim differentiation requires a departure from this plain and ordinary meaning. Edwards suggests that, because claims 1 and 6 use different language to describe how feeding and conforming relate to each other, *see* '530 pat. col. 21:62-65 ("the feeding continuing such that the wire follows the blood flow"), the Court should "give meaning to" the difference. But Edwards has not clearly articulated what the difference is, nor why its proposed construction accurately captures the difference. Instead, Edwards' chosen construction is based primarily on the word choice in a single sentence composed by an Endoheart attorney during this litigation – a statement Endoheart's counsel later amended. (D.I. 83 at 76; D.I. 82 at 17 n.14) Edwards has not explained why extrinsic evidence of how the patentee's litigation counsel characterized the claims, many years after the patent application was filed, is probative of how a person of ordinary skill in the art would have understood the claims at the time of the invention. Thus, having no persuasive reason for doing so, the Court will not read Edwards' proposed limitation into the claim.

III. CONCLUSION

An Order follows.