IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AORTIC INNOVATIONS LLC, Plaintiff, v. EDWARDS LIFESCIENCES CORPORATION, EDWARDS LIFESCIENCES LLC, and EDWARDS LIFESCIENCES (U.S.) INC., Defendants.	))))))))))))	Case No. 1:21-cv-01377-JPM

CLAIM CONSTRUCTION ORDER

This case is before the Court for claim construction pursuant to Markman v. Westview Instruments, Inc., 52 F.3d 967, 979 (Fed. Cir. 1995), aff'd, 517 U.S. 370 (1996). A Markman hearing was held on January 25, 2023. (ECF No. 113.) Present were John Campbell, Jr., Casey Shomaker, and Geoffrey Smith, counsel for Plaintiff, and Christy Lea, Brian Barnes, Brian Horne, John Sganga, Brian Egan, Anthony David Raucci, Craig Summers, Joshua Stowell, and Matthew Lubozynski, counsel for Defendants. (Id.)

I. BACKGROUND

This is a civil action for patent infringement of one or more of the claims of U.S. Patent No. 11,127,735 ("the '735 Patent"), U.S. Patent No. 10,881,538 ("the '538 Patent"), U.S. Patent No. 10,966,846 ("the '846 Patent"), and U.S. Patent No. 10,987,236 ("the '236 Patent"). (ECF No. 1.) The portion of this action relating to the '538 Patent, the '846 Patent, and the '236 Patent has been stayed pending Inter Partes Review. (ECF No. 78.)

Edwards v. Aortic Innovations
U.S. Patent 11,337,834
Edwards Ex. 1140

A. Factual Background

Plaintiff Aortic Innovations LLC ("Aortic") is a Florida corporation, with its principal place of business in Hillsboro Beach, Florida. (ECF No. 1 ¶ 7.)

Defendant Edwards Lifesciences Corporation is a Delaware corporation, with its principal place of business in Irvine, California. (Id. ¶ 8.) Defendant Edwards Lifesciences LLC is a Delaware limited liability company, with its principal place of business in Irvine, California. (Id. ¶ 9.) Defendant Edwards Lifesciences (U.S.) Inc. is a Delaware corporation, with its principal place of business in Irvine, California. (Id. ¶ 10.)

Transcatheter aortic valve replacement ("TAVR") is a procedure in which a replacement aortic heart valve can be installed in a patient's heart by passing the replacement valve through a catheter. (Id. ¶ 3.) This process avoids the need for patients to undergo open heart surgery for a valve replacement, which carries higher risks of complications. (Id.) Open heart surgery may not be suitable for certain high-risk patients, but these same patients may instead be able to obtain a heart valve replacement through TAVR. (Id.) The catheter is inserted either through an artery of a patient or through a small incision made directly in the heart. (Id.; ECF No. 113 at PageID 6620–21.)

Aortic was founded in 2011 to "develop the ideas of Dr. Ali Shahriari to help patients with damaged aortic valves." (ECF No. 1 ¶ 2.) Dr. Shahriari is a cardiothoracic surgeon, and holds patents, including the patents at issue in this case, related to TAVR technology. (Id. ¶¶ 3–4.) Defendants Edwards Lifesciences Corporation, Edwards Lifesciences LLC, and Edwards Lifesciences (U.S.) Inc. (collectively "Defendants") manufacture and sell transcatheter heart valves, including the SAPIEN 3 Ultra, which Aortic accuses of infringement. (Id. ¶ 5.)

B. Procedural Background

Aortic filed its Claim Construction Opening Brief and associated Appendix and Declaration on November 21, 2022. (ECF Nos. 83–85.) Defendants filed their Claim Construction Answering Brief and associated Declaration on December 14, 2022. (ECF No. 96–97.)

Defendants filed their Claim Construction Opening Brief and associated Declaration on November 21, 2022. (ECF Nos. 81–82.) Plaintiff filed its Claim Construction Answering Brief and associated Declaration and Appendix on December 14, 2022. (ECF No. 93–95.)

The Parties filed a Joint Claim Construction and Prehearing Statement on December 21, 2022. (ECF No. 101.) The Court held a Claims Construction Hearing on January 25, 2023. (ECF No. 113.) Defendants filed a Supplemental Claim Construction Brief on February 1, 2023. (ECF No. 116.)

C. The Patents-in-Suit

The '735 Patent describes a heart valve replacement device for endovascular repair. (ECF No. 1-1 at PageID 159 (the '735 Patent).) The heart valve replacement device includes "a plurality of fibers" to create a seal between the device and the patient's tissue. (The '735 Patent, Abstract.) The '735 Patent has one independent claim, describing an endovascular transcatheter valve assembly with a number of portions including an outer frame, an inner frame, and an outer seal formed of outwardly extending fibers. (The '735 Patent, cl. 1.) The outer frame is formed from a metallic material and is formed by a plurality of struts. (Id.) The inner frame engages a prosthetic heart valve having prosthetic leaflets. (Id.)

The '735 Patent teaches two basic embodiments. (See ECF No. 81 at PageID 3732–36.) Each embodiment contains two frames, with one being generally referred to as the "outer frame" or "self-expanding frame" and the other one being generally referred to as the "inner frame" or

"balloon-expandable frame." In one embodiment, the balloon-expandable/inner frame rests within the self-expanding/outer frame. (Id.; the '735 Patent, Figs. 20–21.) In a second embodiment, the balloon-expandable/inner frame is attached to the end of the self-expanding/outer frame. (ECF No. 81 at PageID 3735–36; the '735 Patent, figs. 17–19.) Combining these two types of devices improves over the prior art because the self-expanding frame "significantly improves the accuracy and control of the deployment of the device" and stabilizes the device to permit accurate expansion of the balloon-expandable frame. (ECF No. 81 at PageID 3732; the '735 Patent, col. 15 ln. 8–11, col. 11 ln. 24–36, col. 14 ln. 46–56, col. 17 ln. 21–25, col. 19 ln. 25–35.)

Plaintiff additionally alleges infringement of the '538 Patent, the '846 Patent, and the '236 Patent. (See ECF No. 1.) However, the portion of this action relating to these three patents has been stayed pending Inter Partes Review, and these patents do not form the basis of any claim construction disputes at this time. (ECF Nos. 78, 101.)

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) (quoting Innova/Pure Water, Inc. v. Safari Water Filtration Systems, Inc., 381 F.3d 1111, 1115 (Fed. Cir. 2004)). Courts, as a matter of law, must construe the claims of a patent in order to ascertain precisely what it is that is patented. See id.; see also Markman v. Westview Instruments, Inc., 517 U.S. 370, 387 (1996).

In engaging in that exercise, the words in the claims are "generally given their ordinary and customary meaning," that 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." Phillips, 415 F.3d at 1312–13 (internal citations and quotation marks omitted). "There are only two exceptions to this general rule: 1)

when a patentee sets out a definition and acts as his own lexicographer, or 2) when the patentee disavows the full scope of a claim term either in the specification or during prosecution." Thorner v. Sony Comput. Ent. America LLC, 669 F.3d 1362, 1365 (Fed. Cir. 2012) (citing Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1580 (Fed. Cir. 1996)). This ordinary and customary meaning "may be readily apparent even to lay judges," and where that is the case, claim construction involves "little more than the application of the widely accepted meaning of commonly understood words." Id. at 1314 (citing Brown v. 3M, 265 F.3d 1349, 1352 (Fed. Cir. 2001)).

However, as the ordinary and customary meaning is often not immediately apparent, courts must look to other sources of evidence—"the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art." Id. (citing Innova, 381 F.3d at 1116). In Phillips, the United States Court of Appeals for the Federal Circuit provided guidance on the relative weight given to evidence from these various sources. Id.

First, "the claims themselves provide substantial guidance as to the meaning of particular claim terms," particularly the "context in which a term is used in the asserted claim." Id. at 1314. But because claims are also part of a "fully integrated written instrument," they must "be read in view of the specification, of which they are a part." Markman, 52 F.3d at 978, 979 (citations omitted). As the Federal Circuit has stressed, "[a] patent's specification provides necessary context for understanding the claims, and is always highly relevant to the claim construction analysis." Abbott Labs. v. Sandoz, Inc., 566 F.3d 1282, 1288 (Fed. Cir. 2009) (en banc in part) (quoting Phillips, 415 F.3d at 1315). Further, "sometimes the specification offers practically incontrovertible directions about claim meaning," as when inventors "act as their own

lexicographers and give a specialized definition of claim terms," or "intentionally disclaim, or disavow, subject matter that would otherwise fall within the scope of the claim." Id. (internal citations and quotation marks omitted). But the Court must take care neither "to import limitations into the claims from the specification," nor to allow "the claims to enlarge what is patented beyond what the inventor has described as the invention." Id. at 1288 (internal citations and quotation marks omitted). In addition, "a particular embodiment appearing in the written description may not be read into a claim when the claim language is broader than the embodiment." Resonate Inc. v. Alteon Websystems, Inc., 338 F.3d 1360, 1364–65 (Fed. Cir. 2003).

The prosecution history of the patent is the other type of "intrinsic evidence," along with the specification, courts consider when determining the meaning of disputed terms. Phillips, 415 F.3d at 1317.

Finally, courts may consider extrinsic evidence—that is, "all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." Id. (quoting Markman, 52 F.3d at 980). Such evidence, however, is "less significant than the intrinsic record in determining the legally operative meaning of claim language." Phillips, 415 F.3d at 1317 (internal quotations and citations omitted).

In engaging in a Markman analysis, a court is not required to "repeat or restate every claim term in order to comply with the ruling that claim construction is for the court." U.S. Surgical Corp. v. Ethicon, Inc., 103 F.3d 1554, 1568 (Fed. Cir. 1997). Rather, "[c]laim construction is a matter of resolution of disputed meanings and technical scope, to clarify and when necessary to explain what the patentee covered by the claims, for use in the determination of infringement." Id.

III. CLAIM CONSTRUCTION

A. Agreed-Upon Terms

There are no terms on which the Parties agree.

B. Overview of Disputed Claim Terms

Claim Term No.	Term	Aortic's Proposed Construction	Defendants' Proposed Construction
1	frame	plain and ordinary meaning	a support structure having the strength to retain its expanded configuration and resist collapse
2	outer frame	plain and ordinary meaning	a self-expanding frame having a generally hourglass shape that is positioned outside the inner frame
3	inner frame	plain and ordinary meaning	a balloon-expandable frame that is positioned within the outer frame
4	fibers	plain and ordinary meaning	discrete bundles of collagen threads or filaments
5	outer seal	plain and ordinary meaning	an outer covering through which the outer frame is clearly visible
6	outwardly extending fibers	plain and ordinary meaning	the tips of the fibers extend in a generally outward direction from the frame
7	[preamble of the '735 claim 1]	the preamble is a limitation on the claim	the preamble of claim 1 is not limiting

1. frame

Claim Term No.	Term	Aortic's Proposed Construction	Defendants' Proposed Construction	Court's Construction
1	frame	plain and ordinary meaning	a support structure having the strength to retain its expanded configuration and resist collapse	plain and ordinary meaning

The Parties dispute the term “frame” as it appears in claims 1, 2, 3, 5, and 7 of the ‘735 patent.

Aortic argues that frame should be given its plain and ordinary meaning. (ECF No. 83 at PageID 4271.) Aortic argues that the specification describes an outer frame that is secured to an inner frame, and that it would be duplicative to require that both the outer and inner frame be independently required to provide the same level of structural support. (Id. at PageID 4272.) Aortic argues that the inventor's notes show that the intent was to have the outer frame function as a stent while the inner frame functions to support the heart valve and leaflets. (Id. at PageID 4272–74.) Aortic argues that the prosecution history conflicts with Defendants' proposed construction because the claim was initially rejected by the examiner based on prior art that described the inner frame as being made of animal tissue, synthetic, or polymeric material. (Id. at PageID 4274.) Aortic further argues that the plain and ordinary meaning is supported by the extrinsic record and cites to dictionary definitions defining "frame" as both "a structure that gives shape or support" and "an open structure or rim for encasing, holding, or bordering." (Id. at PageID 4275.) Aortic argues that Defendants' proposed definition would improperly exclude frames that "do not provide sufficient strength to resist collapse even though they are frames that surround, house, enclose, or border another component or are attached to another support." (Id.)

Defendants argue that the frames, as described in the patent, "must remain in their expanded states to form an interference fit to anchor the device in place, to properly deploy the prosthetic valve, and to form a seal." (ECF No. 81 at PageID 3739.) Defendants argue that the frames "can only do so if they have the strength to retain their expanded configurations and resist collapse." (Id.) Defendants argue that a POSITA would have understood this strength to be necessary for the frame to function, and that every frame described in the '735 Patent is formed from a metallic or polymeric material and functions as a stent. (Id. at PageID 3740.) Defendants argue that U.S. Patent No. 5,102,417 ("Palmaz"), which is incorporated into the '735 Patent by

reference, specifies that expandable "tubular members" must have the strength to retain their "expanded and deformed configuration with the enlarged diameter . . . and resist radial collapse." (Id. at PageID 3741.) Defendants argue that their proposed construction is consistent with the extrinsic evidence as well. (Id. at PageID 3742.) Defendants argue that at the time of the '735 Patent's priority date, the two clinically available TAVRs had rigid metallic "frames" and that this was consistent with the "well-understood meaning of frame in engineering disciplines as a structure that does not rely on an external support to maintain its shape." (Id. at PageID 3741–42.) Defendants further argue that Aortic's assertion that the inner frame may be connected to and supported by the outer frame is incorrect, because the inner frame does not expand with the outer frame and must be separately expanded by a balloon. (Id. at PageID 3743.) Defendants argue that the Patent Examiner's definition is not relevant because the claim construction standard is different during prosecution and litigation, and that an Examiner's rejection cannot serve to broaden the claims beyond their ordinary meaning in view of the specification. (Id. at PageID 3744.) Defendants also argue that the ability to resist collapse does not "require a frame to be so strong that it is impervious to all outside forces." (Id.)

In Response, Aortic argues that the '735 Patent describes embodiments where the inner and outer frame are secured to one another. (ECF No. 93 at PageID 5196.) Aortic argues that "[f]or embodiments where the inner and outer frames are stitched or fastened to one another, both 'frames' need not independently provide the same level of structural support for the valve." (Id.) Aortic also argues that a second patent, U.S. Patent No. 6,582,462 was also incorporated by reference into the '735 Patent and expressly describes stents "made from a radially collapsible and re-expandable cylindrical support means for folding and expanding together with the collapsible valve" and teaches that "contractions may occur (<10% diameter reduction) after deflation and

removal of the balloon catheter." (Id. at PageID 5198.) Aortic also argues that the extrinsic evidence supports its interpretation, and that at least one device on the market has a "tubular fabric frame" that is referred to as a "frame" even before it is filled with polymer so that it becomes rigid. (Id. at PageID 5200–01.) Aortic further argues that the mechanical engineering textbook that Defendants cite describes "nonrigid frames" that do not independently provide their own support. (Id. at PageID 5201.)

In Response, Defendants argue that there is a presumption that terms should be given the same meanings in different portions of the claims and that there is nothing in the specification or claims to rebut the presumption that a frame is consistently a rigid support structure. (ECF No. 96 at PageID 5511–12.) Defendants argue that the specification teaches that the inner frame and outer frame form an interference fit with one another, and that this would be impossible if the inner frame were unable to resist collapse. (Id. at PageID 5512–14.)

While Defendants are correct that some of the embodiments require both the inner and outer frames to be rigid support structures that can retain their expanded configuration and resist collapse, reading this limitation into the claim term would be improper. Throughout the specification, the outer frame is repeatedly described as having these characteristics. (See generally the '735 Patent.) Claim 1 expressly requires that the outer frame be made of a metallic material, which would naturally result in a rigid outer frame. (Id., cl. 1.) However, this is not true for the inner frame in every embodiment. (See id.) One embodiment described in the '735 Patent shows the inner frame located within the outer frame. (Id., figs. 20–21.) In this embodiment, the outer frame could be the only frame that needs to be capable of retaining its expanded configuration and resisting collapse. The inner frame is attached and secured to the outer frame, and therefore

the device could function properly even if the inner frame was incapable of resisting collapse on its own.

Defendants argue that the '735 Patent shows that there is a gap between the inner and outer frame in this embodiment before the inner frame is expanded, which must mean that the inner frame is capable of supporting itself in order to provide an interference fit between the frames. (ECF No. 81 at PageID 3739; the '735 Patent, figs. 13–14.) However, the '735 Patent specification does not appear to require that the inner and outer frames be secured by an interference fit, and in fact contemplates other attachment methods such as stitching, soldering, or welding. (the '735 Patent, col. 14 ln. 8 – col. 15 ln. 17.) References to interference fits throughout the '735 Patent generally refer to interference fits between the outer frame and the aortic annulus, and not to interference fits between the inner frame and outer frame. (See, e.g., id. col. 14 ln. 53–56.) The claims also do not have any explicit requirement that either the inner frame or the outer frame be capable of resisting collapse or retaining their expanded configurations. (Id., cls. 1–12.)

There is no reason to deviate from the presumption that claim terms be given their plain and ordinary meaning, and therefore the term "frame" is construed as having its plain and ordinary meaning.

2. outer frame

Claim Term No.	Term	Aortic's Proposed Construction	Defendants' Proposed Construction	Court's Construction
2	outer frame	plain and ordinary meaning	a self-expanding frame having a generally hourglass shape that is positioned outside the inner frame	a self-expanding frame

The Parties dispute the term "outer frame" as it appears in claims 1, 2, 3, 5, and 7 of the '735 Patent.

Aortic argues that the Defendants' proposed construction initially reflects the plain and ordinary meaning of the term, but then departs from this meaning by reading in the limitations that the outer frame be self-expanding and generally hourglass shaped. (ECF No. 83 at PageID 4277–78.) Aortic argues that the '735 Patent's specification explicitly indicates that the outer frame may be balloon expandable. (Id. at PageID 4278.) Aortic also argues that the specification contemplates the outer frame having shapes other than hourglasses, such as prisms, cones, or other geometric shapes. (Id. at PageID 4279.) Aortic further argues that Defendants did not make the argument that the outer frame must have an hourglass shape during IPR proceedings, and that they identified prior art that included outer frames that were not self-expanding or hourglass-shaped. (Id.)

Defendants argue that the patent uniformly describes the outer frame as being self-expanding, and that the term should therefore be construed to include that feature. (ECF No. 81 at PageID 3745.) Defendants argue that the terms "outer frame" and "self-expanding frame" are used interchangeably in the patent, and that such "interchangeable use of the two terms is akin to a definition equating the two." (Id. at PageID 3745–46 (citing Edwards Lifesciences LLC v. Cook Inc., 582 F.3d 1322, 1329 (Fed. Cir. 2009)).) Defendants argue that the portion of the specification describing a balloon-expandable frame that engages with the aortic annulus does not refer to the outer frame, but rather refers to the embodiment shown in figures 2–7 and 17–19, where the self-expanding frame terminates where the balloon-expandible frame begins. (Id. at PageID 3746.) Defendants argue that the outer frame is described as having a "generally hourglass shape," that this shape is critical in order for the device to function properly, and that every embodiment described in the patent shares a similar hourglass shape to avoid obstructing the coronary arteries. (Id. at PageID 3747.)

In Response, Aortic argues that it is "it is improper to read limitations from a preferred embodiment described in the specification—even if it is the only embodiment—into the claims absent a clear indication in the intrinsic record that the patentee intended the claims to be so limited." (ECF No. 93 at PageID 5204–05 (citing Liebel-Flarsheim Co. v. Medrad, Inc., 358 F.3d 898, 911 (Fed. Cir. 2004)).) Aortic argues that the specification references the interchangeability of self-expanding and balloon expandable stents as outer frames, and that the case law does not require "self-expanding" to be read into the "outer frame" claim term. (Id. at PageID 5205.) Aortic also argues that the patent does not treat an hourglass shape as "critical" or "essential" and reiterates that the specification contemplates that the outer frame may have other shapes. (Id. at PageID 5207.)

In Response, Defendants reiterate many of their earlier arguments. Defendants also argue that the specification never describes the outer frame as being balloon-expandable, and that the intrinsic evidence overwhelmingly supports that the outer frame must be self-expanding. (ECF No. 96 at PageID 5519.) Defendants also argue that the inventor's drawings show outer frames that are repeatedly labeled as a "self-expanding frame." (Id. at PageID 5520.) Defendants argue that the portion of the frame that is described as potentially being shaped as a prism, cone, or other geometric shape is only part of the complete outer frame, and that even when the outer frame is shaped in a different geometric shape, it will still have a generally hourglass shape. (Id. at PageID 5520–22.)

i. Disavowal of Claim Scope

A disavowal of claim term scope "does not require express statements by the patentee identifying the surrendered claim scope. Rather, it may be implicit, so long as it is sufficiently clear." Rembrandt Patent Innovations, LLC v. Apple, Inc., 716 F. App'x 965, 972 (Fed. Cir. 2017).

"Where the specification makes clear that the invention does not include a particular feature, that feature is deemed to be outside the reach of the claims of the patent, even though the language of the claims, read without reference to the specification, might be considered broad enough to encompass the feature in question." SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc., 242 F.3d 1337, 1341 (Fed. Cir. 2001). However, the standard for disavowal is "exacting," and "[t]o constitute disclaimer, there must be a clear and unmistakable disclaimer. Thorner, 669 F.3d at 1366–67.

Factors that collectively may demonstrate an implicit disavowal may include the specification disparaging certain embodiments or features, statements that the invention itself is in a configuration that excludes certain features, and a statement in the specification that all embodiments of the present invention do not include the feature or features at issue. Thorner, 669 F.3d at 1366 (discussing SciMed, 669 F.3d 1337). However, the existence of any of these factors standing alone is generally insufficient to constitute a disavowal. Id. "Mere criticism of a particular embodiment encompassed in the plain meaning of a claim term is not sufficient to rise to the level of clear disavowal." Id. at 1366. "It is likewise not enough that the only embodiments, or all of the embodiments, contain a particular limitation." Id.

The '735 Patent consistently describes the outer frame as being self-expanding throughout the specifications. (See the '735 Patent.) The two described embodiments describe the outer frame as being self-expanding, and the specification repeatedly refers to the outer frame as being self-expanding. (See id.) While Aortic argues that the specification states that the outer frame may be balloon-expandable, the section they cite to actually describes the inner frame and not the outer frame. (Id., col. 5 ln. 48–63; ECF No. 83 at PageID 4278.)

However, at no point in the specification does the inventor disparage the use of a balloon-expandable outer frame, state that the invention itself relies on a self-expanding outer frame, or state that all embodiments have a self-expanding outer frame. (See the '735 Patent.) While the only two described embodiments have self-expanding frames, this factor alone is not sufficient to demonstrate a clear disavowal of an outer frame that could be expanded using different means. Thorner, 669 F.3d at 1366 ("It is likewise not enough that the only embodiments, or all of the embodiments, contain a particular limitation.").

While the inventor does describe the outer frame as being self-expanding throughout the specification, these descriptions do not rise to the level required to constitute a clear disavowal of outer frames that are not self-expanding.

ii. Inventor Acting as Lexicographer

"Absent a clear disavowal or contrary definition in the specification or the prosecution history, the patentee is entitled to the full scope of its claim language." Home Diagnostics, Inc. v. LifeScan, Inc., 381 F.3d 1352, 1358 (Fed. Cir. 2004.)

> To act as its own lexicographer, a patentee must "clearly set forth a definition of the disputed claim term" other than its plain and ordinary meaning. CCS Fitness, Inc. v. Brunswick Corp., 288 F.3d 1359, 1366 (Fed.Cir.2002). It is not enough for a patentee to simply disclose a single embodiment or use a word in the same manner in all embodiments, the patentee must "clearly express an intent" to redefine the term.

Thorner, 669 F.3d at 1365.

If a specification consistently uses two terms interchangeably, this may also serve as "a definition equating the two." Edwards, 582 F.3d at 1329 (holding that the consistent interchangeable use of the terms "graft" and "intraluminal graft" justified a construction that all claimed graft devices must be intraluminal.); see also Tate Access Floors, Inc. v. Maxcess Technologies, Inc., 222 F.3d 958, 968 (Fed. Cir. 2000) ("it is readily apparent that the terms 'body

portion' and 'layer' are used interchangeably in the specification, and therefore should be construed in the same manner"). When a patentee uses certain terms interchangeably throughout the written description and prosecution history, one of ordinary skill in the art would understand that these are the same items. Bell Atl. Network Servs., 262 F.3d 1258, 1275 (Fed. Cir. 2001) ("The . . . patent uses the terms 'transceiver,' 'ADSL/AVR,' and 'ADSL/AVR transceiver' interchangeably throughout the written description and the prosecution history. Therefore, one of ordinary skill in the art would understand that the transceiver described in claim 1 is the same transceiver described in claim 21.").

Throughout the patent, the inventor uses the terms "outer frame," "self-expanding frame," and "self-expanding outer frame" interchangeably to refer to the same structure.[1] The below excerpt from the specification describing one embodiment is illustrative of this interchangeable use:

> The dual-frame **214** of the proximal component **212** includes a self-expanding outer frame **216** and a balloon-expandable inner frame **218** that is secured to the self-expanding outer frame **216** and houses the valve **32**. Referring now to FIG. 9, the self-expanding outer frame **216** has a generally hourglass shape and is formed from a metallic material, such as, nitinol, stainless steel, or other implant grade metallic material. It should be appreciated that in other embodiments the outer frame **216** may be formed from a polymeric material. The outer frame **216** includes an elongated proximal section **220**, an inwardly tapered section **222**, an outwardly tapered middle section **62**, and an elongated distal section **64**.
>
> . . .
>
> The outwardly tapered middle section **62** of the self- expanding frame **216** has the proximal end **68** and a distal end **72** connected to the proximal end **74** of the elongated distal section **64**.

[1] The specification also uses the term "frame" alone to refer to this same structure on occasion. (See e.g., the '735 Patent col. 12 ln. 36.)

(The '735 Patent, col. 12 ln. 11–23, 64–67 (emphasis added).) In this description, item number **216** is referred to interchangeably as an "outer frame," "self-expanding frame," and "self-expanding outer frame" and each of these terms refer to the same component, as illustrated by the reference to the same numbered component. (Id.) The interchangeable use of these terms in the above-quoted citation is not an isolated instance, and these terms are consistently used interchangeably throughout the specification to refer to the same structure. (Id. col. 12 ln. 11 – col. 14 ln. 66.) The patent specification similarly interchanges the terms "outer frame," "self-expanding frame," and "self-expanding outer frame" when referring to another similar structure, item number **416**, in the second described embodiment. (See e.g., id. col. 17 ln. 58 – col. 19 ln. 42.)

Given this consistent interchangeable use of these terms, one of ordinary skill in the art would have understood that these are the same items, and that they should be given the same constructions. Because of this, the specification requires the outer frame to be a self-expanding frame.

iii. "Having a Generally Hourglass Shape"

The inventor's reference to outer frames with a generally hourglass shape does not rise to the level required to function as a clear disavowal of outer frames that do not have an hourglass shape. Both described embodiments show and describe an outer frame with a generally hourglass shape, but this alone is insufficient to serve as a clear disavowal. Thorner, 669 F.3d at 1366. The specification notes that in "some embodiments, the self-expanding frame may have an hourglass shape," but it does not describe the outer frame as having an hourglass shape consistently when referring to the frame. (The '735 Patent, col. 3 ln 4–5 (emphasis added).) This wording implies that an hourglass shape is one possible shape that the frame may have, but that it is not the only

possible option, and some embodiments might not have such a shape. Additionally, there is no interchangeability of the terms, and the frame is not described as always having an hourglass shape. (See id.) These statements do not rise to the level of a clear disavowal, and there is likewise no evidence that the inventor sought to act as his own lexicographer as it relates to the hourglass shape.

iv. "Positioned Outside the Inner Frame"

The Parties do not address the portions of Defendants' proposed construction relating to "positioned outside the inner frame," but it appears that Aortic agrees that this reflects the plain and ordinary meaning. (ECF No. 83 at PageID 4277.) However, this construction would exclude the embodiment shown in Figures 17–19, where one end of the balloon-expandable frame is connected to an end of the self-expanding frame and neither frame is located inside or outside of the other. The relevant portion describing Figure 17 and describing this connection is:

> The balloon-expandable frame **34** is attached to a self-expanding frame **350**. In the illustrative embodiment, the distal end **52** of the balloon-expandable frame **34** is secured to the proximal end **54** of the frame **350** by stitching or sewing the frames **34**, **350** together, thereby forming the frame **26** of the transcatheter valve component **312**. It should be appreciated that in other embodiments the frames **34**, **350** may be secured together via welding or other fasteners. The frames **34**, **350** may also be formed as a single, monolithic frame.

(the '735 Patent, col. 16 ln. 5–14.) This wording describes an embodiment where the two frames are connected linearly, not coaxially, and neither frame is inside or outside of the other. (Id.) This is further illustrated in the relevant figure accompanying this description. (Id. fig. 17.) Despite being frequently referred to as an "outer frame" throughout the specification and claims, this frame is only an "outer" frame in one of the two preferred embodiments.

Based on this description of a preferred embodiment, requiring the "outer" frame to be located outside the "inner" frame would exclude a preferred embodiment from the scope of the

claims. Because construction of a claim term such that a preferred embodiment in the specification would not fall within the scope of the patent claim is "rarely, if ever, correct," it would be improper to read such a limitation into the claim term. Vitronics, 90 F.3d at 1583.

3. inner frame

Claim Term No.	Term	Aortic's Proposed Construction	Defendants' Proposed Construction	Court's Construction
3	inner frame	plain and ordinary meaning	a balloon-expandable frame that is positioned within the outer frame	a balloon-expandable frame

The Parties dispute the term "inner frame" as it appears in claims 1 and 5 of the '735 Patent.

Aortic's arguments for their proposed construction of inner frame are similar to the arguments that it made for its proposed construction of outer frame. (Compare ECF No. 83 at PageID 4277–80 with ECF No. 83 at PageID 4280–81.) Aortic argues that while the '735 Patent describes the inner frame as balloon-expandable nothing in the claims, specifications, or file history limit the inner frame to only balloon-expandable frames. (Id. at PageID 4280.) Aortic argues that it would be improper to import such a claim limitation from the preferred embodiment. (Id.)

Similarly, Defendants raise many of the same arguments for "inner frame" as they did for "outer frame." (Compare ECF No. 81 at PageID 3745–47 with ECF No. 81 at PageID 3747–48.) Defendants argue that the "patent uniformly describes the 'inner frame' as a balloon-expandable frame positioned within the 'outer frame.'" (Id. at PageID 3747.) Defendants argue that "inner frame" and "balloon-expandable frame" are used interchangeably, and that this interchangeability

is akin to a definition equating the two. (Id. at PageID 3747–48 (citing Edwards Lifesciences, 582 F.3d at 1329).)

In Response, Aortic argues that balloon-expandability is not a "critical" feature of the inner frame. (ECF No. 93 at PageID 5207.) Aortic also argues that the specification states "for 'some embodiments' that the 'balloon-expandable frame may be an inner frame,'" showing that the inner frame is not limited and may include frames other than balloon-expandable ones. (Id.) Aortic also argues that balloon-expansion of the inner frame is not a critical feature, since the device could still function if the inner frame was self-expanding, or not require separate expansion at all. (Id.)

In Response, Defendants argue that Aortic does not dispute the assertion that the '735 Patent refers to the inner frame as being balloon-expandable, or that the specification uses the terms "inner frame" and "balloon-expandable frame" interchangeably. (ECF No. 96 at PageID 5522.) Defendants argue that no invention broader than one using a balloon-expandable inner frame is described in the patent. (Id. at PageID 5522–23.)

i. Disavowal of Claim Scope

For similar reasons as those in the "outer frame" term, the specification does not support a clear disavowal of inner frames that are not balloon-expandable. While the '735 Patent frequently refers to the inner frame as being balloon-expandable, there are no factors present that would support a clear disavowal other than each preferred embodiment being balloon-expandable. (See generally the '735 Patent; Thorner, 669 F.3d at 1366 (discussing factors to consider for disavowal).) Each embodiment containing the same limitation is insufficient standing alone to constitute a clear and unmistakable disavowal of claim scope. Thorner, 669 F.3d at 1366–67.

ii. Inventor Acting as Lexicographer

Likewise, for similar reasons as discussed above in relation to the "outer frame" term, the inventor has acted as his own lexicographer to give the same definitions to "inner frame," "balloon-expandable frame," and "balloon-expandable inner frame" through consistent interchangeable use of the terms. The below excerpt from the specification describing one embodiment is illustrative of this interchangeable use:

> As described above, the outer frame **216** of the dual-frame **214** is secured to a balloon-expandable inner frame **218,** which is positioned in the passageway **232.** As shown in FIG. **10,** the frame **218** houses the valve **32.** The balloon-expandable frame **218** is embodied as a balloon-expandable tubular stent **244** that has a length **246** of approximately 15 mm. In other embodiments, the stent **244** may be longer or shorter depending on, for example, the patient's anatomy. The stent **244** is tubular and is constructed of a metallic material, such as, nitinol, stainless steel, or other implant grade metallic material, in an open-cell configuration. It should be appreciated that in other embodiments the stent **244** may be formed from a polymeric material and may be formed in, for example, a Z-stent configuration. In the illustrative embodiment, the outer surface **248** of the stent **244** is covered with low-profile polyester, ePTFE, or other nonporous covering material **250** that prevents fluid from passing through the outer surface **248.** However, it should be appreciated that the stent **244** may be covered with standard polyester, ePTFE or other nonporous materials.
>
> As shown in FIG. **10,** the stent **244** of the inner frame **218** has a diameter **252.** As described in greater detail below, the balloon-expandable frame **218** is expandable during implantation from an unexpanded diameter (not shown) to the expanded diameter **252.** In the illustrative embodiment, the expanded diameter **252** is equal to approximately 26 mm when the inner frame **218** is expanded.

(The '735 Patent, col. 13 ln. 40–66 (emphasis added).) In this description, item number **218** is referred to interchangeably as an "inner frame," "balloon-expandable frame," and "balloon-expandable inner frame." (Id.) Each of these terms refer to the same component, as illustrated by the reference to the same numbered component. (Id.) This interchangeable use is not an isolated instance, and these terms are consistently used interchangeably throughout the specification to refer to the same structure. (Id. col. 12 ln. 11 – col. 14 ln. 66.)

Given this consistent interchangeable use of these terms, one of ordinary skill in the art would have understood that these are the same items, and that they should be given the same constructions. Because of this, the specification requires the inner frame to be a balloon-expandable frame.

iii. "Positioned Within the Outer Frame"

For the same reasons discussed with regards to the outer frame, it is also inappropriate to require the inner frame to be positioned within an outer frame, since this would place a preferred embodiment outside the scope of the claims.

4. fibers

Claim Term No.	Term	Aortic's Proposed Construction	Defendants' Proposed Construction	Court's Construction
4	fibers	plain and ordinary meaning	discrete bundles of collagen threads or filaments	plain and ordinary meaning

The parties dispute the term "fibers" as it appears in claims 1, 4, 8, and 10 of the '735 Patent.

Aortic argues that the claim language and specification guide a plain meaning of the term. (ECF No. 83 at PageID 4281.) Aortic argues that limiting the term to discrete bundles of collagen fibers is incorrect, because there is nothing in the specification or claims requiring a limitation that the fibers be arranged in bundles or that they must be made of collagen. (Id. at PageID 4281.) Aortic argues that the fact that collagen fibers are specifically referenced in dependent claim 10 demonstrates that the term "fibers" alone is broader in scope than exclusively collagen fibers. (Id. at PageID 4281–82.) Aortic argues that a POSITA would understand that the referenced sealing

material could include non-collagen fibers as well as sealing materials that are not assembled in discrete bundles. (Id. at PageID 4282.)

Defendants argue that Aortic disclaimed "any claim scope beyond the arrangement of fibers depicted in the figures of the '735 patent" during IPR proceedings. (ECF No. 81 at PageID 3749.) Defendants argue that Aortic distinguished the '735 Patent from the prior art by arguing that the '735 Patent depicts "sparsely distributed" fibers that are distinct from the fibers in the prior art that are "opaque due to density." (Id. at PageID 3748.) Defendants argue that the accused product does not have a "sparse distribution" of fibers, and its fibers are instead "opaque." (Id. at PageID 3749.) Defendants argue that the fibers must be collagen, because every description of fibers discloses that the fibers are "collagen fibers." (Id.) Defendants also argue that the fact that the fibers are collagen is significant because collagen is resorbable into the body, in contrast to other types of fibers. (Id. at PageID 3750.) Defendants argue that claim differentiation cannot be used to broaden claims beyond their correct scope, and that the prosecution history supports the interpretation that the fibers must have been made of collagen. (Id. at PageID 3750–51.)

In Response, Aortic argues that none of its statements in IPR proceedings served to limit the fibers to "discrete bundles." (ECF No. 93 at PageID 5208.) Aortic argues that its statements instead related to the goals of reducing the size and bulkiness of the sealing materials to aid in endovascular delivery of the devices. (Id.) Aortic argues that there is nothing in the specification that limits fibers to only being collagen or acts as a disclaimer. (Id. at PageID 5210.) Aortic also argues that the provisional application, which is incorporated by reference in the '735 specification, expressly references fibers that are not made of collagen. (Id.) Aortic also argues that the prosecution history does not support such a limitation, and that later office actions clarify that the fibers are not limited to only collagen fibers. (Id. at PageID 5212.)

In Response, Defendants re-iterate their arguments that Aortic has expressly disclaimed any fibers that are not arranged in discrete bundles and that the prosecution history supports the inference that the fibers must be collagen. (ECF No. 96 at PageID 5523–26.)

The specification does not support a finding that Aortic clearly disclaimed fibers other than those in "discrete bundles." In support of their argument, Defendants cite statements by Aortic that make no reference to the specific grouping arrangement of these fibers, and instead discuss the density of the arrangement of these fibers.[2] (ECF No. 81 at PageID 3748.) Defendants' argument that the fibers must be limited to collagen fibers is likewise unconvincing, and treads dangerously close to the "cardinal sin" of reading a claim limitation from the written specification. Phillips, 415 F.3d at 1320. That dependent claim 10 differentiates collagen fibers from fibers more generally shows that "fibers" standing alone was not meant to refer exclusively to collagen fibers. Such a limiting construction would make it such that dependent claim 10 would have no scope and therefore be meaningless, and a construction that renders a dependent claim meaningless is generally disfavored. Littelfuse, Inc. v. Mersen USA EP Corp., 29 F.4th 1376, 1380 (Fed. Cir. 2022). Because the inventors have not made a clear disclaimer and Defendants' proposed construction would result in a meaningless claim, the Court will not adopt Defendants' proposed construction.

There is no reason before the Court to deviate from the presumption that claim terms be given their plain and ordinary meaning, and therefore the term "fibers" is construed as having its plain and ordinary meaning.

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[2] Defendants appear to conflate these two characteristics. It is possible to have fibers that are sparsely distributed while also not being arranged in discrete bundles. One such example is that generally hair on a person's head grows far more densely than the hairs on their arms or legs. This arm and leg hair is not required to be tied up in ponytails across the body simply because it is more sparsely distributed than head hair.

5. outer seal

Claim Term No.	Term	Aortic's Proposed Construction	Defendants' Proposed Construction	Court's Construction
5	outer seal	plain and ordinary meaning	an outer covering through which the outer frame is clearly visible	plain and ordinary meaning

The Parties dispute the term "outer seal" as it appears in claims 1, 6, 9, and 12 of the '735 Patent.

Aortic argues that there is no requirement that the outer frame be clearly visible through the outer seal, and that Defendants are attempting to add a claim limitation. (ECF No. 83 at PageID 4284–85.) Aortic argues that its statements made during IPR proceedings did not serve as a clear disavowal of claim scope, and instead related to Aortic's questioning of Defendants' expert witness. (Id. at PageID 4285.) Aortic also argues that such a construction would be ambiguous and conflict with the representations that Defendants made during IPR proceedings. (Id. at PageID 4286.)

Defendants argue that Aortic made a clear and unequivocal disclaimer of claim scope during previous IPR proceedings for any outer seal through which the outer frame is not clearly visible. (ECF No. 81 at PageID 3752.) Defendants point to IPR proceedings where Aortic "further argued that '[t]he Patent's sparse distribution of fibers through which the outer frame is clearly visible looks nothing like the thick, opaque outer coverings seen in' the prior art and that 'these differences are material when the crimp profile is in question.'" (Id.) Defendants argue that this differentiation from the prior art serves as a clear and unequivocal disclaimer. (Id.)

In Response, Aortic argues that Defendants take "portions of the IPRs out of context and mischaracterize[] Aortic's assertions." (ECF No. 93 at PageID 5213.) Aortic also argues that the

case law Defendants cite to support their position can be distinguished from the instant action. (Id. at PageID 5214.)

In Response, Defendants reiterate their argument that Aortic disclaimed any "outer seal" through which the outer frame is not "clearly visible." (ECF No. 96 at PageID 5526.) Defendants also argue that the construction is not ambiguous because it follows from Aortic's own description of the patent figures and Aortic's use of the term "opaque.". (Id. at PageID 5527.)

"[S]tatements made by a patent owner during an IPR proceeding can be considered during claim construction and relied upon to support a finding of prosecution disclaimer." Aylus Networks, Inc. v. Apple Inc., 856 F.3d 1353, 1361 (Fed. Cir. 2017). However, "to invoke the doctrine of prosecution disclaimer, any such statements must 'be both clear and unmistakable.'" Id. (citing Omega Eng'g, Inc, v. Raytek Corp., 334 F.3d 1314, 1326 (Fed. Cir. 2003)).

Defendants' characterization of Aortic's statements as a "clear and unequivocal disclaimer" is unconvincing. (ECF No. 81 at PageID 3752.) Aortic's statements were made during IPR proceedings for other patents, not for the '735 Patent. (Id. at PageID 3748.) It does not appear that Aortic intended these statements to be a disclaimer, but rather they were meant to challenge Defendants' expert and highlight an improvement on the prior art. (ECF No. 93 at PageID 5213–14.) Aortic's statements can be characterized as drawing a distinction between the '735 Patent's outer seal and the prior art seals with thick, opaque outer coverings, but these statements do not rise to the level of serving as a disclaimer of any covering through which the outer frame is not "clearly visible." (ECF No. 81 at PageID 3752.)

Defendants' proposal would also risk creating ambiguity and confusion, since the '735 Patent does not make any reference to the opacity of the outer seal and might require a separate and potentially confusing investigation into the definition of "clearly visible." (See the '735

Patent.) In contrast, the plain and ordinary meaning adequately represents the outer seal as described in the '735 Patent.

6. outwardly extending fibers

Claim Term No.	Term	Aortic's Proposed Construction	Defendants' Proposed Construction	Court's Construction
6	outwardly extending fibers	plain and ordinary meaning	the tips of the fibers extend in a generally outward direction from the frame	fibers that extend in a generally outward direction from the frame

The parties dispute the term "outwardly extending fibers" as it appears in claims 1, 8, and 10 of the '735 Patent.

Aortic argues that this term is used according to its plain and ordinary meaning. (ECF No. 83 at PageID 4284.) Aortic argues that the prosecution history supports this interpretation, because the Examiner initially rejected the application based on prior art having loops of fiber that the Examiner asserted disclosed "fibers positioned radially outwardly of the outer frame . . . wherein the first portion of fibers extend radially outwardly of the outer frame." (Id. at PageID 4288.) Aortic argues that it did not dispute this assertion during prosecution, and instead distinguished the '735 Patent application for other reasons. (Id.)

Aortic argues that Edwards has drawn its proposed construction from the PTAB's IPR institution decision for U.S. Patent No. 10,966,846 ("the '846 Patent"), in which the PTAB stated "[w]e understand the requirement for 'outwardly extending,' in accordance with its plain and customary meaning, to mean that the tips of the fibers must extend in a generally outward direction from the frame." (ECF No. 83 at PageID 4289.) Aortic notes that it does not generally disagree with this interpretation, however it disagrees with Defendants' assertion that "tips" must refer to the ends of linear fibers and excludes outwardly extending fiber loops. (Id.) Aortic argues that

Greenhalgh and the '735 Patent specification show examples of outwardly extending fibers that are not exclusively the ends of linear fibers. (Id. at PageID 4289–91.) Aortic argues that the plain and ordinary meaning is sufficient, but asks that if the Court does adopt the PTAB's preliminary interpretation, that it also clarify that a "tip" might also include the tip of an outwardly extending fiber loop, and is not limited to the end of a linear fiber. (Id. at PageID 4292.)

Defendants reference the PTAB's Institution Decision for the '846 Patent and argue that the PTAB has already concluded that the plain and ordinary meaning of "outwardly extending fibers" requires that the tips of the fibers extend in a generally outward direction from the frame. (ECF No. 81 at PageID 3752–53.) Defendants argue that the Court should adopt this same construction. (Id.)

In Response, Aortic reiterates its argument that the term "'outwardly extending fibers' is used according to its plain and ordinary meaning in the intrinsic record to refer to *fibers* that extend in a generally outward direction from the frame." (ECF No. 93 at PageID 5214 (emphasis in original).) Aortic argues that Defendants have mischaracterized the prosecution history and IPR proceedings and reiterates its argument that "outwardly extending fibers" can include outwardly extending fiber loops. (Id. at PageID 5214–5217.)

In Response, Defendants argue that the tips of the fibers shown in the '735 Patent figures still extend and terminate in a generally outward direction from the frame, even if a few of the tips curve and point slightly towards the frame. (ECF No. 96 at PageID 5528.) Defendants also argue that the PTAB's characterization of Greenhalgh during prosecution is not binding, since examiners apply the broadest reasonable interpretation standard, which is different from the standard that applies in the instant action. (Id. at PageID 5529.) Defendants also argue that the inventor's notebook supports its interpretation that the inventor envisioned fibers similar to those on a bottle

brush, which has radially extending fibers with a tip that terminates away from the base of the brush. (Id. at PageID 5530.)

It appears that the Parties are largely in agreement on the proposed construction of this term, and the only significant issue on which they disagree is whether the construction should include references to "tips" of the fibers and whether such "tips" could include loops of fiber, or are instead limited to the tips of a linear fiber. As Aortic highlights, the '735 Patent figures show embodiments having at least some fibers that appear to loop back on themselves and terminate in a direction that is not directly radially outward and may even face back towards the frame. (The '735 Patent, fig. 20.) The fibers illustrated are certainly not straight fibers extending perfectly radially from the frame, as would be the case in a bottle brush. (See ECF No. 96 at PageID 5530.) The fibers shown in the '735 Patent do, however, extend in a generally outward direction from the frame along their length. (See the '735 Patent.) Aortic makes a credible argument that certain types of loops, especially ones with an elliptical or oval shape, could be considered to have a "tip" that extends outwardly. "Tips" of the fibers do not appear to be referenced anywhere in the '735 Patent, and adding in this limitation would serve to import a limitation that is not present in the claims, specification, or prosecution history.

It appears that the plain and ordinary meaning of this term is adequate to explain the term. However, since it appears that the plain and ordinary meaning of the term will not sufficiently resolve the Parties' disputes relating to the "tip" portion of the proposed constructions, the Court will construe the term to mean "fibers that extend in a generally outward direction from the frame." See O2 Micro Int'l Ltd. v. Beyond Innovation Tech. Co., Ltd., 521 F.3d 1351, 1361 (Fed. Cir. 2008) ("A determination that a claim term 'needs no construction' or has the 'plain and ordinary

meaning' may be inadequate when a term has more than one 'ordinary' meaning or when reliance on a term's 'ordinary' meaning does not resolve the Parties' dispute.").

7. [preamble of the '735 Patent claim 1]

Claim Term No.	Term	Aortic's Proposed Construction	Defendants' Proposed Construction	Court's Construction
7	[preamble of the '735 claim 1]	the preamble is a limitation on the claim	the preamble of claim 1 is not limiting	the preamble of claim 1 is not limiting

The parties dispute whether the preamble of claim 1 of the '735 Patent should be limiting.

Aortic argues that the preamble of claim 1 should be a limitation on the claim because "it provides antecedent basis to a claim term in the body of the claim and also gives life and meaning to the claim." (ECF No. 83 at PageID 4292 (citing Seachange Int'l, Inc. v. C-COR, Inc., 413 F.3d, 1361, 1367–77; Pitney Bowes, Inc. v. Hewlett-Packard Co., 182 F.3d 1298, 1305).) Aortic argues that other portions of the specification similarly teach transcatheter valve assemblies that are delivered endovascularly. (Id.) Aortic also highlights that the preamble was specifically amended during prosecution to add the term "endovascular" in response to a rejection by the examiner, and that such a reliance on the preamble during prosecution serves to transform the preamble into a claim limitation. (Id. at PageID 4292–93.) Aortic argues that Defendants' position is inconsistent because Defendants treated the preamble as a limitation during IPR proceedings. (Id. at PageID 4293.)

Defendants argue that the preamble sets out an intended use of the claimed device via a particular delivery route, and does not lay out any structural requirements for the device. (ECF No. 81 at PageID 3754.) Defendants argue that claim 1 sets out the structure of the claimed valve, and the preamble is not necessary to understand limitations or terms in the claim body. (Id.)

Defendants argue that the prosecution history supports its position, because Aortic did not treat the preamble as limiting in its remarks when it made the amendment during prosecution. (Id. At PageID 3755.) Defendants also argue that Aortic's arguments should be rejected because construing the preamble to be limiting would render claim 1 indefinite since it would combine method and apparatus claims. (Id.)

In Response, Aortic argues that the preamble provides an antecedent basis to the phrase "the valve assembly" that appears in the body of claim 1. (ECF No. 93 at PageID 5217.) Aortic argues that the preamble describes structural design features that make the valve assembly a suitable endovascular device. (Id.) Aortic also argues that the preamble being limiting would not render claim 1 indefinite, because it reflects device design features or capabilities, and not an activity required of a user. (Id.)

In Response, Defendants argue that there are not structural features or limitations that the preamble would add to the claims, and that the preamble is better characterized as an intended use for the apparatus. (ECF No. 96 at PageID 5530.) Defendants argue that the preamble does not provide an antecedent basis for the term "valve assembly" and the claim drafter "did not rely on the preamble language to define or refine the scope of the asserted claims." (Id. at PageID 5531.) Defendants also argue that the specification discloses other delivery methods besides endovascular delivery. (Id.)

"Preamble language that merely states the purpose or intended use of an invention is generally not treated as limiting the scope of the claim." Bicon, Inc. v. Straumann Co., 441 F.3d 945, 952 (Fed. Cir. 2006). Likewise, "[i]f the body of the claim 'sets out the complete invention,' the preamble is not ordinarily treated as limiting the scope of the claim." Id. (quoting Schumer v. Lab. Computer Sys., Inc., 308 F.3d 1304, 1310 (Fed. Cir. 2002)). "However, the preamble is

regarded as limiting if it recites essential structure that is important to the invention or necessary to give meaning to the claim." Id. "Moreover, when the limitations in the body of the claim 'rely upon and derive antecedent basis from the preamble, then the preamble may act as a necessary component of the claimed invention.'" Id. (quoting Eaton Corp. v. Rockwell Int'l Corp., 323 F.3d 1332, 1339 (Fed. Cir. 2003)). A preamble may also be limiting if it is "'necessary to give life, meaning, and vitality' to the claim." Pitney Bowes, Inc. v. Hewlett-Packard Co., 182 F.3d 1298, 1305 (Fed. Cir. 1999).

"Clear reliance on a preamble during prosecution can distinguish a claimed invention from the prior art and render the preamble a claim limitation." Marrin v. Griffin, 599 F.3d 1290, 1294 (Fed. Cir. 2010); Catalina Mktg. Int'l Inc. v. Coolsavings.com, Inc., 289 F.3d 801, 808-809 (Fed. Cir. 2002) ("reliance on the preamble during prosecution to distinguish the claimed invention from the prior art transforms the preamble into a claim limitation because such reliance indicates use of the preamble to define, in part, the claimed invention").

Claim 1 of the '735 Patent sets out the complete invention, and the preamble does not recite "essential structure that is important to the invention or necessary to give meaning to the claim." Bicon, 441 F.3d at 952. The preamble is better characterized as stating the purpose and intended use of the invention as a transcatheter valve assembly that may be delivered endovascularly. Id. Each component of the valve assembly (the outer frame, inner frame, outer seal, and features related to each of these components) is recited in the body of claim 1 itself, and it is not necessary to look to the preamble to give meaning to the claim. (The '735 Patent, cl. 1.) Because the preamble "merely states the purpose or intended use of an invention," it would "generally not [be] treated as limiting the scope of the claim." Bicon, 441 F.3d at 952.

While the "endovascular" limitation was added to the preamble during prosecution, it is not clear that this change was clearly relied on for the purpose of distinguishing the claim from the prior art. (See ECF No. 82-1 at PageID 4203–4216.) The addition was made in response to an office action rejecting claim 1[3] as obvious under pre-AIA 35 U.S.C. 103(a). (ECF No. 82-1 at PageID 4199–200.) The Examiner's rejection was based on obviousness related to the outer seal, and the orientation of fibers that form this seal. (Id.) The Examiner stated that "[i]t would have been obvious to a person of ordinary skill in the art at the time of the invention to modify Nguyen et al. to include radially extending fibers as taught in Greenhalgh in order to further improve the seal of the device once implanted and prevent leakage." (Id. at PageID 4200 ¶ 26.) The Examiner further described a limitation describing how the device could be implanted such that it compressed the native valve leaflets and formed a seal with the fibers as being "a recitation of intended use." (Id. ¶ 27.) These rejections relate primarily to the sealing surface and its fibers, as well as how the device's sealing surfaces function once the device is implanted. This is further reflected in the inventor's amendments made in response to the office action, showing that in addition to adding "endovascular" to the preamble, the inventors added additional limitations, most of which relate to the outer seal. (Id. at PageID 4205–06.)

Aortic's arguments that "endovascular" was added to the preamble in order to distinguish the invention over the US Publication 20120123529 ("Levi") prior art do not rise to the level required to show "clear reliance" on the preamble to distinguish the invention from the prior art. Marrin, 599 F.3d at 1294. When amending the claims, the inventor described Levi as teaching "an outer skirt that billows outwardly and around the apices of the stent frame," but noted that this

[3] Claim 1 in the final issued '735 Patent was originally claim 11 at this stage of prosecution, and it is referred to as such by the inventor and Examiner. (See ECF No. 82-1 at PageID 4205.)

design "increases [the] overall valve profile, which is not desired." (ECF No. 82-1 at PageID 4213.) However, the Examiner's obviousness rejection of claim 1 was not based on Levi, but instead was based solely on Nguyen et al. (WO 2006/124649; US family version US 2006/0259136) ("Nguyen") in view of Greenhalgh (US 2002/0052649) ("Greenhalgh"). (Id. at PageID 4199.)

While the inventor referenced Levi in the response to the rejection, there is nothing pointing to the conclusion that this reference was related to the addition of "endovascular" to the preamble. Levi was clearly distinguished by amendments made in the body of claim 1 itself, where the inventor added a limitation that "an end of the most proximal apices of the outer frame are uncovered by the outer seal and the graft covering." (ECF No. 82-1 at PageID 4206.) It appears that the addition of this text was intended to distinguish the claim from Levi, and the addition of "endovascular" does not serve to add any significant additional distinction from the prior art. While it is certainly desirable to reduce the profile of an implant to facilitate implantation and improve patient outcomes, this desirability was already clear by the unamended preamble which recited that the device was a "transcatheter valve assembly." (Id. at PageID 4205.) Naturally, it would be desirable to be able to implant the device with the smallest catheter possible, whether the catheter is inserted endovascularly or transapically.[4] (ECF No. 113 at PageID 6620–21.)

The addition of "endovascular" serves only to add a "purpose or intended use" of the transcatheter valve assembly, and therefore does not serve as a limitation. (ECF No. 82-1 at PageID 4205; See Bicon, 441 F.3d at 952.)

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[4] Endovascular delivery is accomplished by inserting the catheter through an artery or vein in order to access the heart, while transapical delivery is accomplished by inserting the catheter into the heart directly. (ECF No. 113 at PageID 6620–21.)

IV. SUMMARY OF CONSTRUCTION

Claim Term No.	Term	Court's Construction
1	frame	plain and ordinary meaning
2	outer frame	a self-expanding frame
3	inner frame	a balloon-expandable frame
4	fibers	plain and ordinary meaning
5	outer seal	plain and ordinary meaning
6	outwardly extending fibers	fibers that extend in a generally outward direction from the frame
7	[preamble of the '735 claim 1]	the preamble of claim 1 is not limiting

SO ORDERED, this 9th day of May, 2023.

s/ Jon P. McCalla
JON P. McCALLA
UNITED STATES DISTRICT JUDGE

From: noreply@courtdrive.com <noreply@courtdrive.com>
Sent: Tuesday, May 9, 2023 10:21 AM
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