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I. INTRODUCTION

Pursuant to Local Patent Rule (LPR) 4-4, Aortic respectfully submits this opening claim construction brief as to U.S. Patent No 11,129,735 (“the ’735 Patent”).¹ Other than confirming the preamble—which recites “[a]n endovascular transcatheter valve assembly”—as a limitation, Aortic does not believe that any terms in the ’735 require construction. Defendants, Edwards Lifesciences Corporation, Edwards Lifesciences LLC, and Edwards Lifesciences (U.S.) Inc. (collectively, “Edwards”) propose six terms for construction. For all six of the terms identified by Edwards for construction, Edwards improperly seeks to import limitations from the specification or the IPRs into the claims to manufacture non-infringement arguments. But Edwards violates a “cardinal” rule of claim construction—*i.e.*, that “it is improper to read limitations from a preferred embodiment described in the specification.” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1320, 1323 (Fed. Cir. 2005) (en banc). Further, the statements from the IPRs that Edwards relies on to support its proposed constructions are misconstrued by Edwards and taken out of context. In the proper context, the IPR statements support Aortic’s plain meaning constructions—not Edwards’.

Undermining its arguments in this case, Edwards is taking contradictory positions in front of the PTAB in its IPR filings on the ’735 patent and others. In those filings, Edwards agrees with Aortic that no claim terms require construction, and it certainly does not proffer any of the overly narrow, litigation-inspired constructions it offers here. *E.g.*, Ex. D, IPR2022-00549, Paper 1 at 30 (APP183) (“The claim terms should receive their ordinary and customary meaning as understood by POSITAs at the time of filing and in accordance with the specification and the prosecution

¹ The ’735 patent is attached hereto as Ex. A (APP001-APP034). Aortic attaches declarations from a person having ordinary skill in the art at the time of the inventions supporting its constructions (referred to as the “Brecker Decl.” (Ex. B; APP035-APP138), and “Brecker Resp. Decl. (Ex. C; APP139-APP178).

history.”); Ex. E; IPR2022-00549, Ex. 1003 [Edwards’s expert Dr. Buller’s ’735 Patent IPR Declaration] at 8-9 (APP211-212) (“I have construed each claim term in accordance with its ordinary and customary meaning under the required standard.”). Because Aortic’s plain meaning constructions are supported by the intrinsic record and are consistent with Edwards IPR positions, they should be adopted by the Court in the litigation.

II. LEGAL STANDARD

During claim construction “[c]ourts do not rewrite claims; instead, [they] give effect to the terms chosen by the patentees.” *K-2 Corp. v. Salomon S.A.*, 191 F.3d 1356, 1364 (Fed. Cir. 1999). Accordingly, claim terms “are generally given their ordinary and customary meanings as understood by a person of ordinary skill in the art when read in the context of the specification and prosecution history”; indeed, courts apply a “heavy presumption that claim terms carry their full ordinary and customary meaning.” *Thorner v. Sony Computer Entm’t Am. LLC*, 669 F.3d 1362, 1365 (Fed. Cir. 2012) (citation omitted); *Omega Engineering, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1323 (Fed. Cir. 2003) (internal quotes omitted). “Although the specification may indicate that certain embodiments are preferred, particular embodiments appearing in the specification will not be read into the claims when the claim language is broader than the embodiments.” *Electro Med. Sys., S.A. v. Cooper Life Sciences, Inc.*, 34 F.3d 1048, 1054 (Fed. Cir. 1994); *Liebel-Flarsheim Co.*, 358 F.3d 898 at 913 (“[I]t 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.”)); *see also Phillips*, 415 F.3d at 1323.

The prosecution history may also be helpful in understanding claim term, because “[l]ike the specification, the prosecution history provides evidence of how the PTO and the inventor

understood the patent.” *Phillips*, 415 F.3d at 1317. Further, although extrinsic evidence can be relevant, it is “less significant than the intrinsic record in determining the legally operative meaning of claim language.” *Phillips*, 415 F.3d at 1317 (quoting *C.R. Bard, Inc. v. United States Surgical Corp.*, 388 F.3d 858, 862 (Fed. Cir. 2004)).

III. DISPUTED TERMS OF THE ’735 PATENT

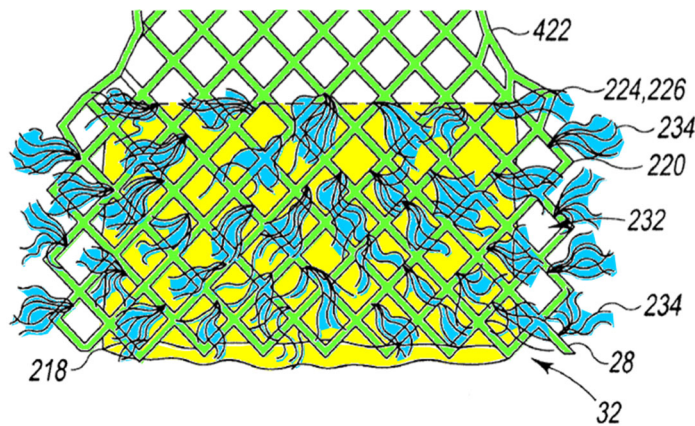
A. “Frame”

Term	Aortic’s construction	Edwards’ proposal
“frame” (claims 1, 2, 3, 5, and 7)	plain and ordinary meaning	A support structure having the strength to retain its expanded configuration and resist collapse

The term “frame” as it appears in the ’735 claims is used according to its plain and ordinary meaning in the intrinsic record to encompass frames that provide support as well as frames that house or enclose another component. The term “frame” appears in the phrases “outer frame” and the “inner frame.” The ’735 patent claims that the “outer frame is formed from a metallic material and defines an open cell configuration” and “is formed by a plurality of struts that adjoin each other at the inflow end to form apices.” ’735 patent, claim 1. For the “inner frame” the ’735 patent claims specify that the “inner frame ... engages a prosthetic heart valve having prosthetic leaflets” and “includes a cylindrically extending inner graft covering extending at least partially radially outwardly of the prosthetic heart valve and radially inwardly of the outer frame for providing sealing to the prosthetic heart valve.” ’735 patent, claim 1. Accordingly, the term “frame” refers broadly to metallic “frames” that provide support to the valve assembly—*i.e.*, the “outer frame”—and frames that extend cylindrically around or house another component like valve leaflets—*i.e.*, the “inner frame.” Ex. B, Brecker Decl., ¶¶46-57; Ex. C, Resp. Brecker Decl., ¶¶8-12, 14-15.

The ’735 patent specification confirms Aortic’s plain meaning interpretation of the term “frame” as encompassing supporting and/or surrounding structures. While the specification

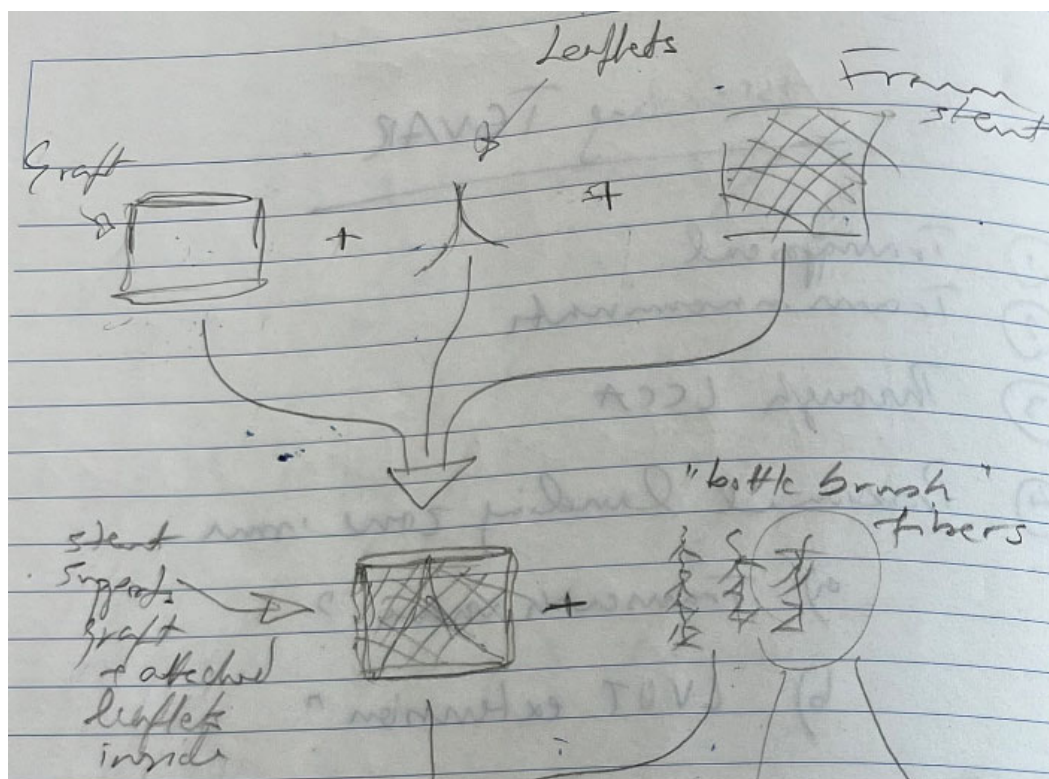
describes embodiments of the “outer frame” that provide support to the valve assembly where the outer frame is “formed in an open-cell stent configuration” and “formed from a metallic material, such as, nitinol, stainless steel, or other implant grade metallic material” (’735 patent, col. 17:63-64; 18:65-67), the specification also describes embodiments of the “inner frame” that “houses the valve 32” “may be formed from a polymeric material” and may be covered with low-profile or standard “polyester, ePTFE, or other nonporous covering material.” ’735 Patent, col. 13:50-59; col. 19:19-22. These “frames” are depicted, for example, in Figure 20 of the ’735 patent which shows a structural (e.g., metallic) outer frame (green), and a thin, wavy cylindrical inner frame (yellow) that encloses the prosthetic heart valve.



’735 patent, Fig. 20 (an.). Ex. B, Brecker Decl., ¶48; Ex. C, Brecker Resp. Decl. at ¶¶8-12, 14-15.

Further, the specification describes embodiments where the “outer frame 416 ... is **secured to** a ... inner frame 218.” ’735 patent, col. 19:19-22. Because the inner frame is secured to the outer frame, there is simply no reason for both “frames” to independently provide the same level of structural support for the valve—as Edwards contends—because support for the valve assembly is provided by the outer frame. Ex. B, Brecker Decl., ¶54; Ex. C, Brecker Resp. Decl. at ¶10. Indeed, this is consistent with Dr. Shahariari’s 2012 conception drawings which depict, in one

example, an outer frame as a stent and an inner frame as a graft and states “stent supports graft + attached leaflets inside.”



Ex. F, (Dr. Shahriari's notebook excerpt) at APP233. This image from Dr. Shahriari's notebook of the graft being combined with leaflets is effectively represented as FIG. 10 of the '735 Patent where an undulating covering is shown housing the leaflets:

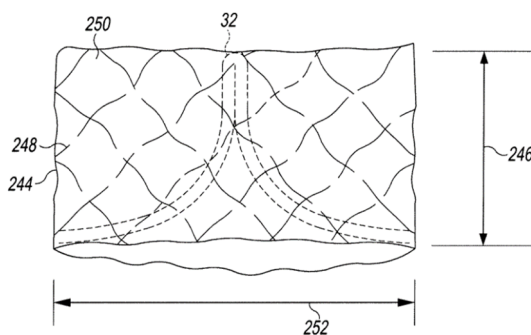


Fig. 10

Aortic’s plain meaning application of the term “frame”—which does not require that both the outer frame and inner frame independently provide support for the valve assembly—is thus consistent with full scope of the term “frame” as described in the specification and Dr. Shahriari’s invention drawings.

Aortic’s plain meaning interpretation of the term “frame” is also consistent with the file history. During prosecution of the ’735 patent application, the Examiner identified frame 12 and skirt 21 in the Nguyen reference (U.S. Patent Pub. No. US2006/0259136) as corresponding to the “outer frame” and the “inner frame” elements in rejecting then claim 11 (later claim 1) of the ’735 patent:

- | | |
|-----|--|
| 22. | Referring to claim 11, <u>Nguyen et al.</u> discloses a transcatheter valve assembly comprising: |
| a. | an <u>outer frame(12)</u> , wherein the outer frame is formed from a metallic material(page 12, lines 6-9) and defines an open cell configuration(Fig. 1A); |
| b. | an <u>inner frame(skirt, 21)</u> that engages a prosthetic heart valve(page 5, lines 12-20) having prosthetic leaflets, wherein the inner frame includes a cylindrically extending inner graft |

Ex. G, U.S. Patent App. No. 17/170,957 (’735 Patent File History) at APP292. Nguyen describes frame 12 as a “structure formed by laser cutting or etching a metal alloy tube comprising, for example, stainless steel or a shape memory material such as nickel titanium.” Ex. H, Nguyen at [0039]; Fig. 1A. Correspondingly, skirt 21 in Nguyen is described as being “cut from animal pericardial tissue ... or synthetic or polymeric material” and as “affixed to frame 12 and the leaflets 22.” Ex. H, Nguyen at [0046]. In other words, skirt 21 houses the leaflets but does not provide structural support. Aortic did not dispute the Examiner’s identification of frame 12—described as a metal structure—as an “outer frame” nor the identification of skirt 21—described as animal tissue or synthetic or polymeric material—as the “inner frame.” The Examiner’s and Aortic’s application

of the claims during prosecution confirms the plain meaning of “frame” as both supporting and/or enclosing structures. Ex. B, Brecker Decl., ¶¶49-50.

Aortic’s plain meaning interpretation of the term “frame” is also consistent with extrinsic evidence. Indeed, the dictionary defines the term “frame” as including supporting or enclosing structures. *E.g.*, Ex. I, American Heritage College Dictionary (4th ed. 2007) at 550 (defining “frame” both as “[a] structure that gives shape or support” and as “[a]n open structure or rim for encasing, holding, or bordering.”); Ex. J, Webster’s Dictionary of the English Language (2012) at 82 (defining “frame” as “a supporting or enclosing structure”). Thus, the extrinsic evidence further supports that the term “frame” is used in accordance with its plain meaning in the ’735 patent.

Edwards’ proposed construction of “frame”—“a support structure having the strength to retain its expanded configuration and resist collapse”—is incorrect because it fails to encompass the full scope of the plain and ordinary meaning of the term “frame” as it is used in the intrinsic record. Specifically, Edwards’ proposal attempts to 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. But as noted above, there is no need for both the outer frame and the inner frame to independently provide sufficient strength to retain an expanded configuration and resist collapse. That is especially the case here because the claims and specification provide that the inner frame is secured to the metallic outer frame. *See, e.g.*, ’735 patent, col. 19:19-22 (“the outer frame 416 ... is secured to a balloon-expandable inner frame 218, which is positioned in the passageway 232 and houses the valve 32 ”); claim 1 (“wherein the outer frame is secured to the inner graft covering by stitching a proximal portion of the outer frame”). Ex. B, Brecker Decl., ¶54. Because the metallic outer frame provides structural support and the inner frame (described in some examples of the specification as polymeric), is secured to the outer

frame, there is no need for both the inner frame and the outer frame to independently provide support for the entire valve assembly. Edwards’ one-size-fits-all approach which treats the “outer frame” and the “inner frame” the same and requires that both independently provide sufficient strength to retain an expanded configuration and resist collapse is not appropriate here where the intrinsic record describes the two frames differently and provides that the “inner frame” is secured to the “outer frame.”

Edwards’ proposed construction of “frame” is also incorrect because it adds ambiguity to the claim term. Edwards’ proposal requiring that a “frame” must resist collapse does not make sense in the context of the ’735 patent or transcatheter aortic valves because such valves are designed to be crimped—*i.e.*, collapsed—onto a balloon catheter for delivery. ’735 patent, claim 1 (specifying that “the valve assembly has a radially compressed orientation and a radially expanded orientation.”); Ex. B, Brecker Decl., ¶53. Edwards’ proposal is also ambiguous because it imports “strength” and “resist collapse” limitations without specifying the strength or forces that a “frame” must resist in order to meet Edwards’ definition of a “frame”. Accordingly, Edwards’ proposal—which adds ambiguity to the claim term, should be rejected.

Edwards’ proposed construction is also inconsistent with its IPR interpretation of the term in its petition to the Patent Office. For example, neither Edwards nor its IPR expert, Dr. Buller, suggested a non-plain and ordinary meaning construction for the term “frame”, much less one that limited the term “frame” to a “support structure having the strength to retain its expanded configuration and resist collapse.” Ex. D, IPR2022-00549, Paper 1 [Petition] at 30 (APP183) (“The claim terms should receive their ordinary and customary meaning as understood by POSITAs at the time of filing and in accordance with the specification and the prosecution history.”); Ex. E, IPR2022-00549, Ex. 1003 [Buller Declaration] at 8-9 (APP211-212) (“I have construed each claim

term in accordance with its ordinary and customary meaning under the required standard.”). In fact, Dr. Buller acknowledged in the IPRs that “a skirt inside the stent, it’s sewn on the inside of the stent, which AI’s position would mean that it is an inner frame.” Ex. K, IPR2021-00034, [Buller Tr.] at 40:21-23; *see also id.* 311:17-21 (“The SAPIEN valve has fabric on the inside of the frame, which, using your position, becomes the inner frame.” Likewise, Edwards relied on the “(PET) fabric cuffs” and “inner skirts” of the Cribier, Spenser, and Levi cited art in the ’735 patent IPR as disclosing the “inner frame” of the ’735 patent claims. Ex. D, IPR2022-00549, Paper 1 [Petition] at 38-40. Edwards cannot have it both ways. Having argued that the “fabric cuffs” and “inner skirts” in the IPR references are “inner frames”, it should not be heard to argue a contrary position here that both “frames”—the “outer frame” and “inner frame”—must independently have “the strength to retain its expanded configuration and resist collapse.” Ex. B, Brecker Decl., ¶¶55-57. Accordingly, Edwards’ ambiguous, inconsistent, litigation-inspired proposal that does not give the term “frame” its full plain meaning as reflected in the intrinsic record should be rejected.

B. “Outer frame”

Term	Aortic’s construction	Edwards’ proposal
outer frame (claims 1, 2, 3, 5, 7)	Plain and ordinary meaning	A self-expanding frame having a generally hourglass shape that is positioned outside the inner frame

The term “outer frame” in the ’735 patent is used according to its plain and ordinary meaning in the art and no further construction is required. A portion of Edwards’ proposed construction reflects a plain and ordinary meaning of the term—*i.e.*, “frame ... that is positioned outside the inner frame.” This plain and ordinary interpretation of the claim term is consistent with the specification which shows and describes that the outer frame is positioned outside the inner frame which houses the valve assembly. ’735 patent, col. 19:19-22 (“the outer frame 416 ... is secured to ... inner frame 218, which is positioned in the passageway 232 and houses the valve

32”); Figure 20. It is also consistent with various dictionaries which define the term “outer” in a consistent fashion. *See, e.g.*, Ex. L, American Heritage College Dictionary (5th ed. 2012) at 594 (“outer” “Located on the outside ... Farther from the center or middle.”); Ex. I, American Heritage College Dictionary (4th ed. 2007) at 987 (“outer” “1. Located on the outside; external.”); Ex. M, Merriam Webster’s Collegiate Dictionary (11th ed. 2004) at 881 (“outer” ... “situated farther out”).

Edwards’ proposal crosses the line and departs from the plain and ordinary meaning, however, by attempting to read in details from the specification that are not included in the claims. Specifically, Edwards’ proposal requires that the outer frame be “self-expanding” and that it have a “generally hourglass shape.” But, neither of these features is required by the plain language of the claims. Moreover, neither the specification nor the file history disavow or disclaim “outer frames” that are not self-expanding or that have shapes other than an hourglass. To the contrary, the ’735 patent specification indicates that the outer frame can be balloon-expandable and have a non-hourglass shape. Indeed, regarding the “outer frame” being balloon expandable (as opposed to self-expanding), the ’735 patent specification describes that “[i]n some embodiments, operating the balloon-expandable frame may include **advancing an outer surface of the balloon-expandable frame into engagement with the aortic annulus.**” ’735 patent, col. 4:48-55 (emphasis added). Because the outer frame surface engages the aortic annulus, the foregoing passage demonstrates that the outer frame—in some embodiments—is balloon-expandable. Ex. B, Brecker Decl., ¶¶34-35. Likewise, in other embodiments, the specification teaches that the “[e]xpansion of the balloon-expandable inner frame 218 engages the inner frame 218 with the outer frame 416 and compresses the collagen fibers/hydrogel coated proximal section 220 of the outer frame 416 against the aortic annulus 210.” ’735 patent, col. 19:38-45; 18:16-21; 19:38-42. As Dr. Brecker testified, “[a] POSA would appreciate that this passage ... describes the additional

expansion of the outer frame (which is described as oversized relative to the diameter of the aortic annulus) by the balloon and inner frame to compress the fibers of the outer frame against the native aortic annulus.” Ex. B, Brecker Decl., ¶34. Accordingly, because the specification describes outer frames that are both self-expanding and balloon expandable, the term should not be limited to only self-expanding “outer frames.”

A “generally hourglass shape”—as proposed by Edwards—should also not be read in as a requirement. Edwards’ hourglass shape restriction excludes embodiments in the specification which disclose, for example, that “section 220 [the proximal portion of the outer frame] may be shaped as a prism, cone, or other geometric shape depending on the patient’s anatomy.” ’735 Patent, col. 18:7-10. Because the “outer frame” may be “shaped as a prism, cone, or other geometric shape” it should not be restricted to a “generally hourglass shape.” *Philips*, 415 F.3d at 1315 (“[A] claim construction that excludes preferred embodiments is rarely, if ever, correct.”).

Edwards’ proposal is also inconsistent with its representation of the meaning of “outer frame” in the IPRs before the Patent Office. Neither Edwards nor its expert, Dr. Buller, construed or interpreted “outer frame” as limited it to a “self-expanding” outer frame having a “generally hourglass shape.” Ex. D, IPR2022-00549, Paper 1 [Petition] at 30 (APP183); Ex. E, IPR2022-00549, Ex. 1003 [Buller Declaration] at 8-9 (APP211-212). Likewise, the art identified by Edwards in the ’735 patent IPR was not limited to an “outer frame” that was “self-expanding” with a “generally hourglass shape”. Indeed, Edwards relied on the Cribier, Walther, Spenser, and Levi prior art in the ’735 patent IPR, all of which include balloon-expandable, non-hourglass shaped outer frames. Ex. D, IPR2022-00549, Paper 1 [Petition] at 36 (identifying non-hourglass, balloon expandable frame of Cribier (Sapien) valve as an “outer frame”); 43 (Walther); 69-70 (Spenser); 101-102 (Levi). Edwards’ reliance on the plain meaning of the term “outer frame” which did not

require that it be “self-expanding” or have a “generally hourglass shape” in the IPRs further demonstrates that its overly narrow proposed construction here is incorrect.

C. “Inner frame”

Term	Aortic’s construction	Edwards’ proposal
inner frame (claims 1, 5)	Plain and ordinary meaning	A balloon-expandable frame that is positioned within the outer frame

The term “inner frame” is used consistently with its plain and ordinary meaning in the ’735 Patent and requires no additional construction. Indeed, the plain and ordinary meaning of “inner frame” is reflected in the specification which shows and describes that the inner frame is positioned within the outer frame. ’735 patent, col. 19:19-22 (“the outer frame 416 ... is secured to ... inner frame 218, which is positioned in the passageway 232 and houses the valve 32”); Figure 20. Aortic’s interpretation of “inner frame” is also supported by contemporaneous dictionaries which define the term “inner” in a similar fashion. *See, e.g.*, Ex. I, American Heritage College Dictionary (4th ed. 2007) at 715 (“inner” “1. Located or occurring farther inside.”); Ex. L, American Heritage College Dictionary (5th ed. 2012) at 436 (“inner” “1. Located farther inside.”); Ex. M, Merriam Webster’s Collegiate Dictionary (11th ed. 2004) at 645 (“inner” “situated farther in”); Ex. B, Brecker Decl., ¶¶41-45.

Although a portion of Edwards’ proposal for “inner frame” reflects a plain and ordinary meaning of the term—i.e., “frame ... that is positioned within the outer frame”, the remainder departs from the plain meaning of the term by requiring that the “inner frame” be only balloon-expandable. Yet, although the ’735 patent describes the “inner frame” as balloon expandable, neither the claims, specification, nor the file history limit the “inner frame” to be only balloon expandable. Edwards’ proposal commits the “cardinal sin” of claim construction—importing limitations from the preferred embodiment. *Phillips*, 415 F.3d at 1320, 1323. Further, neither the

specification nor the prosecution history disclaim or disavow “inner frames” that are not balloon-expandable. *Retractable Techs*, 653 F.3d 1296 at 1306. Accordingly, there is no reason to limit the term “inner frame” to balloon expandable inner frames and the term should be given its plain and ordinary meaning.

D. “Fibers”

Term	Aortic’s construction	Edwards’ proposal
“fibers” (claims 1, 4, 8, and 10)	plain and ordinary meaning	Discrete bundles of collagen threads or filaments

The meaning of the term “fibers” is apparent from both the claim language and specification and the plain meaning of the term should apply. ’735 patent, col. 4:19-23 (“a plurality of fibers may be attached to the self-expanding frame”); Figure 20.² Indeed, a POSA would understand fibers in the context of the ’735 patent to generally refer to thread-like objects or structures. Ex. B, Brecker Decl., ¶65; *see also* Ex. I, American Heritage College Dictionary (4th ed. 2007) at 514 (“fiber” “a thread like object or structure.”); Ex. L, American Heritage College Dictionary (5th ed. 2012) at 314 (“fiber” “a slender threadlike structure”).

Edwards’ proposed construction requiring “a discrete bundle of collagen threads or filaments” is incorrect because it seeks to restrict “fibers” to “discrete bundles” made from “collagen.” Nothing in the claims, however, requires that the claimed “fibers” be assembled as “discrete bundles” or made from “collagen.” To the contrary, claims 1, 4, and 8 all reference “fibers”, while dependent claim 10 claims “collagen fibers.” ’735 patent, claim 10 (“wherein the outwardly extending fibers are collagen fibers”). The specific reference to “collagen fibers” in

² *See also*, additional intrinsic evidence not restricting “fibers” to collagen fibers discussed further below. Ex. N, U.S. Provisional App. No. 61/723,446, claim 1; Ex. G, U.S. Patent App. No. 17/170,957 (’735 Patent Prosecution History, May 21, 2021 Amendment and Response) at APP273.

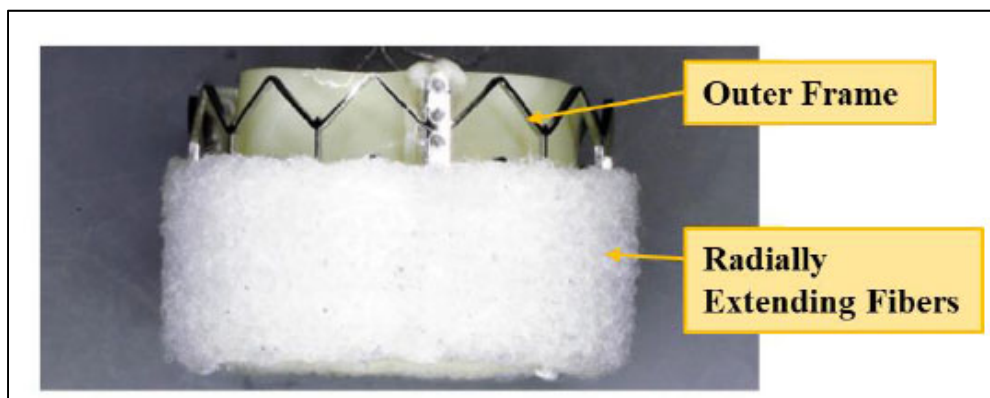
dependent claim 10 demonstrates that the term “fibers” in independent claim 1 and other claims is broader in scope than “collagen fibers.” *Phillips*, 415 F.3d at 1315 (“[T]he presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim.”). Edwards’ requirement that all claimed “fibers” be “collagen fibers” violates the principle of claim differentiation and would render the recitation of “collagen fibers” in claim 10 superfluous. *Biocon*, 441 F.3d at 950–52.

Likewise, nothing in the specification requires limiting “fibers” to only collagen fibers or discrete bundles. Indeed, Edwards points to no statements of disavowal or disclaimer that require restricting “fibers” to only “discrete bundles” and fibers made from “collagen.” *Retractable Techs.*, 653 F.3d at 1306. Rather, the specification expressly describes “collagen fibers” as a sealing material in an “illustrative embodiment” [’735 Patent, col. 18:24-25] and then goes on to describe that “[i]n other embodiments the outer frame 216 may be covered with ... **other sealing materials.**” ’735 Patent, col. 18:29-31. As Dr. Brecker testified, “[a] POSA would appreciate that ‘other sealing materials’ encompasses non-collagen fibers as well as fiber sealing materials that are not assembled in discrete bundles.” Ex. B, Brecker Decl., ¶66; Ex. C at ¶33. Further, the specification and Aortic’s provisional patent application that is incorporated by reference in the ’735 specification, expressly reference and claim “fibers” that are not specifically required to be collagen fibers. ’735 patent, col. 3:28-32 (referencing “a plurality of fibers”); 4:19-23 (“a plurality of fibers may be attached ...”); Ex. N, U.S. Provisional App. No. 61/723,446, claim 1 (claiming “a plurality of fibers”). Accordingly, the specification does not support Edwards’ proposal.

The ’735 patent prosecution history also does not support Edwards’ proposed construction, but rather confirms the plain and ordinary meaning of the term. While the Examiner initially interpreted the term “fibers” as collagen fibers, Aortic told the Examiner that the meaning of

“fibers” was not limited to “collagen fibers” but rather “is the ordinary meaning of fibers.” Ex. G, U.S. Patent App. No. 17/170,957 at APP273 (“Applicant notes ... the USPTO commentary on collagen fibers. Applicant submits that the claim term of fibers found in claim 11 and many other claims is the ordinary meaning of fibers.”) Aortic also pointed the Examiner to then claim 26 (which became claim 10) as specifically reciting “collagen fibers” indicating that the term “fibers” is broader. *Id.* (“New claim 26 recites that the fibers are collagen fibers.”) The Examiner did not disagree with Aortic’s explanation and subsequently allowed the ’735 patent claims. Ex. G, U.S. Patent App. No. 17/170,957 (Notice of Allowance) at APP254-255. This further demonstrates that Edwards’ proposal requiring the fibers to be collagen is incorrect and that the plain and ordinary meaning should apply.

Edwards’ proposed construction of “fibers” is also inconsistent with its IPRs positions in its petitions to the Patent Office. There, Edwards interpreted the term “fibers” according to its plain and ordinary meaning and did not require “collagen fibers” or “discrete bundles.” Ex. D, IPR2022-00549, Paper 1 [Petition] at 30 (APP183); Ex. E, IPR2022-00549, Ex. 1003, [Buller Declaration] at 8-9 (APP211-212). Indeed, the art identified by Edwards in the ’735 patent IPR was not limited to “fibers” made from “collagen” or those arranged only in “discrete bundles”. For example, Edwards relied on non-collagen fibers that are not discretely bundled in the Walther references as providing the claimed “fibers” of the ’735 patent claims.



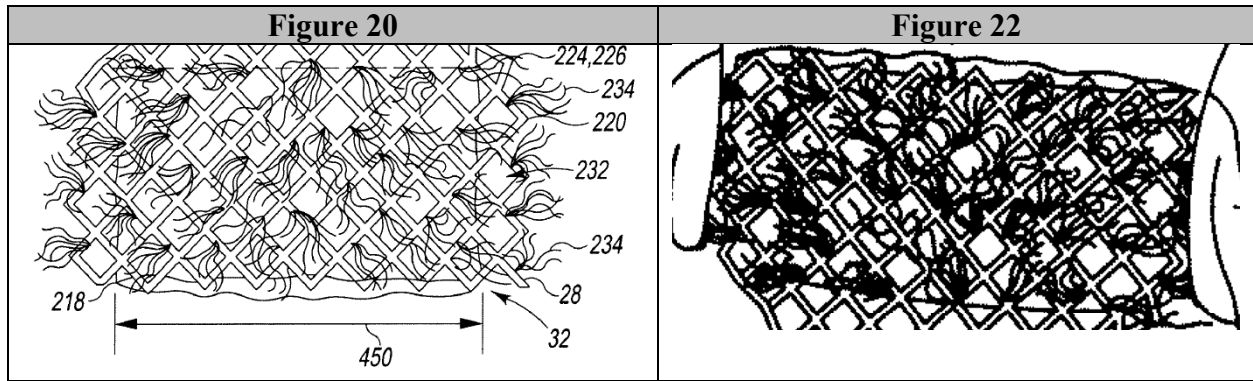
Ex. D, IPR2022-00549, Paper 1 [Petition] at 6, 42-44 (identifying Walther’s PET polyester “outer cloth” as satisfying the “fibers” element). Edwards’ adoption of the plain meaning of “fibers” in the IPRs confirms that it is the correct construction that should be applied in the litigation as well.

E. “Outer seal”

Term	Aortic construction	Edwards proposal
“outer seal” (claims 1, 6, 9, and 12)	plain and ordinary meaning	An outer covering through which the outer frame is clearly visible

A POSA would understand the term “outer seal” as it is used in the ’735 patent to refer to the plain and ordinary meaning—*i.e.*, an outer sealing material. Ex. B, Brecker Decl., ¶71. As claim 1 of the ’735 patent makes clear, the “outer seal” “is formed of outwardly extending fibers positioned externally to the outer frame”, “prevent[s] paravalvular leaks”, and “at least partially extends over at least two most proximal rows of cells formed in the outer frame.” ’735 patent, claim 1. Further, as discussed above, the specification teaches embodiments where the “outer frame” may be covered with fibers, hydrogels, or other sealing materials. ’735 Patent, col. 18:24-31. Accordingly, the term “outer seal” requires no further definition beyond what is already in the claims.

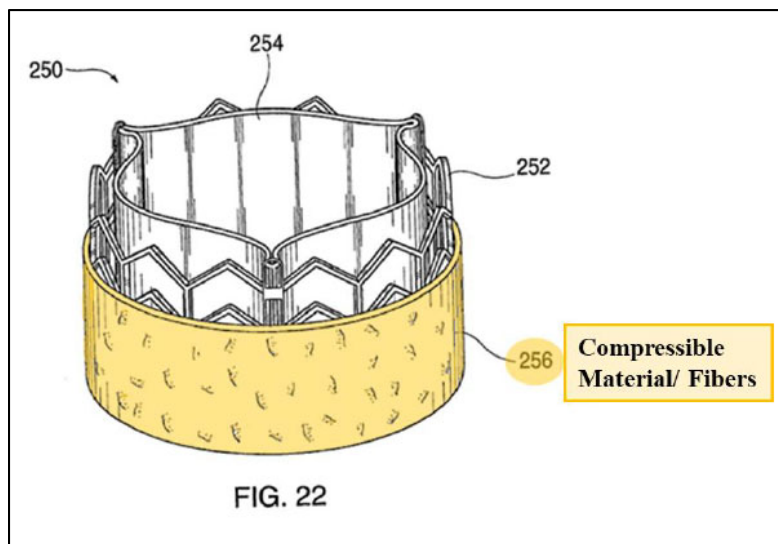
Edwards proposed construction of “outer seal” improperly attempts to add in limitations not found in the claims—*i.e.*, that the “outer frame is clearly visible” though the outer seal. But there is no requirement that that outer frame be “clearly visible” though the outer seal. Indeed, the written specification does not require or mention the visibility of the outer frame though the outer seal. Further, the figures of the ’735 Patent show varying levels of visibility of the outer frame though the outer seal. *See, e.g.*, ’735 patent, Figure 20 and Figure 22 below.



Edwards' may claim that the "clearly visible" limitation is based on statements made by Aortic in certain IPRs—but not the '735 IPR—where Aortic questioned the credibility of Edwards' expert witness, Dr. Buller. Specifically, in the IPRs the parties have disputed whether some of the alleged prior art TAVR valves with thick, bulky skirts would have a low enough profile to be delivered endovascularly—*i.e.*, small enough to be delivered through blood vessels. During Dr. Buller's cross-examination, Aortic's IPR counsel, questioned Dr. Buller on whether the fiber density shown the "exemplary figures" of Aortic's patent was the same as that in the prior art at issue. Dr. Buller repeatedly denied any differences. Ex. K, Buller-Depo., 155:25-156:12; 157:11-158:25, 159:12-13; 160:14-24. As a result, in a section entitled "Dr. Buller's Testimony Should Be Given No Weight In View Of His Discrediting Testimony On Cross", Aortic explained that Dr. Buller's testimony should be discredited given the visible differences between the thick, bulky skirts in the prior art and the fibers shown in exemplary figures in the patent and Dr. Buller's refusal to acknowledge any differences. *See, e.g.*, Ex. O, IPR2022-00034, Patent Owner Response at 47-54. But Aortic's statements demonstrated Dr. Buller's lack of credibility given his testimony on the fiber density of the two valves. Aortic's statement did not distinguish the cited art on the basis that it does not disclose an "outer seal" with clear visibility of the outer frame. Moreover, there is no clear disclaimer or disavowal of claim scope requiring that the "outer seal" be limited to only "outer seals" through which the frame is clearly visible. *Continental Circuits LLC v. Intel Corp.*, 915 F.3d 788, 797 (Fed. Cir. 2019).

Not only is Edwards’ proposed construction not required by the specification and prosecution history, Edwards’ proposal also adds ambiguity to the claims. Specifically, Edwards’ proposal requires one to assess “clear visibility” of the outer frame though the “outer seal” in order for it to qualify as an “outer seal.” Indeed, as Dr. Brecker noted “is a vague outline of the outer frame through the outer seal sufficient or is something more required?” Ex. B, Brecker Decl., ¶73. Likewise, “if some portions of the outer frame are clearly visible, but other portions are not does that indicate ‘clear visibility’ of the outer frame though the outer seal?” *Id.* The added ambiguity further demonstrates that Edwards’ proposal is incorrect.

In addition—like its other constructions—Edwards’ proposed construction here is also in conflict with its IPR assertions in its petitions to the Patent Office. Indeed, in the ’735 patent IPR, Edwards applied the plain meaning of the term “outer seal” and did not require that the outer frame be “clearly visible” though the outer seals it identified. Ex. D, IPR2022-00549, Paper 1 [Petition] at 30 (APP183); Ex. E, IPR2022-00549, Ex. 1003 [Buller Declaration] at 8-9 (APP211-212). For example, Edwards identified the “compressible material/ fibers” of the Spencer II reference as the “outer seal” despite the fact that the outer frame does not appear to be clearly visible though the outer seal.

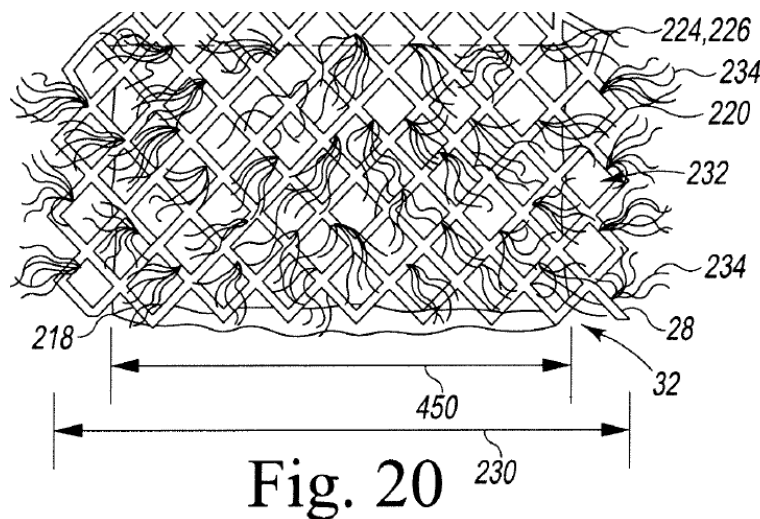


Ex. D, IPR2022-00549, Paper 1 [Petition] at 77-79 (identifying Spenser II “compressible material” as an “outer seal”). Edwards’ inconsistent position here further demonstrates that its litigation-inspired proposed construction should be rejected in favor of the plain meaning of the term.

F. “Outwardly extending fibers”

Term	Aortic’s construction	Edwards’ proposal
“outwardly extending fibers” (claims 1, 8, and 10)	plain and ordinary meaning	The tips of the fibers extend in a generally outward direction from the frame

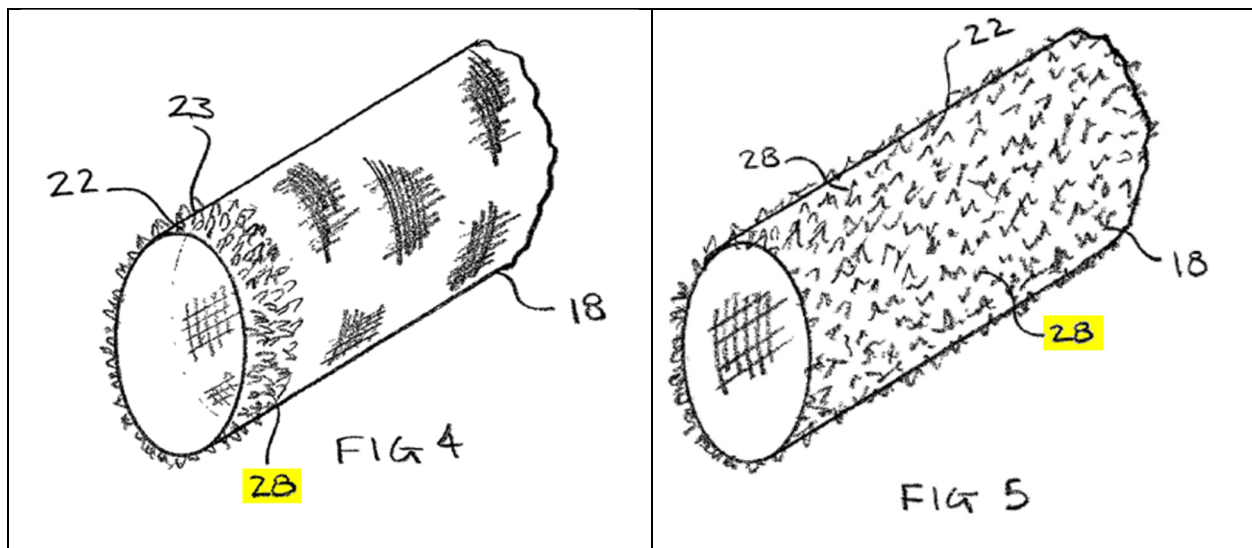
As the intrinsic record makes clear, the term “outwardly extending fibers” is used according to its plain and ordinary meaning—*i.e.*, fibers that extend in a generally outward direction from the frame. For example, Figure 20 shows examples of “outwardly extending fibers.”



’735 patent, Figure 20; *see also* Figures 11-13. The specification also describes that “[t]he fibers 234 extend outwardly from the proximal section 220” of the outer frame. ’735 patent, col. 18:27-28.

The prosecution history further confirms the meaning of the term “outwardly extending fibers”. During prosecution of the ’735 patent claims, the Examiner rejected the claims and referenced the “outwardly extending fibers” limitation in particular in view of the U.S. Patent App. Pub. No. 20020052649 (“Greenhalgh”), Figures 4 and 5. Claim 11 at the time (which was later

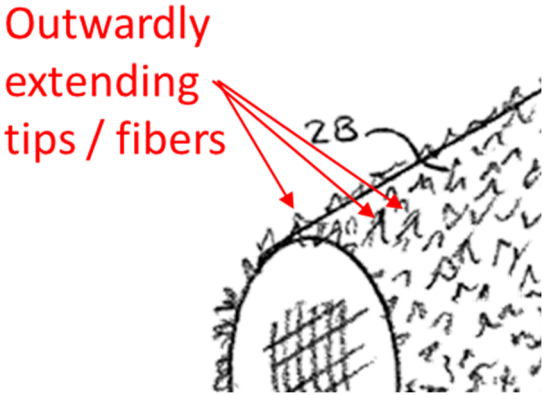
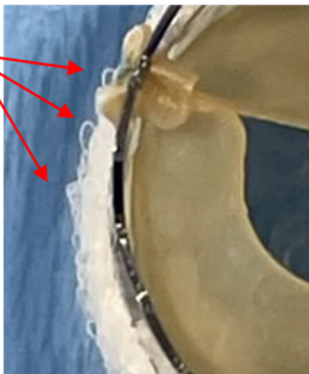
renumbered as claim 1) included the limitation “wherein the outer seal is formed of outwardly extending fibers positioned externally to the outer frame”. Ex. G, U.S. Patent App. No. 17/170,957 at APP297. In rejecting the claims, the Examiner stated “Greenhalgh discloses fibers positioned radially outwardly of the outer frame ... wherein the first portion of *fibers extend radially outwardly of the outer frame* (See Figs. 4-5, radially extending fibers, 22/28).” Ex. G, U.S. Patent App. No. 17/170,957 (’735 Patent Prosecution History, April 30, 2021 Non-Final Rejection) at APP292-293 (emphasis added). As shown in Figures 4 and 5 below, Greenhalgh discloses fiber “*loops 28* which extend outwardly from the substrate 18.” Ex. P, Greenhalgh, [0032]-[0033].



Following the Examiner’s rejection, Aortic did not dispute the Examiner’s assertion that Greenhalgh’s “loops” reflect outwardly extending fibers. Rather, Aortic distinguished Greenhalgh for other reasons. Ex. G, U.S. Patent App. No. 17/170,957 (’735 Patent Prosecution History, May 21, 2021 Amendment) at APP273-279. Ultimately, the Examiner agreed with Aortic and allowed the claims. Accordingly, the prosecution history demonstrates that fiber loops like those depicted in Greenhalgh are examples of “outwardly extending fibers” within the meaning of the claims. Ex. B, Brecker Decl., ¶81.

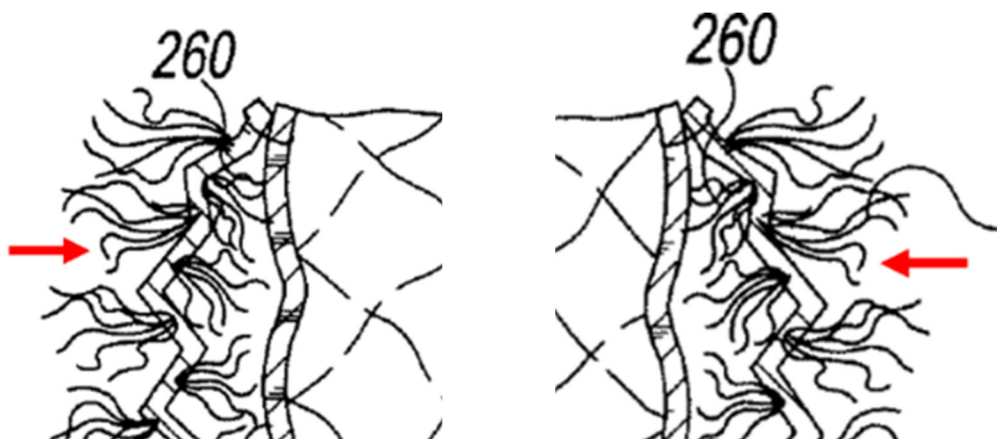
Edwards appears to derive its proposed construction of “outwardly extending fibers”—*i.e.*, “the tips of the fibers extend in a generally outward direction from the frame”—from the institution decision in the ’846 Patent IPR. In the ’846 Petition, Edwards argued that the woven PET skirt of Levi discloses “outwardly extending fibers.” Ex. Q, IPR2022-00034, Petition at 84. In its Patent Owner Preliminary Response, Aortic argued that woven PET skirts like those in Levi, do not have “outwardly extending fibers.” Ex. O, IPR2022-00034, POPR at 50 (APP812). In the Institution Decision, the PTAB agreed with Aortic regarding the Levi reference because “the type of woven PET fibers utilized for cardiovascular applications are tightly woven and do not extend outward from the surface”. Ex. R, IPR2022-00034, Institution Decision at 26-27 (APP844-845). In reaching its preliminary decision, 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 as shown, for example, in Figures 8, 9, 11–14, and 20 of the ’846 patent.” *Id.*

While Aortic does not generally disagree with the PTAB’s preliminary interpretation of “outwardly extending fibers” in the institution decision, Aortic does disagree with how Edwards reads the PTAB’s interpretation. Specifically, Edwards appears to argue that fiber “tips” are limited to the ends of linear fibers and exclude outwardly extending fiber loops. Indeed, in its non-infringement contentions, Edwards asserts that the accused Sapien 3 Ultra does not have “outwardly extending fibers” because outwardly extending fiber loops do not have tips. Ex. S; Edwards’ Exhibit D to Preliminary Non-Infringement Contentions at 3 (“SAPIEN 3 Ultra’s outer skirt has an outer layer made of PET loops. The outer layer does not have tips.”) But the plain meaning of the term “tip” is defined as “the end of a pointed or projecting object.” Ex. T, American Heritage Dictionary 5th (2012) at 854. Accordingly, pointed or projecting fiber loops—like those in Greenhalgh and the Sapien 3 Ultra—do have “tips” that are outwardly extending—it’s the looped end of the projecting fiber.

Greenhalgh	Sapien 3 Ultra
	

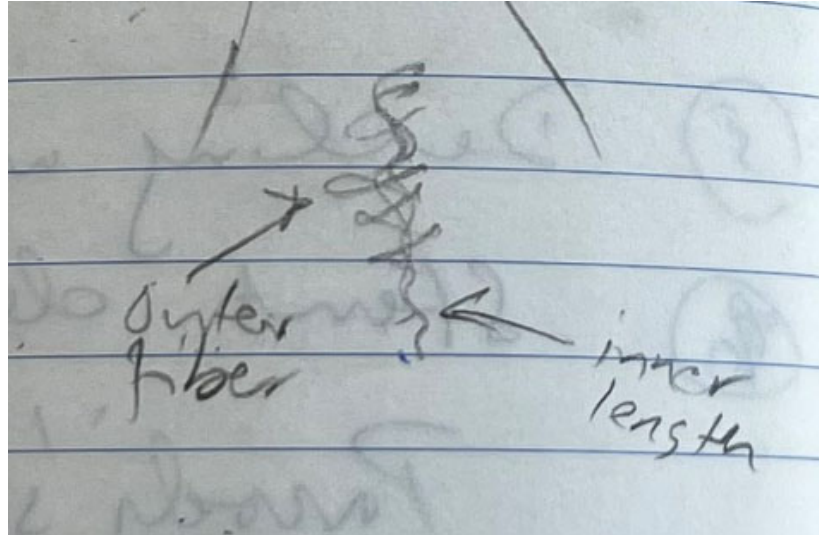
Ex. P; U.S. Patent App. Pub. No. 2002/0052649 (Greenhalgh), Figures 4, 5; Ex. U (Sapien 3 Ultra).

Further, Edwards' incorrect interpretation of "tips" as referring to the end of a linear fiber and excluding outwardly extending fiber loops, conflicts with the '735 patent specification and file history. The '735 patent figures show in some examples outwardly extending fibers with ends—i.e., "tips" according to Edwards' interpretation—that curve around and extend inwardly even though the fiber itself extends generally outwardly from the frame.



'735 Patent, Fig. 12 (annotated portions); Brecker Decl. B at ¶78. Likewise, in the '735 patent file history, as noted above, both the Examiner and Aortic agreed that the outwardly extending fiber loops of Greenhalgh were “outwardly extending fibers.”³

And finally, just as before, Dr. Shahriari’s disclosure notebook is helpful. In the notebook, one of the images illustrates loops of “outer fiber” on the frame:



Ex. F (Dr. Shahriari notebook excerpt).

Accordingly, because the term fiber “tip” does not appear anywhere in the '735 patent specification and the specification expressly teaches that “[t]he **fibers** 234 extend outwardly” ('735 patent, 18:27-28), the plain and ordinary meaning interpretation of the term “outwardly extending fibers” is “**fibers** that extend in a generally outward direction from the frame.” To the extent that the Court is inclined to adopt the PTAB’s preliminary interpretation as the correct construction, Aortic respectfully requests that the Court clarify that “outwardly extending” fiber “tips” encompass the tips of outwardly extending fiber loops like those in the Greenhalgh prior art reference.

³ Indeed, it does not appear that the PTAB considered Greenhalgh or the '735 Patent file history in interpreting the term “outwardly extending fibers” in the '846 Patent IPR given that neither party argued any claim constructions and the PTAB neither mentioned Greenhalgh or the '735 patent file history in interpreting the plain meaning of the “outwardly extending fiber” term.

G. Claim 1 Preamble: “An endovascular transcatheter valve assembly”

Term	Aortic’s construction	Edwards’s proposal
Preamble of claim 1 / “An endovascular transcatheter valve assembly”	The preamble of claim 1 is limiting.	The preamble of claim 1 is not limiting.

The preamble of claim 1 of the ’735 patent is 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. *Seachange Int’l*, 413 F.3d at 1367-77; *Pitney Bowes*, 182 F.3d at 1305. Indeed, the phrase “the valve assembly” that appears in the body of claim 1 of the ’735 patent (*see* col 22:1) refers back to and derives antecedent basis from “[a]n endovascular transcatheter valve assembly” appearing in the claim 1 preamble (*see* col. 21:17). This demonstrates that the preamble should be construed to be a limitation on the claim. *Seachange Int’l*, 413 F.3d at 1367-77.

The preamble also gives life and meaning to the claim further demonstrating that it should be construed as a limitation. *Pitney Bowes*, 182 F.3d at 1305. For example, the Abstract of the ’735 patent mentions a “heart valve replacement device for *endovascular* repair.” ’735 patent, at Abstract. Similarly, other portions of the specification teach transcatheter valve assemblies that are delivered endovascularly. ’735 patent, col. 10:46-51 (teaching a TAVR procedure with “percutaneous access to the common femoral artery”); col. 19:25-42 (teaching a TAVR procedure where “a stiff wire is passed through the aortic valve 202 into the left ventricle 204.”) Further, the preamble of claim 11 (which later became claim 1) was specifically amended during prosecution to add the term “endovascular”, among others, following a rejection by the Examiner.

11. (Currently Amended) <u>An endovascular</u> transcatheter valve assembly comprising:

U.S. Patent App. No. 17/170,957 (’735 Patent Prosecution History, May 21, 2021 Amendment and Response) at 2, 6. The “endovascular” amendment to the claim preamble further demonstrates

that the preamble provides life and meaning. *Catalina Mktg. Int'l Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 808-809 (Fed. Cir. 2002) (“[R]eliance 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.”)

Additionally, other elements in claim 1 are directed to the valve assembly being delivered endovascularly. As Dr. Brecker testified “the ‘proximal apices’ and the ‘radially compressed’ and ‘radially expanded’ orientations of the valve assembly are directed to having a valve assembly that is suitable for endovascular transcatheter delivery” because “[t]he claimed invention’s requirement that the outer frame’s most proximal end be uncovered is advantageous because it allows the frame to elongate when crimped, allowing for a narrower profile ... to facilitate endovascular delivery.” Ex. B, Brecker Decl., ¶88 (referencing Ex. V, IPR2022-00549, Ex. 2002 [Brecker Declaration] ¶¶32). Accordingly, the specification, prosecution history, and claim language all confirm that the preamble gives life and meaning to the claim and should be treated as a limitation thereon. *Pitney Bowes*, 182 F.3d at 1305.

Edwards contends that the preamble is not a limitation. But Edwards’ position here is inconsistent with its position elsewhere. Indeed, in the ’735 patent IPR Edwards treated the claim 1 preamble—an “endovascular transcatheter valve assembly” as a limitation on the claims. Ex. D, IPR2022-00549, Paper 1 [Petition] 32-35; 67-69; 99-101 (addressing the “preamble of claim 1” as a limitation); *see also* Ex. E, IPR2022-00549, Ex. 1003 [Buller Declaration] 62-68; 114-118; 161-166. Edwards’ recognition that the claim 1 preamble is a limitation in the IPRs demonstrates that Aortic’s position is correct.

IV. CONCLUSION

For the reasons noted above, the Court should adopt each of Aortic’s constructions.

Dated: November 21, 2022

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Filer: Aortic Innovations LLC

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