

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

EDWARDS LIFESCIENCES CORPORATION AND
EDWARDS LIFESCIENCES LLC,
Petitioner,

v.

AORTIC INNOVATIONS LLC,
Patent Owner.

Case IPR2023-01232
Patent 11,389,310

**PATENT OWNER AORTIC INNOVATIONS LLC'S PRELIMINARY
RESPONSE**

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2003-2039	Reserved
2040	Excerpts from the opposition proceeding to European Patent 2982337 [Spenser-II-European-Proceeding]
2041-2046	Reserved
2047	Edwards Petition for Inter Partes Review filed in IPR2022-00034 [IPR2022-00034 Petition]
2048-2050	Reserved
2051	Declaration of Stephen J.D. Brecker filed in IPR2022-00034 [Brecker-00034-Decl.]
2052	Deposition Transcript of Nigel P. Buller in IPR2022-00034 [Buller-00034-Depo.]
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2103	Declaration of Stephen J.D. Brecker filed in IPR2022-00556 [Brecker-556-Decl.]
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2126	File History of US Patent Application 2002/0151958 A1 to Chuter [Chuter-FH]
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2128	Declaration of Nigel P. Buller filed in IPR2022-00556 [Buller-556-Decl.]
2129	Edwards Petition for Inter Partes Review filed in IPR2022-00556 [-00556-Pet.]
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I. INTRODUCTION

The Petition should be denied because it fails to demonstrate a reasonable likelihood of prevailing as to any remaining challenged claim.¹ The claims require a “sealing material” including a “plurality of outwardly extending, arcuate fibers” that “extend outwardly of the frame” while remaining “in contact with the frame along the height of the sealing material” in both “the radially compressed orientation and the radially expanded orientation.” Ex. 1001 [’310] cl. 11. Petitioner’s grounds rely upon Spenser II or Chuter as satisfying the “in contact” limitation which, in its combinations, would be added to the frame of Spenser I or Levi.

Petitioner’s Spenser II grounds (Grounds 1-2) are dead on arrival. The Examiner rejected the very same combinations raised here and allowed the claims on the express basis that “the prior art does not disclose or render obvious” a “plurality of fibers [] in contact with the outer frame along the height of the sealing material when the heart valve assembly is in the radially compressed orientation and the radially expanded orientation.” Ex. 1002 [Pros.-Hist.] 21. Similarly, the

¹ Previously challenged claims 1-3, 5, and 7-8 and unchallenged claims 4, 6, and 9-10 have been disclaimed, (Ex. 2138) and thus cannot be a basis for institution. See Section IV; 37 C.F.R. § 42.107(e).

Board also found that Spenser II's compressible material "corresponds to an outer graft covering" that "would be between the surface-residing fibers and the metallic outer frame" and, thus, the "surface-residing fibers" would not contact the frame. Ex. 1120 [-00034FWD] 48; Ex. 2124 [-00556FWD] 37-38 (same). Consequently, the Spenser II grounds should be rejected under 35 U.S.C. §325(d) based upon both the Examiner's and the Board's findings and by collateral estoppel. Section II.A. If more is needed, here too, Petitioner fails to show that Spenser II discloses or renders obvious such "contact." Section II.B.

Grounds 3-6 alternatively rely on two distinct Chuter embodiments, (1) a graft/backing layer embodiment and (2) an occluder embodiment without a backing layer. As with Spenser II, Petitioner fails to show that its Chuter backing layer combinations disclose or render obvious "outwardly extending" fibers "in contact with the frame." Section III.A. Petitioner's Chuter occluder combinations fail because Petitioner fails to show that a POSITA would be motivated to combine Chuter's occluding fibers with Spenser I/Levi, or could do so with a reasonable expectation of success. See Section III.B.1. Even if that could be overlooked, Petitioner further fails to show that the resulting combination would satisfy the claims. Section III.B.2.

II. PETITIONER’S SPENSER II COMBINATIONS FAIL (GROUNDS 1-2, ALL CLAIMS).

The remaining claims require “a plurality of outwardly extending arcuate fibers that extend outwardly of the frame” that are “in contact with the frame along the height of the sealing material” in both the “radially compressed orientation” and “radially expanded orientation.” Ex. 1001 [’310] cl. 11. For Grounds 1 and 2, Petitioner contends the “in contact” limitation is satisfied by Spenser II’s compressible material. Pet., 45, 47, 50-51. Petitioner’s Spenser II grounds should be rejected under §325(d) as the very same art and arguments here were rejected by both the Examiner and the Board and should also be barred by collateral estoppel based upon the Board’s unchallenged findings. *See* Section II.A. And, even if the Board were to reconsider Petitioner’s shopworn and repeatedly rejected argument, Petitioner fails to demonstrate that the Spenser II combinations disclose or render obvious outwardly extending fibers that are in contact with the frame along the height of the sealing material. *See* Section II.B.

A. Petitioner’s Spenser II Grounds Should Be Barred By §325(d) And Collateral Estoppel.

For its Spenser II grounds, Petitioner identifies Spenser II’s compressible material as the “sealing material” and the fibers extending outwardly therefrom as the “plurality of fibers.” Pet., 26-33. Petitioner argues that Spenser II “discloses” that these outwardly extending fibers are “in contact with the frame along the

height of the sealing material,” as the claims require. *Id.*, 44-51; Ex. 1001 [’310]

cl. 11. Petitioner’s argument, however, should be rejected under §325(d) because the very same prior art and arguments were rejected by both the Examiner and the Board. See Section II.A.1. The Board’s prior decisions, moreover, give rise to collateral estoppel and preclude Petitioner from arguing that Spenser II’s extending fibers are “in contact with the frame.” See Section II.A.2.

1. Under §325(d), The Spenser II Grounds Should Not Be Again Considered.

In view of the prosecution history and the Board’s prior decisions, the Board should not revisit Petitioner’s Spenser II grounds under §325(d). Under *Advanced Bionics*’ two-part framework, the Board first determines whether the same or substantially the same art or arguments were presented to the Office (including in prosecution or “AIA post-grant proceedings”) and, if so, considers whether the petitioner has demonstrated a material error by the Office. *Advanced Bionics, LLC v. MED-EL Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6, 8, 10 (Feb. 13, 2020) (precedential). Furthermore, “[i]f reasonable minds can disagree regarding the purported treatment of the art or arguments, it cannot be said that the Office erred in a manner material to patentability.” *Id.*, 9.

As to the first prong, the “plurality of fibers is in contact with the frame” limitation played a critical role in prosecution. The Examiner issued several rejections of an earlier iteration of the claims over the very same combinations

raised here, including Spenser II (sometimes called “Dehdashtian” in prosecution), Spenser I, and/or Levi. See Ex. 1002 [Pros-Hist.] 166-175 (rejecting claims over Spenser II/Levi combination), 327-335 (combination including Levi/Spenser II), 454-459 (same), 584-587 (Spenser I and Spenser II), 587-90 (similar), 590-592 (Spenser I, Spenser II, and Levi).

Ultimately, however, the claims were allowed once they were amended to further require that the “outwardly extending” fibers be “in contact with the frame.” *Id.*, 137-142. Leaving no doubt, the Examiner’s Reasons for Allowance found that this limitation was not disclosed or rendered obvious by the prior art:

The following is an examiner’s statement of reasons for allowance: ***the prior art does not disclose or render obvious wherein the plurality of fibers is in contact with the outer frame along the height of the sealing material when the heart valve assembly is in the radially compressed orientation and the radially expanded orientation*** in combination with the recited claim features.

Id., 21.

The Examiner reached this conclusion after considering Dr. Buller’s declarations submitted in support of related IPRs (IPR2021-01527, IPR2022-00549, -00556). See *id.*, 28, 177, 267. The Examiner’s finding further mirrors the Board’s determination that Spenser II’s compressible material “corresponds to an outer graft covering” that is “between the surface-residing fibers and the metallic

outer frame.” Ex. 1120 [-00034FWD] 48; Ex. 2124 [-00556FWD] 37-38 (same); Ex. 2002 [Brecker-Decl.] ¶36. Thus, both the Examiner and the Board found that Spenser II does not disclose “outwardly extending” fibers that are “in contact with the frame.” Accordingly, the first *Advanced Bionics* prong is met.

As to the second prong, Petitioner has not shown any material error by either the Examiner or the Board. Petitioner contends that “the Examiner failed to fully consider the teachings of the prior art” and committed a “material error” in finding that “the prior art does not disclose or render obvious” the “plurality of fibers is in contact with the frame” limitation because Spenser II allegedly “disclose[s] that limitation.” Pet., 85. This is absurd. Fig. 22 makes clear that the outwardly extending fibers are **not** in contact with the frame:

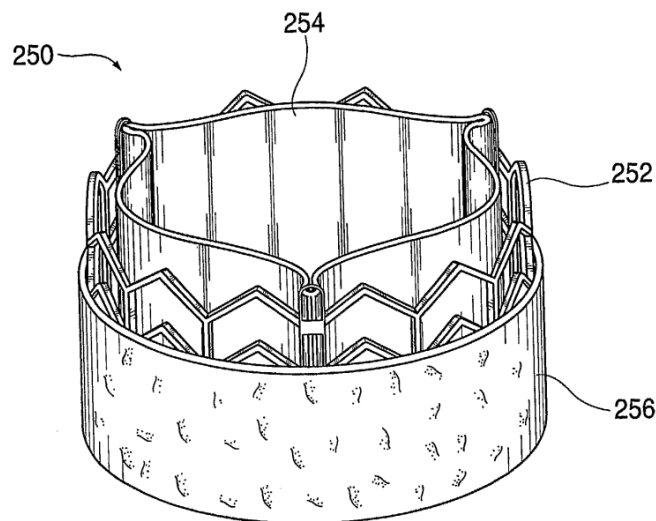


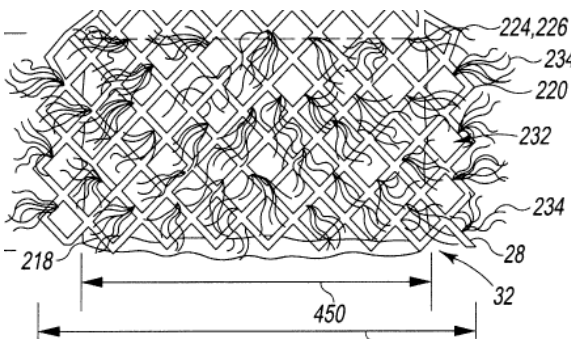
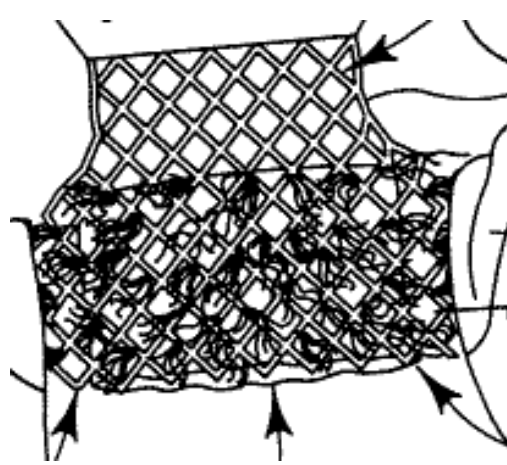
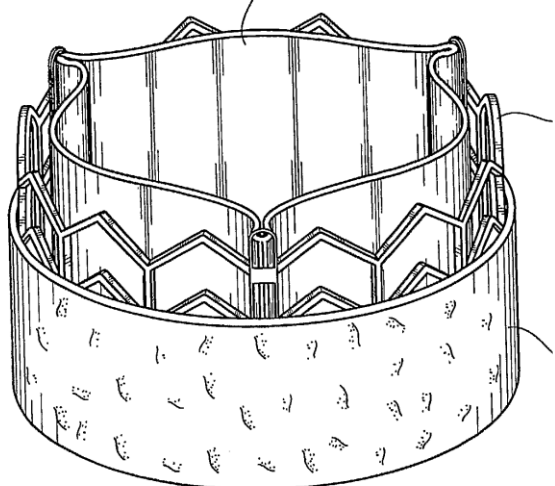
FIG. 22

Ex. 1011 [Spenser-II] Fig. 22. Nor does Spenser II describe its compressible

material's extending fibers as "contact[ing]" the frame. Rather, these fibers "extend[] from the surface" of the "sleeve," "layer," or "cloth" compressible material, which "is disposed along an outer surface of the stent" as shown in Fig.

22. Ex. 1011 [Spenser-II] ¶145; *id.*, cl. 29 ("the compressible material includes a plurality of fibers extending outward from the ***outer surface***."); Ex. 2002 [Breckers-Decl.] ¶40.

Spenser II, in this regard, stands in sharp contrast to the '310's Figs. 20-22, which were cited as support for the limitation (Ex. 1002 [Pros.-Hist.] 143), and which plainly show fibers that both extend "outwardly of" the frame and are "in contact with" the frame:

Unlike The '310's Figures, Spenser II's Outwardly Extending Fibers Are Not In Contact With The Frame	
'310	Spenser II
 Fig. 20 	 FIG. 22

Ex. 1001 ['310] Figs. 20-21; Ex. 1011 [Spenser-II] Fig. 22; Ex. 2002 [Breckner-Decl.] ¶39.

Petitioner, moreover, does not even mention the Board's prior findings that Spenser II's compressible material/graft covering "would be between the surface-residing fibers and the metallic outer frame." Ex. 1120 [-00034FWD] 48; Ex.

2124 [-00556FWD] 37-38 (same). Petitioner certainly does not show that the Board erred in this regard. To the contrary, Petitioner withdrew its appeal of the Board's IPR2022-00034 decision (Ex. 2137) and did not (and cannot) appeal the IPR2022-00556 decision.

Though it acquiesced to the Board's contrary findings, Petitioner nonetheless contends that §325(d) should not apply as the Board has found Petitioner's Spenser I/Spenser II combination is endovascularly deliverable. Pet., 85-89. This is a *non sequitur*. The Examiner did not allow the claims because the prior art was not endovascularly deliverable. The claims were allowed because the very same combinations raised here do not disclose or render obvious a "plurality of outwardly extending [] fibers" that are "in contact with the frame," as confirmed by the Examiner's reasons for allowance. Ex. 1002 [Pros.-Hist.] 21, 137-142. Thus, the actual and express basis for allowance was entirely consistent with and confirmed by the Board's findings.

Accordingly, Petitioner fails to show the Examiner (much less the Board) materially erred, and the second *Advanced Bionics* prong is met. Thus, Petitioner's Spenser II grounds should be denied institution under §325(d).

2. Petitioner Is Precluded From Arguing That Spenser II's Extending Fibers Are "In Contact With The Frame."

As discussed, the Board repeatedly found that Spenser II's compressible material "corresponds to an outer graft covering" which "would be between the

surface-residing fibers and the metallic outer frame.” Ex. 1120 [-00034FWD] 48; Ex. 2124 [-00556FWD] 37-38 (same). Due to the presence of an intervening graft covering between the surface-residing fibers and the frame, Spenser II’s outwardly extending fibers are not “in contact with the frame along the height of the sealing material.” Thus, the Board has already rejected Petitioner’s argument. These findings give rise to collateral estoppel and Petitioner is precluded from rearguing that Spenser II’s outwardly extending fibers are in contact with the frame along the height of the sealing material. Petitioner’s Spenser II grounds are further barred by the law of the case doctrine.

“It is well established that collateral estoppel applies to IPR proceedings.” *Google LLC v. Hammond Dev. Int’l, Inc.*, 54 F.4th 1377, 1381 (Fed. Cir. 2022); *M2M Sols. LLC v. Amazon.com, Inc.*, 2023 U.S. App. LEXIS 4053 at *10-11 (Fed. Cir. Feb. 22, 2023). Collateral estoppel applies where (1) the issue is identical to one decided in the first action; (2) the issue was actually litigated in the first action; (3) resolution of the issue was essential to a final judgment in the first action; and (4) the party against whom collateral estoppel is being asserted had a full and fair opportunity to litigate the issue in the first action. *Google*, 54 F.4th at 1381 (quoting *In re Freeman*, 30 F.3d 1459, 1465 (Fed. Cir. 1994)).

These elements are met. First, the Board’s findings that Spenser II’s compressible material/graft covering “would be between” Spenser II’s extending

“fibers and the outer frame,” was central to its determination that Petitioner’s same Spenser II grounds did not disclose or render obvious limitations requiring that either the “outer seal” or “valve assembly” be “free of an outer graft covering ***between the [first portion of] fibers and the outer frame.***” See Ex. 2124 [-00556FWD] 38-39; Ex. 1120 [-00034FWD] 48-49; Ex. 2132 [’846] cl. 1; Ex. 2133 [’236] cl. 1. Per the Board, Spenser II discloses an outer graft covering between the outwardly extending fibers and the frame.

While the presence of “an outer graft covering” is not specifically at issue, Petitioner’s argument raises the same issue decided by the Board. Petitioner, here, again relies upon Spenser II’s compressible material as the “sealing material” and the fibers extending from the outer surface thereof as the “plurality of fibers.” Pet., 26-33. The Board’s findings that Spenser II’s compressible material/graft covering “would be between” Spenser II’s extending “fibers and the outer frame” conclusively establish that these same extending fibers are not also “in contact with the frame along the height of the sealing material.” Ex. 1120 [-00034FWD] 48; Ex. 2124 [-00556FWD] 37-38 (same). Thus, the issue of whether Spenser II’s fibers “contact [] the frame” was already decided by the Board. See also *Ohio Willow Wood Co. v. Alps South, LLC*, 735 F.3d 1333, 1342 (Fed. Cir. 2013) (“Our precedent does not limit collateral estoppel to patent claims that are identical. Rather, it is the identity of the issues that were litigated that determines whether

collateral estoppel should apply.”); *Rimfrost AS v. Aker BioMarine Antarctic AS*, IPR2018-01730, Paper 35, 21-24 (PTAB Mar. 6, 2020) (similar).

Second, the issue was actually and thoroughly litigated. The finding that there was a graft covering between the fibers and the frame was central to the Board’s determinations that Petitioner’s same Spenser II grounds failed to satisfy the “free of an outer graft covering” limitations. *See* Ex. 2124 [-00556FWD] 38-39; Ex. 1120 [-00034FWD] 48-49; Ex. 2047 [-00034Pet.] 58; Ex. 2129 [-00556Pet.] 75-76, 98-99; Ex. 2108 [IPR2022-00034-Reply] 29-31; IPR2022-00034, Paper 24 (POR), 67-71, 81-89; IPR2022-00034, Paper 36 (Sur-Reply) 19-22; Ex. 2130 [IPR2022-00556-Reply] 19-22; IPR2022-00556, Paper 18 (POR), 35-41; IPR2022-00556, Paper 27 (Sur-Reply) 1-10.

Third, the Board’s findings that Spenser II’s compressible material (*i.e.*, a graft covering) “would be between the surface-residing fibers and the metallic outer frame” were central to its determinations that the “free of an outer graft covering” limitations were not met. The Board noted that this issue was “dispositive” in both proceedings and, thus, essential to both judgments. Ex. 2124 [-00556FWD] 16; Ex. 1120 [-00034FWD] 15.

Fourth, as discussed, Petitioner had a full and fair opportunity to litigate the “free of an outer graft covering” limitations, arguing the limitations throughout both proceedings.

Thus, the four elements for collateral estoppel are met and Petitioner should be barred from arguing that Spenser II's outwardly extending fibers are "in contact with the frame" along the height of the sealing material. Nor, furthermore, can there be any doubt as to the finality of the Board's decisions, as Petitioner has withdrawn its appeal of IPR2022-00034 (Ex. 2137) and its deadline to appeal IPR2022-00556 has passed.

Petitioner's arguments under Spenser II should also be barred by the law of the case doctrine. The Board "cautioned" the parties "against raising issues ... that have previously been heard and decided by the Board in the related cases" as "the doctrine of the law of the case generally bars retrial" of previously resolved issues. IPR2022-00556, Paper 30 (Order Setting Oral Argument) 2-3 (citing *Intergraph Corp. v. Intel Corp.*, 253 F.3d 695, 697–98 (Fed. Cir. 2001); MPEP §706.07(h)(XI)(A) ("a Board decision in an application is the 'law of the case,' and is thus controlling in that application and any subsequent, related application"). The Board noted that "[e]xceptions to this doctrine apply only if: (1) new and materially different evidence is relied upon in the subsequent appeal; (2) an intervening change of controlling legal authority occurred; or (3) the earlier ruling was clearly erroneous and would work a manifest injustice." IPR2022-00556, Paper 30 (Order Setting Oral Argument) 2-3 (citing *Intergraph*, 253 F.3d at 698). None of these exceptions apply. Again, Petitioner's grounds here are identical to

the prior IPRs. Nor has any intervening change of legal authority has been presented, and, again, Petitioner withdrew its appeal of the IPR2022-00034 decision and elected not to challenge the IPR2022-00556 decision. Dr. Buller has, furthermore, accepted the Board’s decision in IPR2022-00034, including as to Fig. 22. Ex. 2122 [Buller-556-Reply-Depo.] 11:5-8, 10:9-11:4, 13:22-14:5.

B. Petitioner Fails To Prove That Spenser II Discloses Or Renders Obvious Fibers That Extend “Outwardly Of The Frame” And Remain “In Contact With The Frame.”

Thus, for numerous reasons, the Board should not even consider Petitioner’s Spenser II grounds. But even if they were to be revisited, Petitioner again fails to prove that its Spenser II combinations disclose or render obvious the “plurality of fibers is in contact with the frame along the height of the sealing material” “in the radially compressed orientation and the radially expanded orientation” limitation. Ex. 1001 [’310] cl. 11. See Section II.B.1. Petitioner’s arguments to the contrary lack merit. See Section II.B.2.

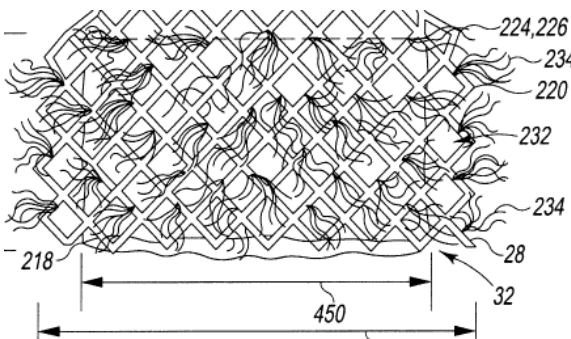
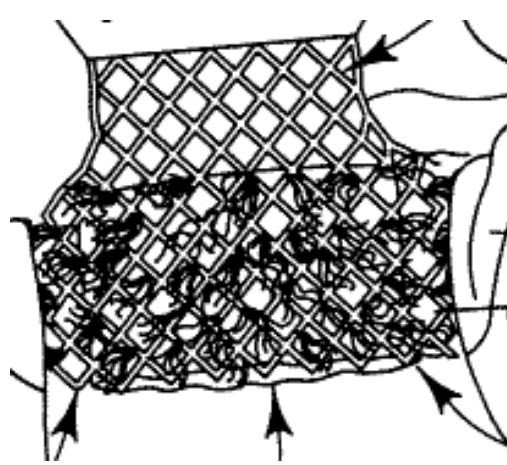
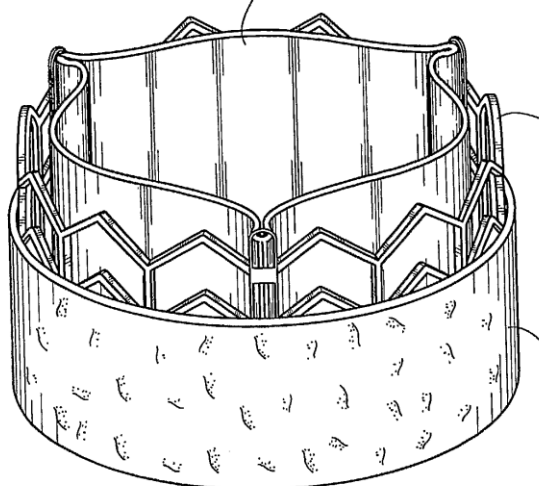
1. Spenser II’s Extending Fibers Are Not In Contact With Its Frame.

Petitioner argues that Spenser II’s Fig. 22 and related discussion “discloses” its “radially extending fibers ... to be in direct contact with the frame.” Pet., 47. Spenser II discloses no such thing.

As the Board has already found, Spenser II’s compressible material is “between the surface-residing fibers and the metallic outer frame.” Ex. 1120 [-

00034FWD] 48; Ex. 2124 [-00556FWD] 37-38 (same). Petitioner does not even mention these findings, much less explain any way in which the Board misapprehended Spenser II.

Nor could it. Spenser II neither discloses nor depicts fibers extending “outwardly of the frame” that are, nonetheless, “in contact with the frame.” And Spenser II’s Fig. 22—depicting fibers extending outwardly from what Petitioner refers to as a “base layer”—bears no resemblance to Figs. 20-22 of the ’310, which the Applicant identified as supporting the limitation:

Unlike The '310's Figures, Spenser II's Outwardly Extending Fibers Are Not In Contact With The Frame	
'310	Spenser II
 Fig. 20 	 FIG. 22

Ex. 1001 ['310] Figs. 20-21; Ex. 1011 [Spenser-II] Fig. 22; Ex. 2136 [-01151-Pet.] 66; *see also* Ex. 1002 [Pros.-Hist.] 143 (identifying '310 Figs. 20-22 as supporting limitation); Ex. 2002 [Brecker-Decl.] ¶39. In accord, the Board has credited Dr. Brecker's testimony that Spenser II's compressible material "look[s] nothing like what is presented in the Patent ... [which] teaches ... outwardly ... extending

fiber[s] ... and the lack of an outer graft covering.” Ex. 1120 [-00034FWD] 44 (citing Ex. 2051 [Brecker-00034-Decl.] ¶¶37-40).

Spenser II, moreover, describes its compressible material as a “layer,” “cloth,” or “sleeve,” with “small fibers extending *from the surface* of the material.” Ex. 1011 [Spenser-II] ¶145. Spenser II’s claim 29 confirms that these fibers “extend[] outward from the outer surface” of the material. *Id.*, cl. 29. There is no disclosure or suggestion that these outer surface residing fibers do or could contact the frame, which is on the opposite surface of the compressible material. Ex. 2002 [Brecker-Decl.] ¶40. Nothing in Spenser II’s description indicates such contact.

And, even if we were to imagine that some of the compressible material’s fibers extending outwardly from the *outer* surface of the base layer were, somehow, “in contact with the frame,” there is no basis upon which to conclude that such contact would be maintained “along the height of the sealing material.” Petitioner does not contend that Spenser II discloses or suggests that the compressible material’s base layer is, itself, formed of outwardly extending fibers, nor does Spenser II indicate anything of the sort. Indeed, Spenser II describes no contact whatsoever between its outwardly extending fibers and the frame. Rather, Figure 22 and the corresponding description only teach fibers extending outwardly from the base layer of the same compressible material that the Board found

“corresponds to an outer graft covering” “between the surface-residing fibers and the metallic outer frame”:

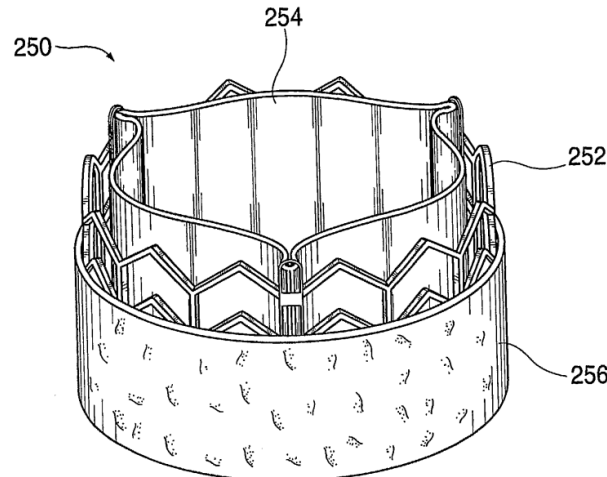


FIG. 22

Ex. 1011 [Spenser-II] Fig. 22, ¶145; Ex. 1120 [-00034FWD] 48; Ex. 2124 [-00556FWD] 37-38 (same); Ex. 2002 [Brecker-Decl.] ¶¶42-43.

2. Petitioner’s Arguments That Spenser II Discloses Or Renders Obvious The “Plurality Of Fibers [] In Contact With The Frame” Limitation Fail.

Petitioner argues, in the alternative, that Spenser II both discloses and renders obvious outwardly extending fibers in contact with the frame. These arguments fail. See Sections II.B.2(a)-(b). Petitioner further argues that Spenser II discloses this limitation under an erroneous construction—directly at-odds with the plain language of the claims—that would merely require any aspect of the “sealing material,” but not necessarily the “plurality of outwardly extending [] fibers,” to be

“in contact with the frame.” This construction is wrong and Petitioner’s corresponding arguments are irrelevant. See Section II.B.2(c).

a. *Petitioner’s Inherency Arguments Fail.*

Ignoring the Board’s conclusive findings to the contrary, Petitioner contends that Spenser II “discloses” its “radially extending fibers ... to be in direct contact with the frame.” Pet., 47. Petitioner argues the limitation is inherently met, relying not upon what Spenser II says, but rather upon what a POSITA supposedly “would have understood” about what “may be” present in Spenser II:

[I]n Spenser II’s embodiments having a cloth/fabric with fibers extending from the surface, **POSITAs would have understood** that at least some of the fibers extending from the surface would be in direct contact with the frame. In a cloth/fabric with fibers extending from a base layer embodiment, **a POSITA would have understood** that the radially extending fibers **may be** attached to the base layer by weaving or knitting the fibers through the base layer.

Pet., 47.

Arguments about what a POSITA supposedly “would have understood” lie in inherency. *Microsoft Corp. v. Biscotti, Inc.*, 878 F.3d 1052, 1065 (Fed. Cir. 2017) (statements that “a [POSITA] would understand the [evidence] as disclosing [the limitation]” could support an argument that a limitation was “inherently disclose[d] ...”); *LBT IP I LLC v. Apple Inc.*, 2023 U.S. App. LEXIS 14376, *8 (Fed. Cir. June 9, 2023) (arguments that “there is no explicit disclosure” of a

limitation but that POSITAs “nevertheless ... would understand this [limitation] is present” are arguments that the limitation “is inherently disclosed.”).

Demonstrating obviousness by inherency requires meeting the “high standard” of showing that the limitation “**necessarily** must be present.” *Par Pharm., Inc. v. TWI Pharms., Inc.*, 773 F.3d 1186, 1195-1196 (Fed. Cir. 2014).

Petitioner, however, falls far short of proving that the fibers extending from the outer surface of Spenser II’s compressible material’s base layer are **necessarily** “in contact with the frame.” As noted, the Board has already found that Spenser II’s compressible material lies “between the surface-residing fibers and the metallic outer frame.” Ex. 1120 [-00034FWD] 48; Ex. 2124 [-00556FWD] 37-38 (same).

What is more, Petitioner’s own statement is self-defeating. Even if Petitioner’s statement were taken as true, the claims would not be met. Petitioner first states that “POSITAs would have understood **that at least some of the fibers** extending from the surface would be in direct contact with the frame.” Pet., 47. No such thing is suggested by Spenser II. See Section II.B.1. But, even if “some” of the extending fibers, somehow, contacted the frame, this would not necessarily indicate contact “along the height of the sealing material.” Certainly, Petitioner has not shown that such “contact” **necessarily** must be present.

Indeed, even Petitioner does not appear to seriously believe that Spenser II

necessarily discloses the limitation given its contrary statement that “the radially extending fibers **may** be attached to the base layer by weaving or knitting the fibers through the base layer.” Pet., 47. Even assuming a cloth’s outwardly extending fibers **may** be woven/knitted through the base layer, this would only confirm that it may not be and, thus, it is not **necessarily** the case. *Par Pharm.*, 773 F.3d at 1196 (“[i]nherency [] may not be established by probabilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.”) (citation omitted); *LBT IP I LLC*, 2023 U.S. App. LEXIS 14376 at **9-10 (Fed. Cir. 2023) (“qualifying language such as ‘presumably,’ ‘maybe,’ and ‘might’” “fails to meet [the] standard for inherent disclosure.”).

Far from being necessarily present, Spenser II does not necessarily disclose multiple aspects of the limitation relating to the fibers being in contact with the frame. As Dr. Brecker explains:

There is no basis upon which to conclude a POSITA reading Spenser II’s disclosure would conclude the outwardly extending fibers are necessarily “in contact with the frame along the height of the sealing material.” Ex. 1001 [’310] cl. 11. Spenser II contains no such disclosure or suggestion.

Starting with what Spenser II does disclose, nothing therein suggests this limitation is necessarily present. Spenser II does not describe or depict fibers extending “outwardly of the frame” while remaining “in contact with the frame.” Rather, Spenser II’s specification only

mentions “fibers extending *from the surface*” of the compressible material, which is described as a “layer,” “cloth,” or “sleeve” that is “disposed along an outer surface of the stent.” Ex. 1011 [Spenser-II] ¶¶145, 55; see also *id.*, cl. 29 (“the compressible material includes a plurality of fibers extending outward from the *outer surface*.”). This is entirely consistent with what we see in Fig. 22, fibers extending from the outer surface of a base layer:

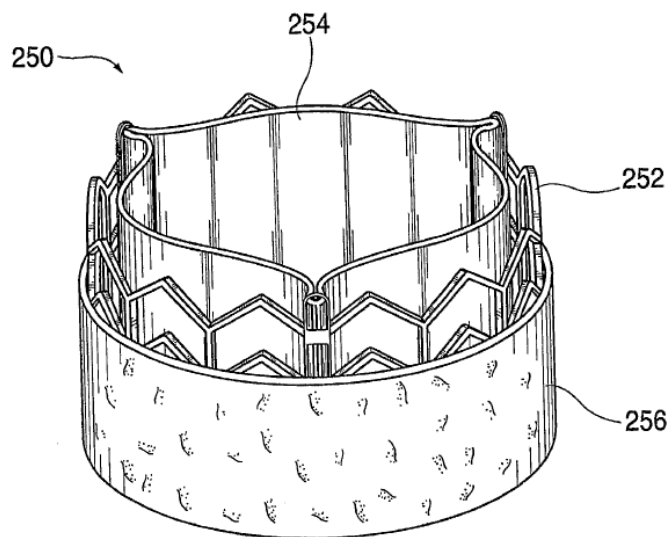


FIG. 22

Id., Fig. 22; Ex. 2136 [-01151-Pet.] 47 (“Spenser II’s compressible material includes a base layer of fibers...”), 66 (“Spenser II’s compressible material may include cloths/fabrics having a base layer ... and fibers extending outwardly from the base layer.”).

Certainly, neither the compressible material’s description nor its depiction in Fig. 22 indicate fibers that extend “outwardly of the frame,” while remaining “in contact with the frame along the height of the sealing material.” There is, at the very least, no basis to believe that this would necessarily be so.

Petitioner argues that the outwardly extending fibers “may” be weaved or knitted through the base layer and would, therefore, be in contact with the frame. Pet., 47. Dr. Buller similarly contends that POSITAs would have understood that the extending fibers “would be attached to the base layer by weaving or knitting the fibers through and around the base layer.” Ex. 1003 [Buller-Decl.] ¶168. But, Spenser II does not disclose how its outwardly extending fibers are attached to the cloth, so there is no basis to conclude that the undisclosed attachment method would necessarily result in the outwardly extending fibers contacting the frame, as further discussed below. Petitioner seems to agree this would not necessarily be so, arguing only that the fibers “may” be weaved or knitted in the manner imagined. Pet., 47. And, as Dehdashtian explains, such fibers may be “partially integrated into the weave” and “placed along the exterior” of the cloth. Ex. 2101 [Dehdashtian] 5:12-24, 3:7-16, 3:37-41.

And, even if we were to assume some of the outwardly extending fibers somehow contacted the frame, there is no basis upon which to conclude the contact would extend “along the height of the sealing material.” The inner surface of Spenser II’s compressible material is not described, and there is no suggestion that any incidental contact would be present along the height of the compressible material, much less that this would necessarily be the case.[]

Petitioner and Dr. Buller’s position is, thus, based on several unsubstantiated assumptions, none of which are shown to necessarily be so. Instead, I fully agree with the Board’s findings that Spenser II’s compressible material/graft covering “would be between the

surface-residing fibers and the metallic outer frame.” Ex. 1120 [-00034FWD] 48; Ex. 2124 [-00556FWD] 37-38 (same). Such fibers would not contact the frame.

Ex. 2002 [Brecker-Decl.] ¶¶50-55.

Petitioner’s argument is, furthermore, inconsistent with its previous positions. Here, Petitioner contends that because Spenser II’s “radially extending fibers” allegedly “may be attached to the base layer by weaving or knitting the fibers through the base layer,” POSITAs “**would have understood** that at least some” of the extending fibers “would be in direct contact with the frame.” Pet., 47. But, in IPR2022-00556 (“-00556”), Dr. Buller and Petitioner argued that Spenser II’s compressible material has outwardly extending fibers on its outer surface that are distinct from allegedly present inwardly extending fibers on its inner surface, and that it is these inwardly facing fibers that “would press against the bars of the outer frame”:

[POSITAs] **would have understood** that ... Spenser II's compressible material would include ... **radially extending fibers on its inward-facing surface that would press against the bars of the outer frame** when disposed along the exterior thereof.

Ex. 2128 [Buller-556-Decl.] ¶195; Ex. 2129 [-00556-Pet.] 72 (similar); Ex. 1128 [Buller-556-Depo.] 123:18-20 (“I regard the disclosure of fibers from the surface to include the inner surface.”), 124:21-23 (“that is an express disclosure of fibers

on the outer and inner surface of the material”), 115:23-116:1, 120:2-3; *see also* Ex. 2134 [Buller-556-Reply-Decl.] ¶82 (POSITAs “**would have understood** that having extending fibers on both the inner and outer surfaces of the compressible material would be helpful in promoting blood clotting.”). Indeed, Dr. Buller was adamant that no reasonable interventional cardiologist could disagree with his assessment. *See* Ex. 1128 [Buller-556-Depo.] 125:7-19, 126:17-127:1.

Thus, previously, Petitioner and Dr. Buller insisted that it is the alleged **inwardly**-facing fibers extending from the inner surface of the compressible material which press against the frame. Now, Petitioner contends that a POSITA “would have understood” that it is the **outwardly** extending fibers from the compressible material’s outer surface that contact the frame. Petitioner’s positions are irreconcilable and under Petitioner’s prior position, the outwardly extending fibers are, due to the intervening compressible material/graft covering and the allegedly inwardly facing fibers, two layers removed from the frame. Ex. 2002 [Breckner-Decl.] ¶¶57-58.

Nor can Petitioner’s position here be reconciled with its position in European opposition proceedings. There, Petitioner dismissed as “unfounded” the notion that Spenser II’s extending fibers would have to “extend **from the stent** through the material and outwardly of it.” Petitioner further insisted that “according to the **only** reasonable interpretation,” the fibers would be understood

to extend from “the outer surface of the compressible material.” Ex. 2040

[Spenser-II-European-Proceeding] 149; *see also id.* (“The description is also in line with this understanding, as becomes clear from *e.g.*, the wording in paragraph [0064] of the patent: ‘The compressible material 256 resembles a cloth or fabric having small fibers extending from the surface of the material.’”). Thus, in European proceedings, Petitioner was adamant that the fibers could not extend from the stent/frame and yet now it argues that a POSITA would necessarily understand the fibers to extend from the stent/frame. Ex. 2002 [Breckner-Decl.]

¶59. Such inconsistent argumentation should not be countenanced.

Having taken multiple, diametrically opposing positions about what Spenser II discloses, Petitioner cannot possibly prove that Spenser II inherently discloses that the outwardly extending fibers contact the frame along the height of the sealing material.

Writing anew without regard to its prior, conflicting positions, Petitioner nevertheless contends that “[t]he prior art disclosed many fabrics ... such as woven or knitted velours” with outwardly extending fibers that “extend through the base layer and, therefore, would be in contact with the frame when disposed along the exterior of a THV.” Pet., 48. Petitioner points to three alleged “examples” of such fabrics: Koch (Ex. 1134), Sauvage (Ex. 1135) and Norris (Ex. 1074). Pet., 47-50. These “examples,” however, do not show that the outwardly extending fibers of

any velour or velour-like woven/knitted fabric would **necessarily** be “in contact with the frame,” much less “along the height of the sealing material.”

As an initial matter, there is no disclosure that Spenser II’s fibers are woven or knitted through to the frame. Nor is such disclosure present in other prior art woven/knitted grafts. Dehdashtian, for instance, teaches that the fibers may be “partially integrated into the weave” and “placed on the exterior of the graft body.” Ex. 2101 [Dehdashtian] 5:12-24, 3:7-16, 3:37-41. Norris, which, like Spenser II and Dehdashtian, teaches fibers/loops extending outwardly from an intervening graft, similarly confirms that fibrous loops may extend from a ground layer **without** contacting the frame. Ex. 2002 [Brecker-Decl.] ¶62. This is illustrated in Norris’ Figs. 1 (shown below with Petitioner’s annotations), 2 and 3:

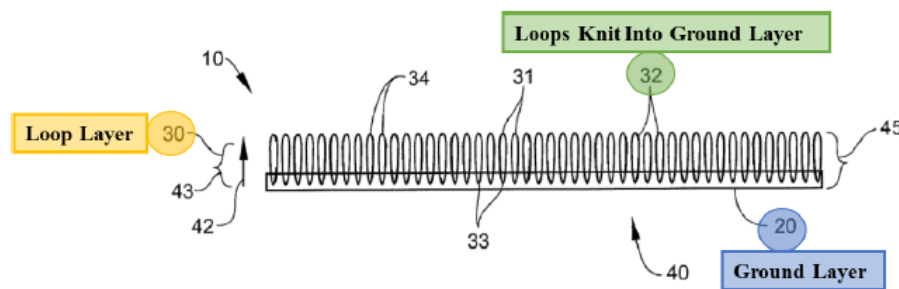


Fig. 1

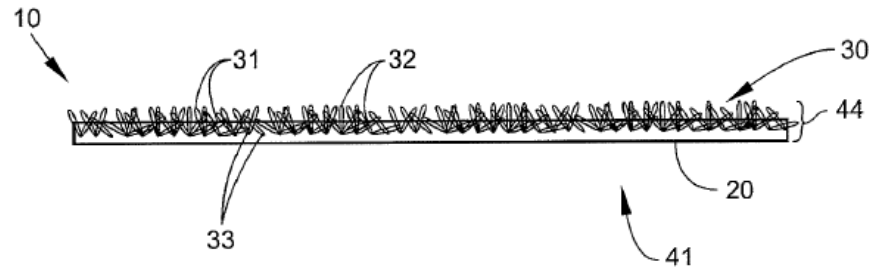


Fig. 2

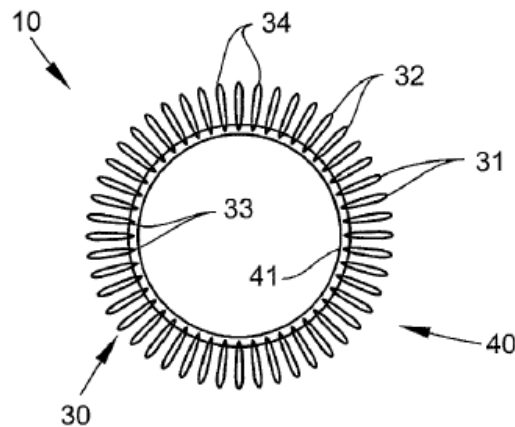


Fig. 3

Pet., 78; Ex. 1074 [Norris] Figs. 1-3. Norris' figures plainly show its loops being knitted into the ground layer without contacting the frame. Nor does Norris contain any disclosure or suggestion that the ground layer, itself, is formed of extending fibers/loops. *See, e.g.*, Ex. 1074 [Norris] 4:22-26 (teaching "a plurality of loops 32 of yarn 31, each loop 32 having a point 33 knit into the ground layer 20."). Thus, the same reference and figures Petitioner relies upon to demonstrate that POSITAs would understand that Spenser II's outwardly extending fibers are ***necessarily*** "in contact with the frame," instead plainly teach the absence of any such "contact." Ex. 2002 [Breckner-Decl.] ¶62. Indeed, Petitioner's Chuter

reference similarly depicts backing layer embodiments wherein the fibers do not extend through to the frame. See Section III.A; Ex. 1116 [Chuter] Figs. 2, 4.

Petitioner alternatively presents yet another inherency argument, asserting that a “POSITA would have understood” that Spenser II “disclose[s]” an alternative embodiment wherein the fibers are “are attached directly to the frame, as opposed to the surface of a cloth.” Pet., 50-51 (citing Ex. 1003 [Buller-Decl.] ¶173; Ex. 1011 [Spenser-II] ¶145). But this argument has, again, already been rejected by the Board which has repeatedly found that Spenser II’s compressible material “corresponds to an outer graft covering” positioned “between the surface-residing fibers and the metallic outer frame.” Ex. 1120 [-00034FWD] 48 (the “fibers extending outwardly ... arise from the surface of the cloth.”); Ex. 2124 [-00556FWD] 37-38 (same). And the Board’s dispositive, and unchallenged, ruling was correct; Spenser II plainly does not disclose any embodiment where the cloth/graft is not between the outwardly extending fibers and the frame. Ex. 2002 [Brecker-Decl.] ¶63.

b. *Petitioner Fails To Prove A POSITA Would Be Motivated To Modify Spenser II So That The Outwardly Extending Fibers Are In Contact With The Frame.*

Petitioner further contends that “POSITAs would have been motivated, and found it obvious, to make Spenser II’s compressible material out of [] velour fabrics” such as disclosed in Norris, Sauvage and Koch, “due to their known

benefits” of “promot[ing] tissue ingrowth,” “enhanc[ing] blood coagulation,” and being “highly compressible.” Pet., 50. Petitioner, however, does not explain the relevance of compressibility to weaving/knitting the outwardly extending fibers through the base layer such that they would be “in contact with the frame.” As discussed, even Norris, which Petitioner repeatedly describes as “highly compressible,” shows none of its extending loops contacting the frame, as confirmed by, *e.g.*, Petitioner’s annotated Fig. 1:

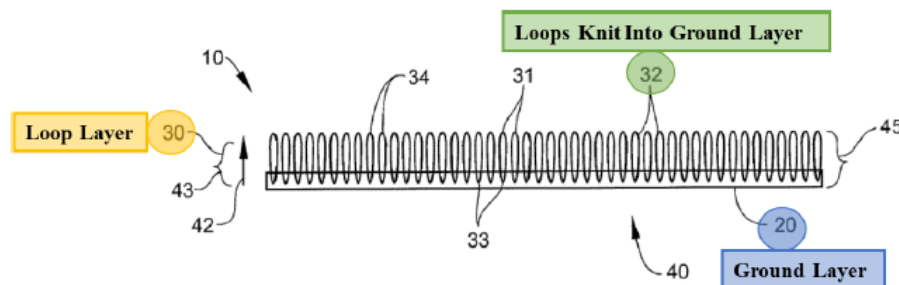


Fig. 1

Pet., 10 (“Norris’s fabric is highly compressible”), 50 (similar), 78; Ex. 1074 [Norris] Fig. 1; *see also* Ex. 1074 [Norris] Figs. 2-3; Ex. 2002 [Brecker-Decl.] ¶66. Norris further teaches that its loops “promote clot formation” and that its “multifilament loop yarn 31 can promote enhanced cellular ingrowth and encapsulation to promote clotting and fixation of the fabric 10 to a vessel wall.” Ex. 1074 [Norris] 6:6-8, 10:14-16, 8:50-52, 9:34-36 (“the loops 32 can comprise a thrombogenic material, such as polyester, that can further enhance clotting.”), 5:57-62, 10:64-11:3. Thus, to the extent POSITAs believed Norris to be of any

relevance, they would conclude that these goals could be achieved without the outwardly extending fibers contacting the frame. Ex. 2002 [Brecker-Decl.] ¶166.

Dr. Buller, in other matters, has argued both that a POSITA would be motivated to make Spenser II's compressible material "as compressible as possible," and that Spenser II expressly discloses fibers extending radially inwardly from the inner surface of its compressible material's base layer, which "press against the bars of the outer frame." *Compare* Ex. 2134 [Buller-556-Reply-Decl.] ¶57 *with id.*, ¶82; Ex. 2128 [Buller-556-Decl.] ¶195. Thus, in Dr. Buller's view, a desire to make Spenser II's cloth as "compressible as possible" is consistent with the presence of inwardly facing fibers that would press against the frame. These inwardly facing fibers, of course, would preclude the outwardly extending fibers from contacting the frame.

As for promoting tissue ingrowth and enhancing blood coagulation, these are just reasons why Spenser II teaches outwardly extending fibers, as Dr. Brecker explains:

The goals of enhancing blood coagulation and promoting tissue ingrowth are each reasons that Spenser II's compressible material may include outwardly extending fibers on its outer surface. Spenser II tells us directly that it is "the fibers" that "encourage coagulation of blood to further fill the gaps and prevent leakage." Ex. 1011 [Spenser-II] ¶145. Further, a growth factor may be applied to the

extending fibers to further promote tissue ingrowth where the cloth attaches to the vessel wall. *Id.*, ¶¶145, 55.

Thus, while enhancing clotting or promoting tissue ingrowth are reasons why Spenser II's compressible material may include outwardly extending fibers, these benefits, already described in Spenser II, would not motivate a POSITA to alter Spenser II in any way.

Nor is there any need for the outwardly extending fibers to contact the frame to confer these pre-existing benefits. As discussed, Dr. Buller himself argued that Spenser II disclosed distinct, inwardly facing fibers and that it is these fibers (not the outwardly facing ones) that “press against the bars of the outer frame.” Ex. 2128 [Buller-556-Decl.] ¶195. Norris, as we have seen, also teaches that outwardly extending fibers may extend partially through the cloth without any requirement that they be in any contact with the frame. *See, e.g.*, Ex. 1074 [Norris] Figs. 1-3. This is further confirmed by Dehdashtian—whose lead inventor apparently contributed Fig. 22 to Spenser II[]—which teaches “additional” outwardly extending fibers that are only “partially” integrated into a woven graft where they are placed on the “exterior” surface of the cloth. Ex. 2101 [Dehdashtian] 5:12-24, 3:7-16, 3:37-41. Quite simply, nothing suggests that a POSITA would be motivated to modify Spenser II by having the outwardly extending fibers contact the frame along the height of the sealing material.

Ex. 2002 [Brecker-Decl.] ¶¶69-71; *compare* Ex. 2102 (listing Spenser, Benichou and Bash as inventors) *with* Ex. 1011.

Thus, Petitioner has not shown why its proffered motivations of promoting tissue ingrowth, enhancing blood coagulation, and high compressibility would motivate POSITAs to address those goals by weaving/knitting the outwardly extending fibers through the base layer such that they would be “in contact with the frame along the height of the sealing material.”

Petitioner’s proposed modification further suffers because neither Norris nor Petitioner’s other “examples” of known velour materials (Sauvage and Koch) are included in Petitioner’s combinations. See Pet., 17. Indeed, to the extent Petitioner is arguing that a POSITA would have modified Spenser II in view of Norris, Sauvage, or Koch, its failure to include them in its combinations is insufficient to “show a motivation to combine existing components in the manner claimed free of hindsight.” *RPX Corp. et al. v. Parity Networks, LLC*, IPR2018-00097, Paper 7, 14 (PTAB Apr. 24, 2018) (“Petitioner also cites to several other references ... but does not assert these references are part of the combination. Relying on knowledge in the art does not ... show a motivation to combine existing components in the manner claimed free of hindsight motivation.”) (denying institution).

Petitioner’s argument is, at best, driven by hindsight. What is more, because none of the references in its combinations disclose the limitation in question, Petitioner must further clear the high bar associated with proving obviousness in

the face of a missing limitation. Indeed, the Federal Circuit has established a rigorous framework for obviousness in the case of a “missing limitation,” and has cautioned that using “common sense” to establish an undisclosed limitation is “the exception rather than the rule.” *Arendi S.A.R.L. v. Apple Inc.*, 832 F.3d 1355, 1361-63 (Fed. Cir. 2016) (“In cases in which ‘common sense’ is used to supply a missing limitation ... our search for a reasoned basis for resort to common sense must be searching.”); *see also DSS Tech. Mgmt. v. Apple Inc.*, 885 F.3d 1367, 1374-75 (Fed. Cir. 2018) (rejecting “ordinary creativity” as a basis for overcoming a missing limitation); *K/S HIMPP v. Hear-Wear Techs., LLC*, 751 F.3d 1362, 1366 (Fed. Cir. 2014) (rejecting “basic knowledge” as a basis for overcoming a missing limitation). And the obviousness analysis must be particularly searching where the missing limitation goes to the “heart of [the] invention.” *Arendi*, 832 F.3d at 1363. This is precisely the case here where the outwardly extending fibers contacting the frame limitation was the basis for allowance. *See* Section II.A.1; Ex. 1002 [Pros.-Hist.] 21.

Thus, for a multitude of reasons, Petitioner has not shown that a POSITA would be motivated to modify Spenser II so as to achieve the claimed invention.

c. *Petitioner’s Argument That Spenser II’s “Sealing Material” Is In Contact With The Frame Is Irrelevant.*

Petitioner also advances arguments under an alternative interpretation of the limitation which would require the “sealing material,” but not necessarily the

“plurality of outwardly extending [] fibers,” to be “in contact with the frame.”

Pet., 44-45.

Petitioner’s argument is meritless. Fatally, its interpretation is utterly at odds with the claims, which expressly require that the “***plurality of fibers is in contact with the frame*** along the height of the sealing material.” Ex. 1001 [’310] cl. 11; Ex. 2002 [Breckner-Decl.] ¶73. An interpretation wherein the claim is rewritten so that the “plurality of fibers” need not be in contact with the frame would be contrary to the plain meaning. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (“the words of a claim ‘are generally given their ordinary and customary meaning.’”). Tellingly, even Petitioner does not contend that this is a correct construction.

Instead, Petitioner contends that it advances its corresponding arguments based on the contention that Patent Owner “suggested,” “rel[ied] on” or “alleged” this interpretation in prosecution and in its infringement contentions. Pet., 44-45, 47. This is false.

Petitioner contends that the Applicant “suggested that this limitation is met if the ‘sealing material is in contact with the outer frame.’” Pet., 44. Petitioner relies on the Applicant’s arguments that Levi could not meet the limitation, at least because its outer skirt (alleged “sealing material”) “billows outwardly” and, therefore, would not be “in contact with the frame along the height of the sealing

material in the radially compressed orientation and the radially expanded orientation.” *Id.*; see Ex. 1002 [Pros.-Hist.] 144-148. But this is entirely consistent with the plain language of the claims requiring the “plurality of outwardly extending [] fibers” to be “in contact with the frame” in both the “radially compressed” and the “radially expanded” orientations. To be sure, Levi’s outer skirt has no outwardly extending fibers, as the Board has repeatedly found. See, e.g., IPR2022-00556, Paper 10, 51 (ID) (Sept. 8, 2022) (citing IPR2022-00034, Paper 14 at 13-27).² But, even if, *arguendo*, Levi’s outer skirt did include outwardly extending fibers (as Petitioner incorrectly argued in prior cases), these imagined fibers could not possibly “contact [] the frame along the height” of the outer skirt where the outer skirt billows outwardly from the frame.

Petitioner further contends that Patent Owner’s infringement contentions “rely on a similar application of the limitation” regarding the accused SAPIEN 3

²Although the Board preliminarily interpreted “outwardly extending” fibers “to mean that the tips of the fibers must extend in a generally outward direction from the frame,” (IPR2022-00556, Paper 10, 51 (ID) (Sept. 8, 2022) the Board later found that Norris’ fibrous loops are “a plurality of radially extending fibers that extend outwardly of the outer frame.” See Ex. 1117 [-01527-FWD] 60, Ex. 1118 [-01584-FWD] 65.

Ultra (“Ultra”) product. Pet., 44-45. In fact, Patent Owner never proposed or relied upon Petitioner’s imagined construction and maintains that Ultra meets the “plurality of fibers is in contact with the frame” limitation under the plain meaning of the claims. In any event, Ultra and the issue of infringement are not before the Board and are, accordingly, irrelevant to the Board’s decision whether to deny institution. *See, e.g.*, 35 U.S.C. §311(b) (limiting IPRs to grounds raised under section 102 or 103).

Thus, Petitioner fails to show that its Spenser II combinations disclose or render obvious outwardly extending fibers which are “in contact with the frame along the height of the sealing material.”

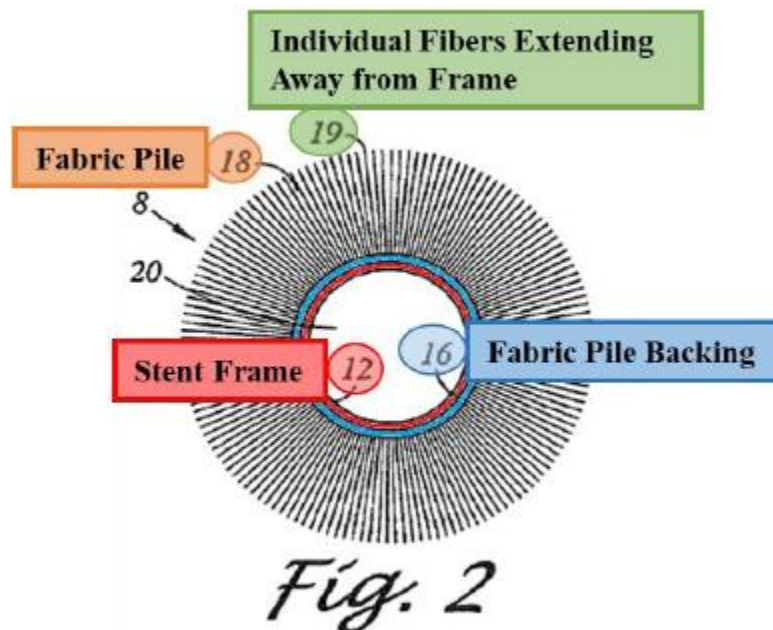
III. PETITIONER’S CHUTER COMBINATIONS FAIL (GROUNDS 3-6, ALL CLAIMS).

Grounds 3-6 (the Chuter grounds/combinations) propose combining Chuter with Spenser I’s or Levi’s frame. Each Chuter ground relies in the alternative on two distinct Chuter embodiments. The first concerns Chuter’s graft embodiment featuring a fabric pile backing. *See, e.g.*, Pet, 77-79. The second concerns Chuter’s occluder embodiment without a backing layer where fibers are secured between twisted wire strands forming a helically wound stent. *See, e.g., id.*, 79. Petitioner, however, fails to demonstrate that any of the Chuter grounds render any claim obvious under either embodiment.

A. Petitioner Fails To Prove That Its Chuter Backing Layer Combinations Disclose Or Render Obvious Fibers That Extend “Outwardly Of The Frame” And Remain “In Contact With The Frame” (All Claims).

The remaining claims require “a plurality of outwardly extending, arcuate fibers that extend outwardly of the frame” that are “in contact with the frame along the height of the sealing material” in both the “radially compressed orientation” and “radially expanded orientation.” Ex. 1001 [’310] cl. 11.

With respect to Chuter’s stent graft embodiment, Petitioner identifies Chuter’s fabric pile 18, including fabric pile backing 16 (or “backing layer,” per Petitioner) as the “sealing material,” and the individual extending fibers 19 as the “plurality of fibers.” Pet., 71. Petitioner’s annotated Chuter Fig. 2 is below:



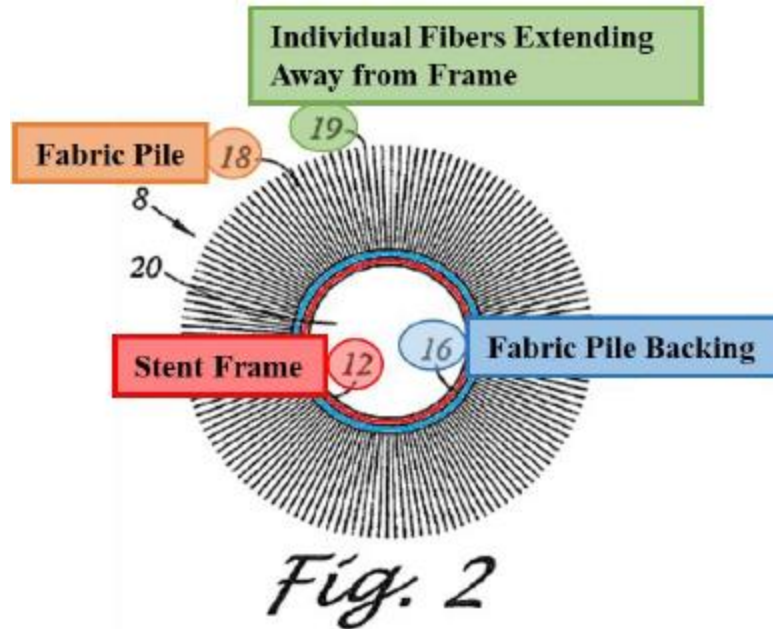
Id.; Ex. 1116 [Chuter] Fig. 2 (annotated).

Chuter, however, does not disclose or depict its outwardly extending fibers being “in contact with the frame,” (Section III.A.1) and Petitioner fails to show that its Chuter backing layer combinations disclose or render obvious such “contact” (Section III.A.2). If more is needed, the Board should deny institution of the Chuter backing layer combinations because substantially the same art and arguments were previously considered by the Office. Section III.A.3.

1. Chuter’s Backing Layer Is Between The Fibers Extending Outwardly Therefrom And The Frame.

Petitioner argues that Chuter “discloses” outwardly extending fibers “in contact with the frame” in its “embodiments having a ‘fabric pile backing’ layer.” Pet., 77-79. Chuter, however, neither depicts nor describes “outwardly extending” fibers “in contact with the frame” in its backing layer embodiments, as Dr. Brecker explains:

Chuter teaches embodiments wherein “a fabric pile 18 made up of individual fibers 19” “[e]xtend[s] circumferentially outwardly from the [fabric pile] backing 16.” Ex. 1116 [Chuter] ¶54, 55 (similar); *see also id.*, ¶¶12-16. Chuter does not describe how these extending fibers are attached to the fabric pile backing. Chuter’s figures, however, reveal how the extending fibers are positioned relative to both the backing layer and the frame. Fig. 2, reproduced below with Petitioner’s annotations, is instructive:



Pet., 78; Ex. 1116 [Chuter] Fig. 2 (annotated); *see also id.*, Fig. 4. As can clearly be seen, Chuter’s individual fibers, which are taught to “[e]xtend[] circumferentially outwardly from the backing 16,” are not in contact with the frame. Rather, the backing layer from which they extend is positioned between these extending fibers and the frame. In accord, Petitioner correctly recognizes that “[t]he fibers of Chuter’s fiber pile backing layer are in contact with the stent frame.” Pet., 78. There is, however, no disclosure or suggestion that the extending fibers contact the frame.

Chuter, moreover, refers to its fabric pile backing as a “graft pouch, sock, or sleeve” with “individual fibers 19” “[e]xtending circumferentially outwardly” therefrom. Ex. 1116 [Chuter] ¶¶25, 54-55. In this regard, Chuter’s backing layer embodiments are entirely consistent with Spenser II’s compressible material, which is also described as a “sleeve,” and which the Board has (correctly, in my opinion) found “corresponds to an outer graft covering” that “would

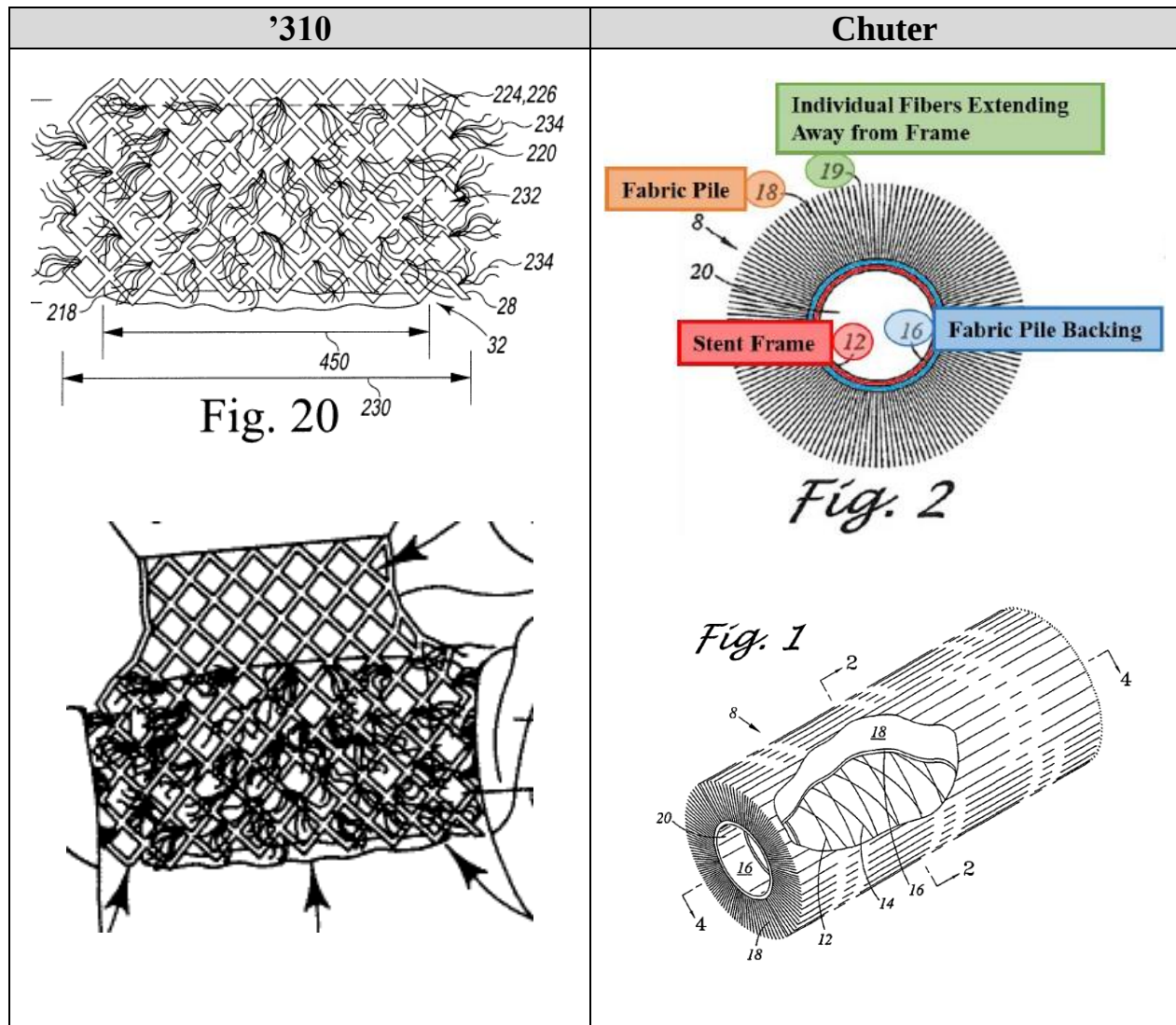
be between the surface-residing fibers and the metallic outer frame.”

Ex. 1120 [-00034FWD] 48; Ex. 2124 [-00556FWD] 37-38 (same);

Ex. 1011 [Spenser-II] ¶145.

Ex. 2002 [Breckler-Decl.] ¶¶81-82.

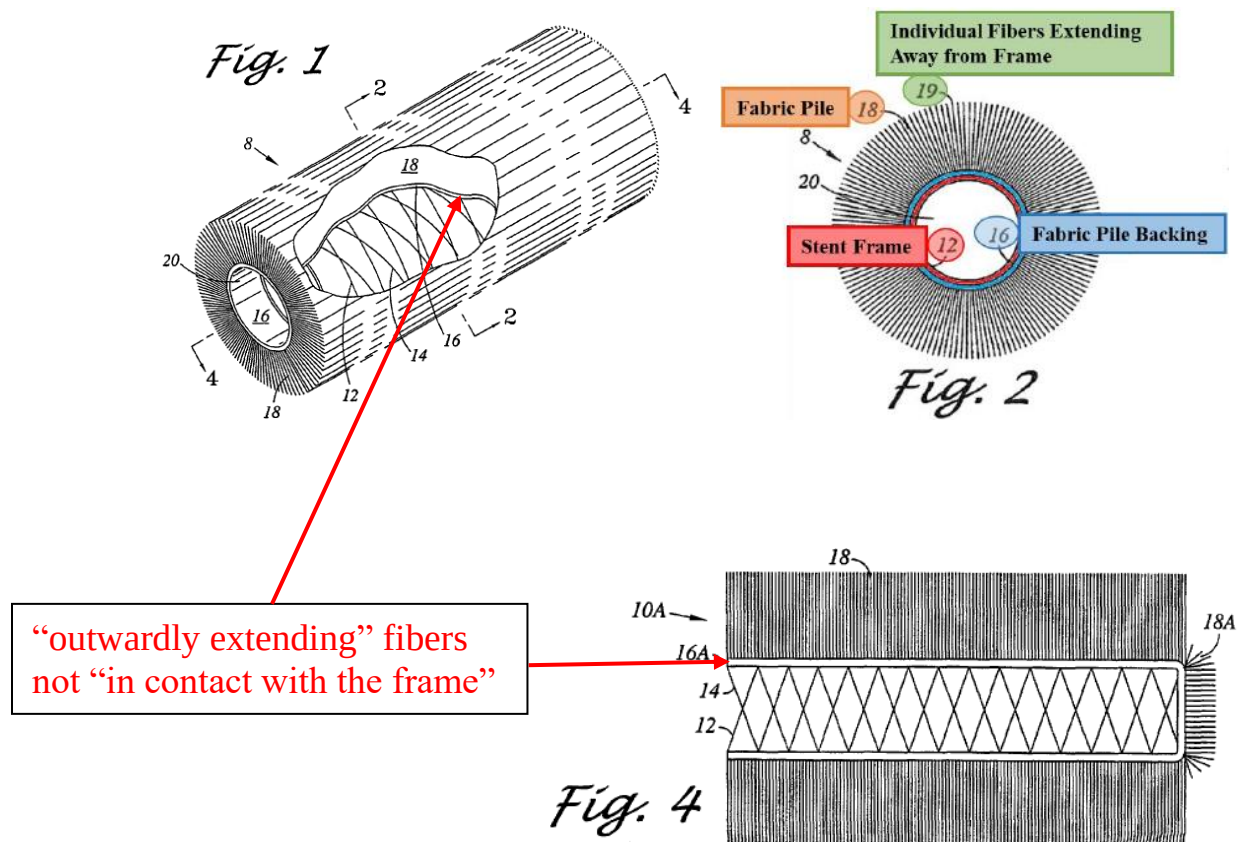
Chuter’s figures, including Petitioner’s annotated Fig. 2, depict fibers extending outwardly from the fiber pile backing and, furthermore, bear no resemblance to Figs. 20-22 of the ’310, which the Applicant identified as supporting the limitation:



Ex. 1001 ['310] Figs. 20-21; Pet., 78; Ex. 1116 [Chuter] Figs. 1-2; Ex. 2002 [Brecker-Decl.] ¶83; *see also* Ex. 1002 [Pros.-Hist.] 143 (identifying '310 Figs. 20-22 as supporting limitation).

And, even if we imagined that some fibers extending outwardly from Chuter's backing layer were, somehow, "in contact with the frame," there is no basis upon which to conclude this contact would be maintained "along the height of the sealing material." Petitioner does not contend that Chuter discloses or

suggests that the backing layer is, itself, formed of outwardly extending fibers, nor does Chuter indicate anything of the sort. Indeed, as discussed, Chuter describes no contact whatsoever between its outwardly extending fibers and the frame. Notably, Chuter's figures (including Petitioner's annotated Fig. 2, below) plainly illustrate Chuter's graft embodiments with fibers extending outwardly from a backing layer, not "in contact with the frame":



Ex. 1116 [Chuter] Figs. 1-2, 4; Pet., 78; Ex. 2002 [Brecker-Decl.] ¶84.

2. Petitioner's Inherency Arguments Fail.

Notwithstanding the foregoing, Petitioner argues that Chuter “discloses” that its “individual fibers extending from Chuter's fabric pile backing layer would be

‘in contact’ with the frame.” Pet., 77-79. As with its Spenser II grounds, however, Petitioner’s argument relies not upon what Chuter says, but rather upon what a POSITA supposedly “would have understood”:

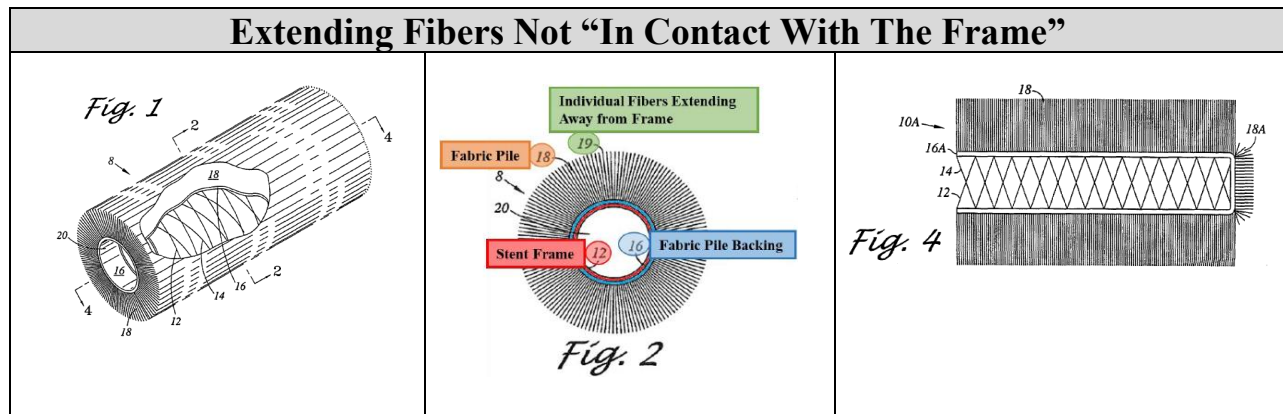
[A]s explained previously for Spenser II, POSITAs **would have understood** that the individual fibers extending from Chuter’s fabric pile backing layer would have been woven or knitted all the way through the thickness of the backing layer, consistent with numerous examples in the prior art. Accordingly, if this limitation requires the radially extending fibers of the sealing material to be in direct contact with the frame, POSITAs **would have understood** that the individual fibers extending from Chuter’s backing layer would be “in contact” with the frame for the same reasons explained with respect to Spenser II’s compressible material.

Pet., 78-79.

As discussed in Section II.B.2(a), arguments about what a POSITA supposedly “would have understood” lie in inherency, requiring Petitioner to meet the “high standard” of showing that the limitation “**necessarily** must be present.” *Par Pharm*, 773 F.3d at 1195-1196; *Microsoft Corp.*, 878 F.3d at 1065; *LBT IP I LLC*, 2023 U.S. App. LEXIS 14376 at *9 (Fed. Cir. 2023). Petitioner, however, falls far short of proving that the fibers extending from the surface of Chuter’s backing layer are “**necessarily**” “in contact with the frame.”

As discussed in Section III.A.1., however, Chuter does not describe the

relied-upon fibers which “[e]xtend[] circumferentially outwardly from the [fabric pile] backing 16” as being “in contact with the frame.” Ex. 1116 [Chuter] ¶¶54, 55 (similar); Ex. 2002 [Breckler-Decl.] ¶87. Nor is any such “contact” shown in Chuter’s figures (including Petitioner’s annotated Fig. 2), much less “along the height of the sealing material”:



Ex. 1116 [Chuter] Figs. 1-2, 4; Pet., 78.

Petitioner’s reliance on the “same reasons” alleged regarding Spenser II further suggests that Petitioner does not believe that the fibers extending outwardly from Chuter’s backing layer *necessarily* “would have been woven or knitted all the way through the thickness of the backing layer ... to be in direct contact with the frame.” Pet., 79. Again, regarding Spenser II’s compressible material, Petitioner argues that the “radially extending fibers *may* be attached to the base layer by weaving or knitting the fibers through the base layer” such that “*at least some of the fibers* extending from the surface would be in direct contact with the frame.” Pet., 47. As discussed, these statements confirm that a POSITA would *not* view

outwardly extending fibers to ***necessarily*** be “in contact with the frame,” much less

“along the height of the sealing material.” See Section II.B.2(a); Ex. 2002

[Brecker-Decl.] ¶88. Yet, Petitioner does not explain why these statements would

not also apply to a POSITA’s understanding of Chuter’s backing layer

embodiments. Nor does Petitioner explain why the Board’s findings that Spenser

II’s outwardly extending fibers “arise from the surface of the cloth” would not

similarly apply to Chuter’s backing layer embodiments. Pet., 78-79; Ex. 1120 [-

00034FWD] 48; Ex. 2124 [-00556FWD] 37-38 (same).

Petitioner, moreover, specifically highlights Norris as an alleged prior art “example[]” of a cloth with outwardly extending fibers being “woven or knitted all the way through the thickness of the backing layer” to be in contact with the frame. Pet., 78-79. But, again, Norris, like Chuter, Spenser II and Dehdashtian, does not disclose any “contact” between the fibers/loops extending outwardly from its graft and the frame. Ex. 2002 [Brecker-Decl.] ¶89. This is illustrated in Norris’ Fig. 1 (below with Petitioner’s annotations), as well as Norris’ Figs. 2 and 3:

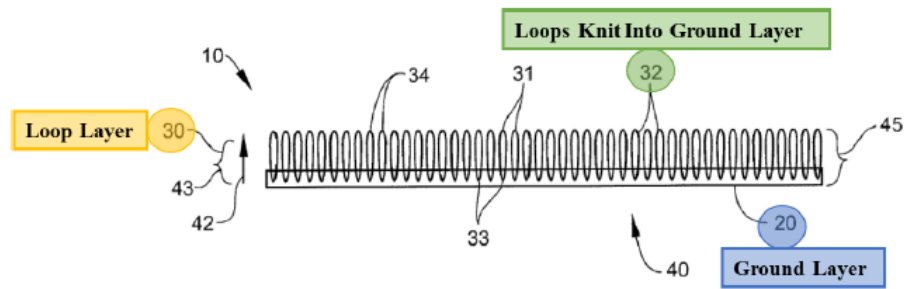


Fig. 1

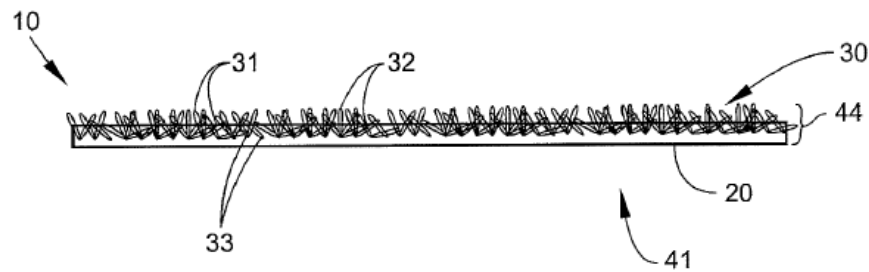


Fig. 2

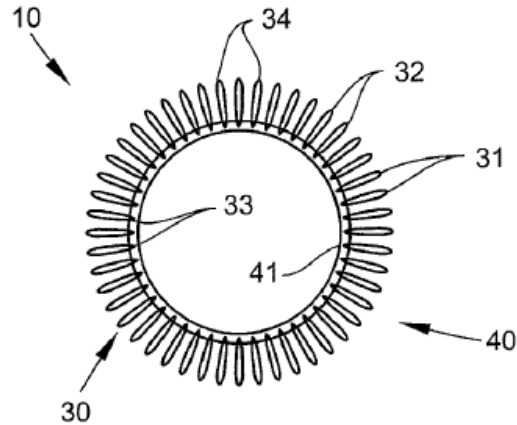


Fig. 3

Pet., 78; Ex. 1074 [Norris] Figs. 1-3; *see also* Ex. 2101 [Dehdashtian] 3:14-16

(teaching extending fibers may be “partially integrated into the weave” and “placed on the exterior of the graft body.”), 5:12-24, 3:37-41. Fatally, while Norris’

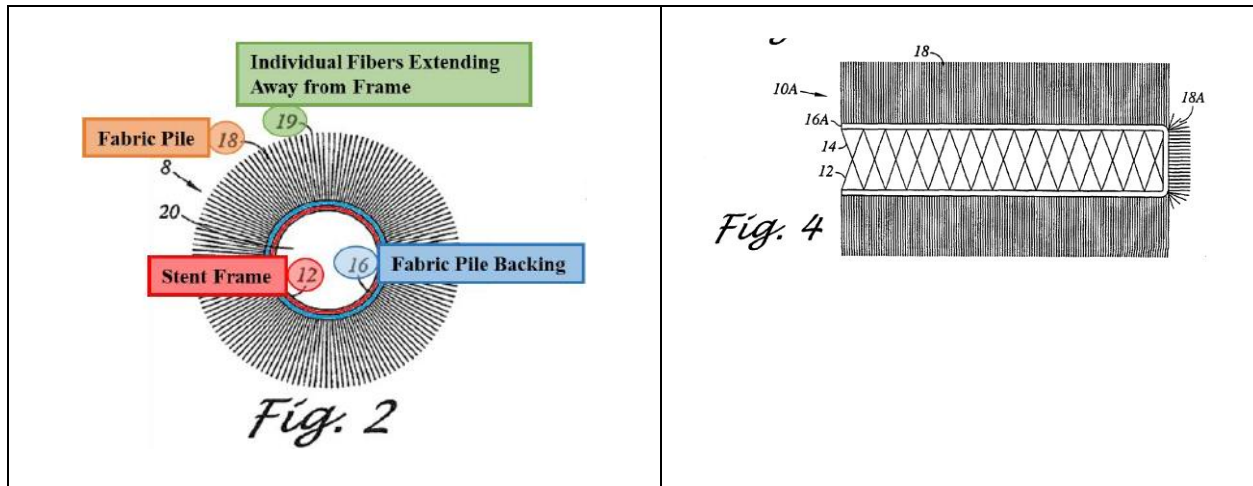
figures clearly show no contact between the outwardly extending loops and the frame, Petitioner contends Chuter's backing layer embodiments have this same "configuration." Pet., 78.

Therefore, Petitioner fails to show that Chuter's backing layer embodiments inherently disclose "outwardly extending" fibers "in contact with the frame."

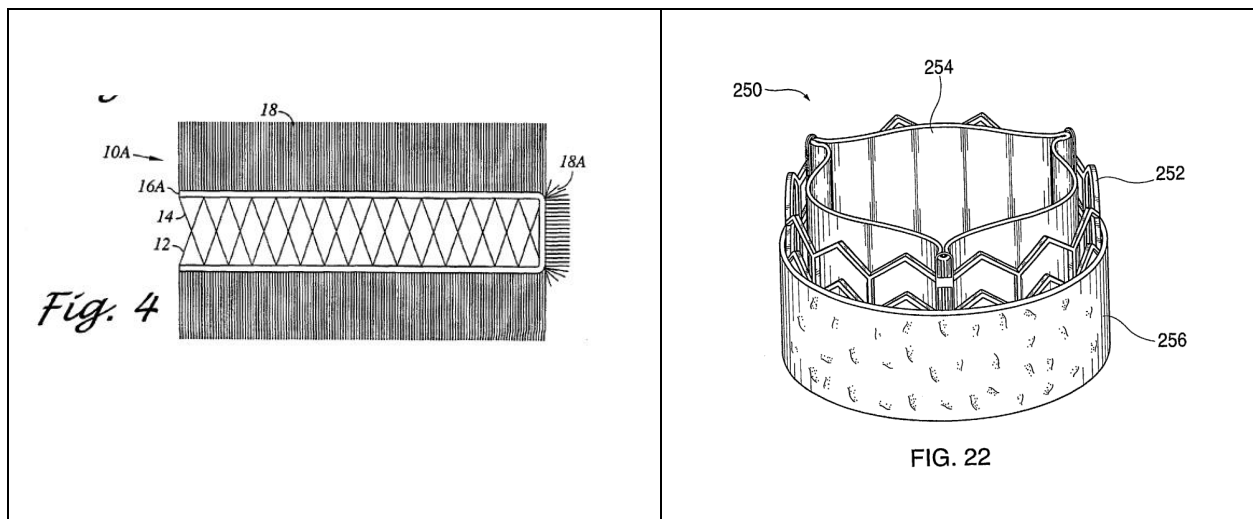
3. The Board Should Deny Institution Of Petitioner's Chuter Backing Layer Combinations Under §325(d).

If more is needed, the Board should further deny institution under §325(d). As detailed in Section II.A.1, the Examiner allowed the claims over the prior art of record—including Spenser II—in view of the "plurality of fibers is in contact with the frame along the height of the sealing material" limitation. See Ex. 1002 [Pros.-Hist.] 21. Indeed, with respect to this limitation, Chuter's fabric pile backing embodiments are materially indistinct from Spenser II's compressible material, which was discussed at length in prosecution. As Dr. Brecker explains:

Chuter discloses embodiments comprising individual fibers extending outwardly from fabric pile backing 16 ("backing layer"), as shown, for example, in Petitioner's annotated Fig. 2 and Chuter's Fig. 4:

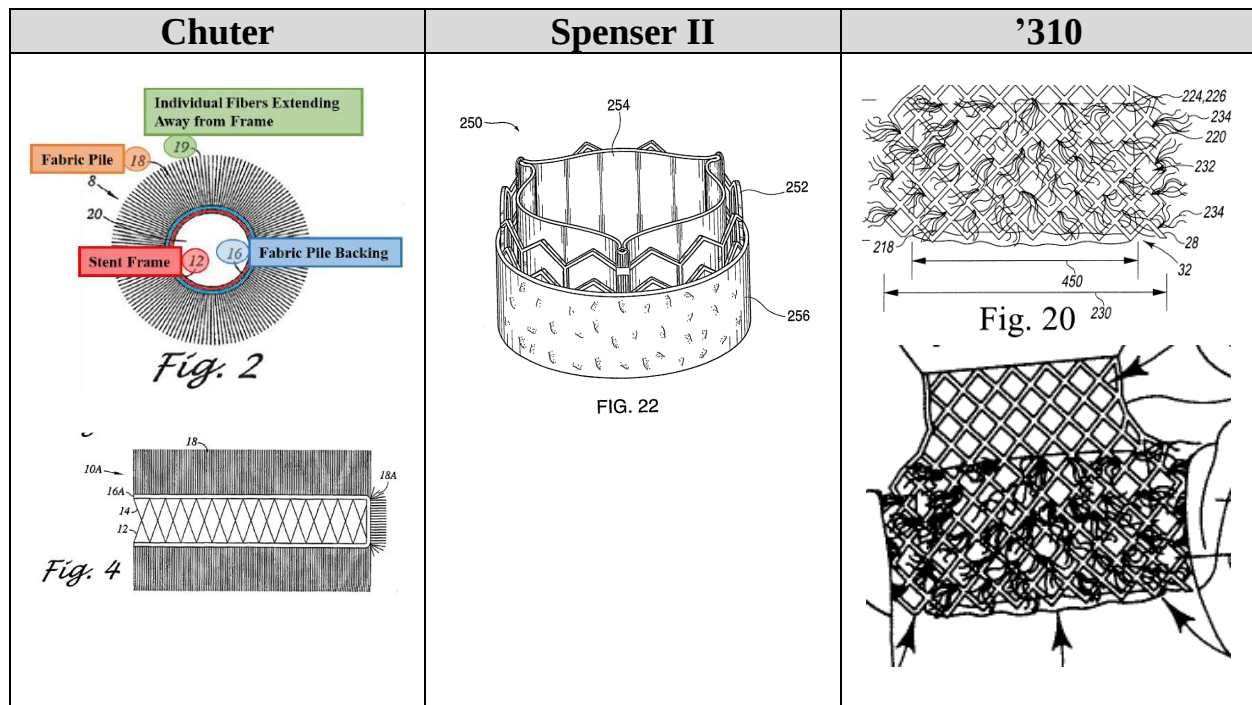


Pet., 78-79; Ex. 1116 [Chuter] Figs. 2, 4, ¶¶54-55. As discussed, and as is clearly visible in the above figures, Chuter does not disclose or suggest outwardly extending fibers that are “in contact with the frame.” Rather, like Spenser II’s Fig. 22, Chuter’s figures show fibers extending from the outer surface of a graft covering:



Indeed, Chuter leaves no doubt in this regard as we can see precisely how the fibers extend from the backing layer. Certainly, neither Chuter’s fabric pile backing layer nor Spenser II’s compressible material show anything like the ’310’s Figs. 20-22 which were cited as support for the limitation (Ex. 1002 [Pros.-Hist.] 143), and plainly

show the fibers in contact with the frame without an intervening graft covering as disclosed in Chuter and Spenser II:



Chuter's description of its graft as a "sleeve" also mirrors the description of Spenser II's compressible material as a "sleeve." Compare Ex. 1116 [Chuter] ¶25 ("[t]he stents of the present invention that employ a graft can extend the full length of the graft. The graft pouch, sock, or *sleeve* can extend beyond one end or both ends of the stent.") with Ex. 1011 [Spenser-II] ¶145 ("[t]he [compressible] material may extend ... entirely around the stent structure, such as in the form of a *sleeve*"). Accordingly, both the depiction and description of Chuter's "sleeve" graft indicates a similar configuration to Spenser II's compressible material. Certainly, there is nothing about either Chuter or Spenser II which suggests any material distinction regarding whether their respective outwardly extending fibers are "in contact with the frame."

Ex. 2002 [Breckner-Decl.] ¶¶92-93.

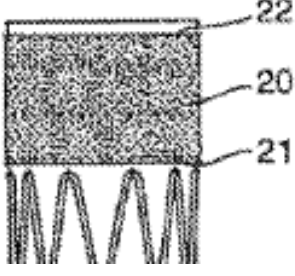
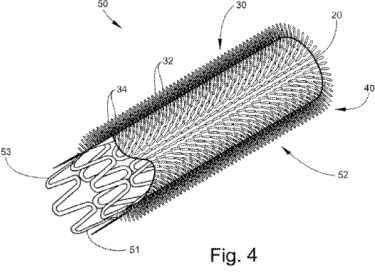
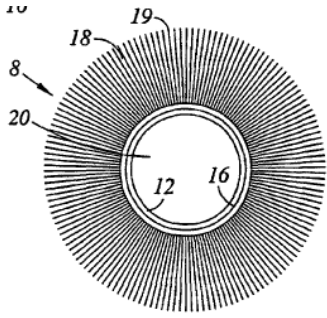
In accord, Chuter repeatedly refers to its backing layer embodiments as “graft” embodiments and Board has determined that Spenser II’s compressible material “corresponds to an outer graft covering” which “**would be between the surface-residing fibers and the metallic outer frame.**” Ex. 1120 [-00034FWD] 48; Ex. 2124 [-00556FWD] 37-38 (same); *see, e.g.*, Ex. 1116 [Chuter] ¶¶12-16, 25, 54.

The Petition, itself makes clear that Petitioner’s reliance on Chuter’s backing layer embodiments is cumulative of Spenser II and the same arguments thereto previously rejected by the Examiner and the Board. Indeed, Petitioner expressly contends that “POSITAs would have understood that the individual fibers extending from Chuter’s backing layer would be ‘in contact’ with the frame **for the same reasons explained with respect to Spenser II’s compressible material.**” Pet., 79.

Given the manifest similarities between Spenser II’s compressible material and Chuter’s fabric pile graft embodiments detailed above, “**substantially the same prior art or arguments** previously were presented to the Office.” *Becton, Dickinson & Co. v. B. Braun Melsungen AG*, IPR2017-01586, Paper 8, 17 (Dec. 15, 2017) (precedential); *Gator Bio, Inc. v. Sartorius Bioanalytical Instruments, Inc.*, IPR2023-00215, Paper 19, 14-17 (PTAB June 20, 2023) (finding reference

which “does not disclose [the limitation] with any more precision or clarity” than reference considered in prosecution, where Petitioner’s proposed combinations relied on either reference to satisfy the same aspects of the challenged claims); *Sonos, Inc. v. Google, LLC*, IPR2021-00963, Paper 9, 10-11 (PTAB Nov. 9, 2021) (finding reference not presented in prosecution “substantially the same” as reference presented prosecution and relied-upon in Petition, where Petitioner relied on both references as “teaching the same subject matter” and “combining with [primary reference] in the same manner”).

If more is needed, the Applicant further expressly discussed additional prior stent graft art that is also cumulative of Chuter’s graft embodiments. Ex. 1002 [Pros.-Hist.] 706-707. The Applicant explained that “[v]arious stent grafts have also been developed that include one or more seals,” including Hartley which “teaches a velour band at a distal end of the stent graft” and Norris, the same Norris which Petitioner includes as additional evidence, which “teaches a stent graft with loops of outwardly extending material.” *Id.* Thus, Hartley and Norris were distinguished in prosecution and they, like Chuter, each teach a graft with fibers extending outwardly therefrom:

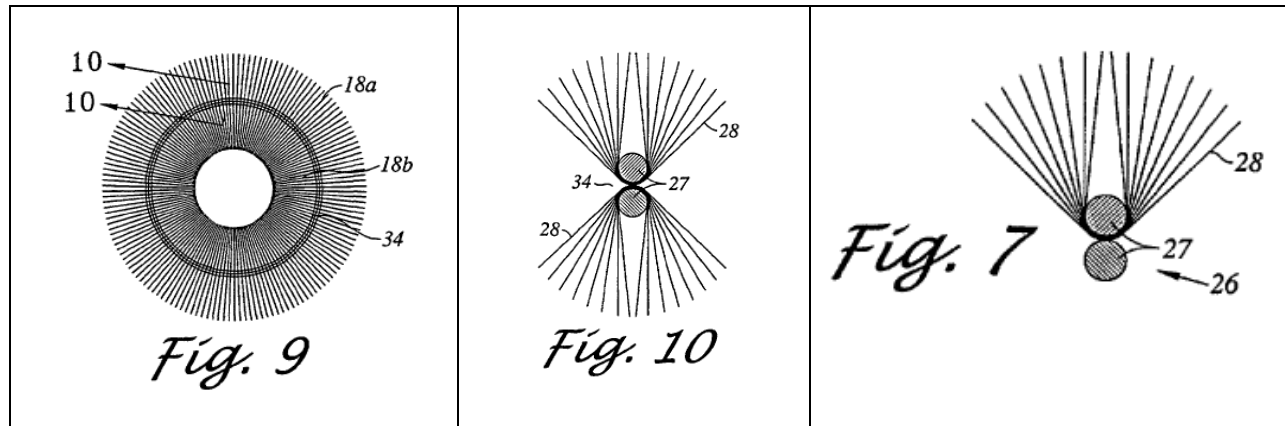
Hartley	Norris	Chuter
	 Fig. 4	 <i>Fig. 2</i>

Id.; Ex. 1116 [Chuter] Fig. 2; Ex. 2002 [Brecker-Decl.] ¶96.

As to the second *Advanced Bionics* prong, Petitioner has not demonstrated any material error by the Office. Petitioner makes no contention that Chuter is not cumulative of Spenser II, only that Chuter was not presented in prosecution. Pet., 85, 89. But, as discussed, Chuter's backing layer embodiments and Petitioner's arguments that Chuter discloses fibers extending outwardly from the backing layer that are "in contact with the frame" are cumulative of both Spenser II and the stent graft art distinguished in prosecution. Conclusively, Petitioner has not shown that the Examiner erred regarding Spenser II, nor does Petitioner even address the Board's findings that Spenser II's cloth/graft covering is "between the outwardly extending fibers and the ... frame." See Section II.B. Thus, the *Advanced Bionics* factors are met, and §325(d) should bar reconsideration of the cumulative backing layer combinations.

B. Petitioner Fails To Show That Its Chuter Occluder Combinations Render The Claims Obvious.

Petitioner alternatively proposes adding the individual extending fibers of Chuter's occluder embodiments ("Chuter-occluder" combinations) without a backing layer (shown below), to the frame of Spenser I or Levi:



Pet., 71-72, 79; Ex. 1116 [Chuter] Figs. 7, 9-10. Petitioner alleges that Chuter's fiber pile represents the "sealing material" and that the individual extending fibers correspond to the "plurality of fibers." Pet., 71-72, 79.

Petitioner's arguments, however, fail to show that a POSITA would be either motivated to make the proposed Chuter-occluder combinations or could do so with a reasonable expectation of success. Section III.B.1. Even if this could be overlooked, Petitioner fails to show the resulting combinations would satisfy the claims. Section III.B.2.

1. Petitioner Fails To Demonstrate A POSITA Would Be Motivated To Combine Chuter's Occluder Embodiments With A Reasonable Expectation Of Success.

Petitioner fails to demonstrate a POSITA would be motivated to combine Chuter's occluder embodiments with the frame of either Spenser I or Levi or could achieve the combinations with a reasonable expectation of success. Starting with motivation, Chuter's occluder, used in a bypass procedure, is intended to stop **all** blood from passing. An occluder is antithetical to a TAVR which is designed to allow blood to pass through the channel. Preventing blood from passing through a TAVR would kill the patient and, consequently, a POSITA would not be motivated to add an occluder to a TAVR.

As Dr. Brecker explains:

Chuter is directed toward "Large Vessel Stents And Occluders," and identifies its field of invention as relating to "intravascular stents for occluding vascular members in humans and animals." Ex. 1116 [Chuter] Title, ¶1. The principal function of an occluder, including Chuter's occluder, is to "prevent all blood flow into" a vessel. *See id.*, ¶5 ("it is extremely important to cut off and occlude the damaged portion of the vessel **to prevent all blood flow into it** and through it to prevent future complications"). In contrast, TAVRs **must** leave the aorta (a large vessel) unobstructed to allow blood to flow through the aorta and prosthetic leaflets. It would, accordingly, be counterintuitive for a POSITA to look to a device designed to occlude a blood vessel when designing a TAVR. Indeed, obstructing all blood

flow through the aorta and aortic valve would lead to death, and even a partially obstructed aorta or aortic valve would have potentially fatal consequences.

Ex. 2002 [Brecker-Decl.] ¶100.

Indeed, in the prosecution of Chuter, Chuter was distinguished from art (Callister) without extending fibers to block off a stent lumen. As Dr. Brecker explains:

Notably, in prosecution of Chuter, Chuter was distinguished from art lacking extending fibers to occlude the stent lumen. In prosecution, Chuter was distinguished from U.S. Patent No. 6,096,052 to Callister (Ex. 2125). Callister, directed towards an occluder for use in the reproductive system, teaches a tubular stent with struts and cells (alternatively described as “braided,” “lattice-like” or having an “open configuration”) and a “permeable mesh member transversely disposed” thereon to “promote tissue ingrowth.” *See, e.g.*, Ex. 2125 [Callister] 1:26-30, 2:1-9, 7:13-16, 7:34-38, 8:4-9. The Examiner issued rejections based, *inter alia*, on the premise that Callister’s permeable mesh, which was not taught to have fibers extending therefrom, disclosed or rendered obvious Chuter’s fiber pile. Ex. 2126 [Chuter-FH] 170-172, 186. In response, Chuter’s applicant explained that:

The fiber pile cannot be a mesh member because the fiber pile cannot expand so that it extends across the expanded lumen of the stent ... ***The fibers of the pile***

must have sufficient length before the stent lumen is expanded to bridge the expanded lumen of the stent.

Id., 145, 165 (same); *see also id.*, 141 (“Mesh layer 16 of Callister et al., which comprises woven or bundled strands, is not a fiber pile.”), 161 (same). In accord, Chuter teaches that its inwardly-extending fibers “substantially occlude the inner bore of the stent” and “plug” the blood vessel. *See* Ex. 1116 [Chuter] ¶¶18, 57. Chuter’s occluder embodiments with only outwardly extending fibers must also perform this function. Otherwise, the device could not “occlude” the stent’s “inner bore.” To accomplish this critical function, as further made clear in prosecution, the fibers must have sufficient length to traverse the stent’s “inner bore” and be densely arranged to immediately form a seal and stop all blood from flowing through the vessel. This teaching regarding the occlusion of the “inner bore,” however, would have no relevance to the spaces and gaps formed between a TAVR frame and the native valve anatomy. Unlike the requirement of a paravalvular leak solution, Chuter’s fibers are designed to form a seal not only across the full width of the vessel, but further without compressing against any solid structure. The dense nature of the occluding fibers secured to Chuter’s twisted wire loops are designed to cause thrombosis and occlusion of the diseased vessel. *Id.*, ¶11 (“the invention is directed to the use of expandable stents and a fabric pile to yield a[n] endovascular occluding stent for sealing off a vascular vessel to induce the thrombosis of large arteries.”). The twisted wire loop stent of Chuter is also uniquely designed for the specific purpose of adapting to the diseased vessels and causing

occlusion. No POSITA would look to this design when considering a TAVR valve and a POSITA would further have concerns about the pro-thrombotic potential of the arrangement of fibers in Chuter.

Ex. 2002 [Brecker-Decl.] ¶101.

As Dr. Brecker further explains, a POSITA reading Chuter would not be motivated to add its occluder fibers to a TAVR:

A POSITA reading Chuter's discussion of its occluder embodiments would readily understand these embodiments to be inconsistent with the purpose of a TAVR. As explained, Chuter's occluders are meant to stop all blood flowing through the vessel, including within the stent. This teaching has no place in a TAVR wherein blood must go through the valve/leaflets within the stent without any risk of surrounding or adjacent thrombosis. Consequently, a POSITA, quite simply, would not be motivated to apply Chuter's occluder teachings in the context of TAVRs and any opposite conclusion seems driven by hindsight.

Ex. 2002 [Brecker-Decl.] ¶102.

In accord, a POSITA would not be motivated to make a combination that "would run contrary to [the primary obviousness reference]'s stated purposes." *Polaris Indus., Inc. v. Arctic Cat, Inc.*, 882 F.3d 1056, 1069-70 (Fed. Cir. 2018); *see also In re Ratti*, 270 F.2d 810, 813 (CCPA 1959) (proposed combination improper where it would change basic principle of operation of one of the references); *Plas-Pak Indus., Inc. v. Sulzer Mixpac AG*, 600 F.App'x 755, 759

(Fed. Cir. 2015) (“A change in a reference’s ‘principle of operation’ is unlikely to motivate a person of ordinary skill to pursue a combination with that reference.”).

The stated purpose of Chuter’s occluder and its principle of operation is to “prevent all blood flow into” a vessel. Ex. 1116 [Chuter] ¶5. A TAVR, by contrast, is meant to allow blood to pass unobstructed through the prosthetic leaflets. Chuter’s occluder, is, fundamentally, ill-suited for a TAVR environment. Petitioner, moreover, provides no explanation for how Chuter’s fibers would be adjusted to allow blood to pass unobstructed through the leaflets.

Petitioner further contends that Spenser II “would have provided POSITAs additional motivation to add Chuter’s fiber pile to Spenser’s and Levi’s valves,” arguing that POSITAs would have “recognized Chuter’s fiber pile as a type of compressible material that could be combined with THV’s to prevent PVL according to Spenser II’s teachings.” Pet., 83. But, as Dr. Brecker explains:

I do not believe Spenser II would provide additional motivation for a POSITA to add Chuter’s occluding fibers to Levi or Spenser I’s frames. Chuter’s fabric pile in its occluder embodiment is very different from Spenser II’s compressible material. Petitioner, here, relies upon occluder embodiments “without [a] ‘backing layer.’” *See, e.g.*, Pet., 79. While both Spenser II’s compressible material and Chuter’s backing layer are described as a “**sleeve**,” Chuter describes its occluder embodiments without a backing layer as a “**plug**.” *Compare* Ex. 1011 [Spenser-II] ¶145; Ex. 1116 [Chuter] ¶25 *with* Ex.

1116 [Chuter] ¶57. Nor are the fibers similar. Whereas Spenser II describes “***small*** fibers extending from the surface of the [compressible] material,” Chuter’s occluding fibers “***must have sufficient length*** before the stent lumen is expanded to bridge the expanded lumen of the stent.” Ex. 1011 [Spenser-II] ¶145; Ex. 2126 [Chuter-FH] 145, 164-165 (same). Thus, Spenser II and Chuter’s occluder embodiments are quite different and, consequently, the former would not motivate a POSITA to adopt the latter.

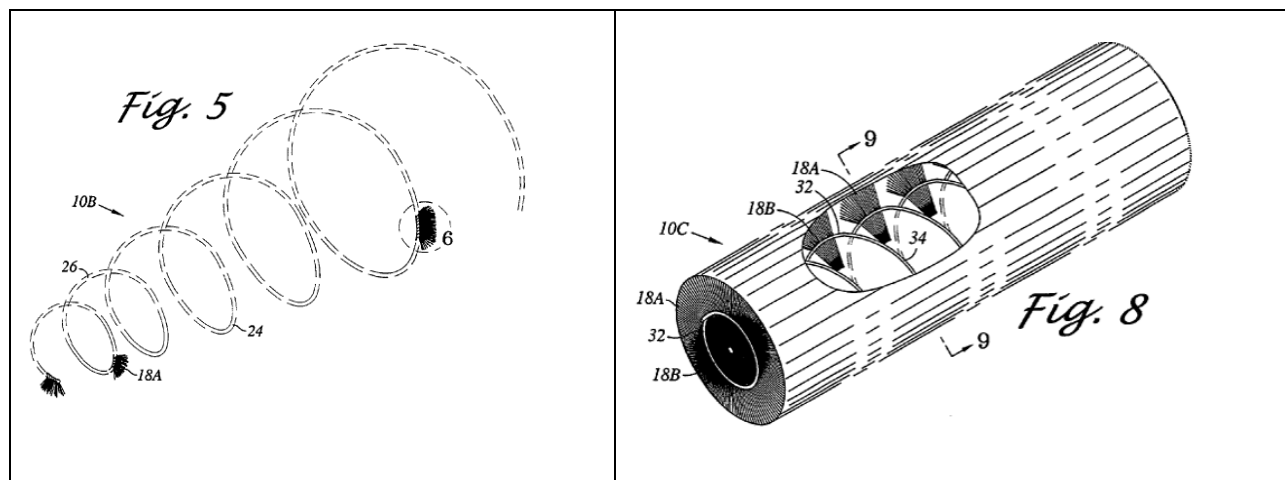
Ex. 2002 [Brecker-Decl.] ¶104.

Even if, *arguendo*, a POSITA were inclined to add occluder fibers to a TAVR, nothing in Chuter suggests a POSITA would be motivated to attach Chuter’s occluding fibers to the frame of Spenser I or Levi or could do so with a reasonable expectation of success. Importantly, Chuter’s occluding fiber pile is formed when the individual fibers are secured by the twisted, helically wound double wires of Chuter’s frame. This method of attachment was used to distinguish Chuter from the prior art in prosecution, wherein the resulting fabric pile was described as a “key element.” See Ex. 2126 [Chuter-FH] 144, 164-165, 43. As Dr. Brecker explains:

[I]t has not been shown that a POSITA would be motivated to add Chuter’s occluding fibers to the frame of Spenser I or Levi or that such a thing could be done with a reasonable expectation of success. Rather, Chuter’s attachment method relies upon placing and securing

fibers between Chuter's "twisted strands" of "helically wound wire," which is not present in the frame of Levi or Spenser I.

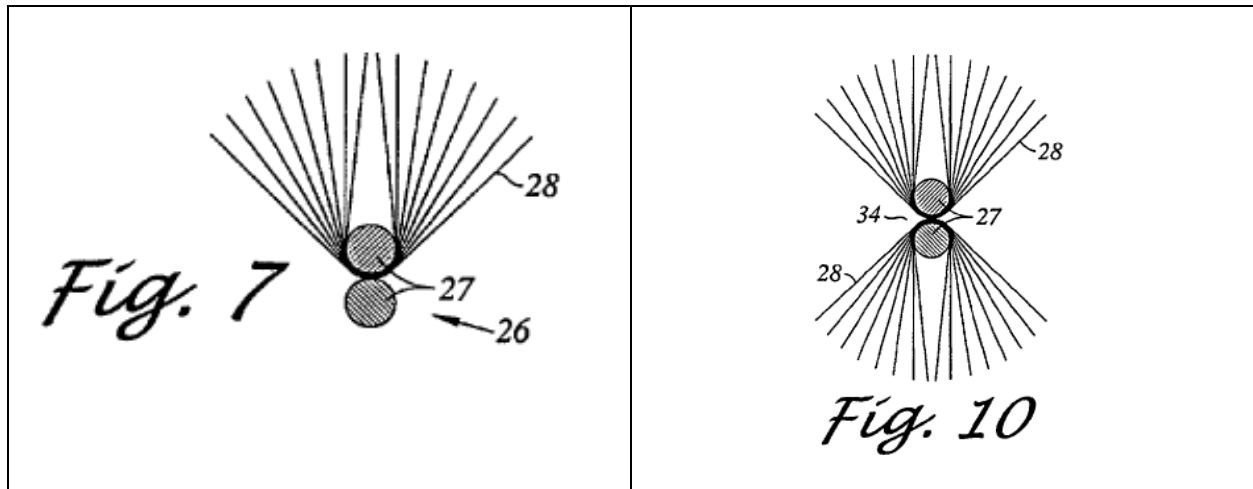
Chuter teaches stents "made of at least one helically wound wire ... comprising [] at least two twisted strands ... securing fibers to form a fiber pile." Ex. 1116 [Chuter] ¶¶17, 18 (same), 56 ("[r]eferring to FIGS. 5-7, the conical shaped occluder 10B comprises a conical shaped stent 24 comprising at least one helically wound double wire strand 26."). Chuter's applicant presented claim amendments requiring the helically wound wire stent further "form[] a plurality of loops," which Chuter's applicant identified as shown in Figs. 5-10:



Ex. 1116 [Chuter] Figs. 5, 8; Ex. 2126 [Chuter-FH] 34-40.

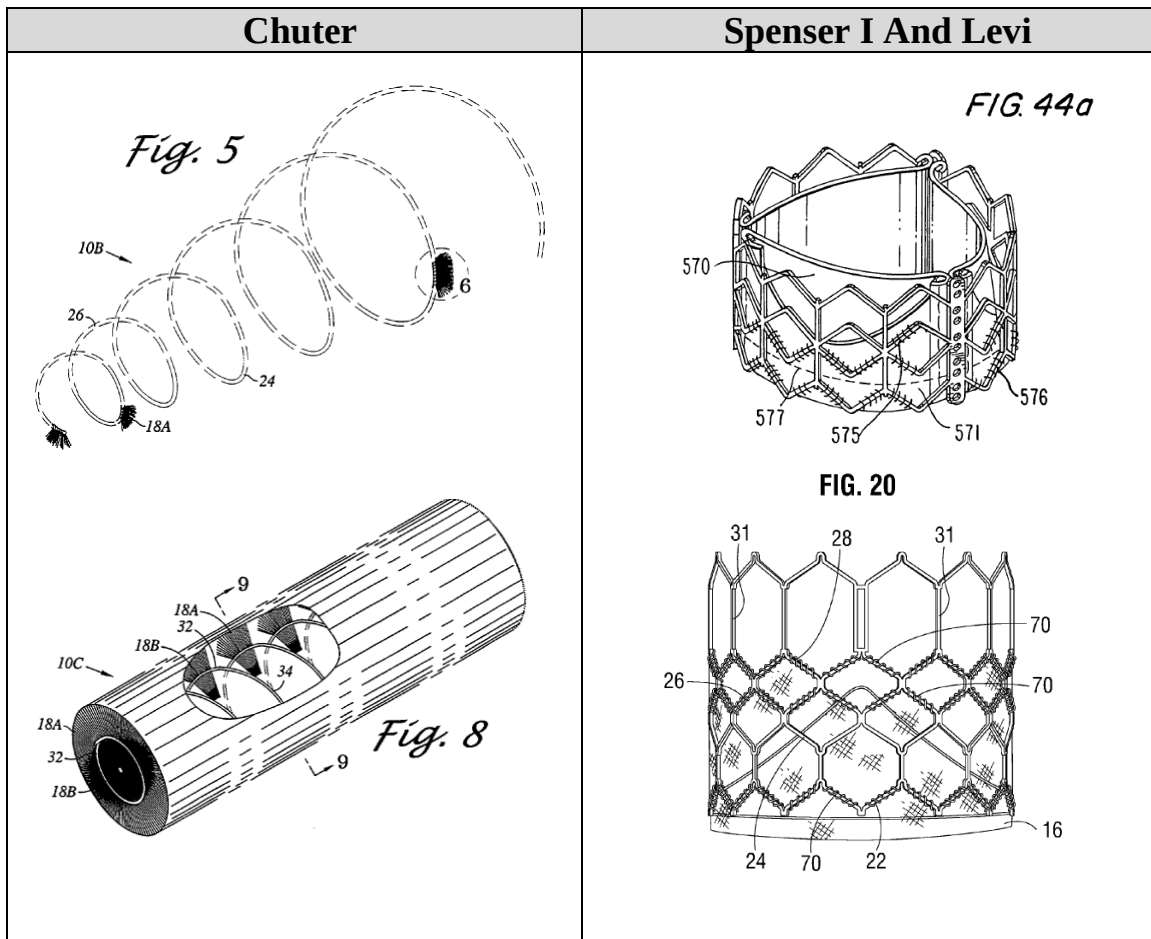
The only "technique" or "method" Chuter teaches for attaching fibers to this helical loop, is by "inner-dispos[ing]" or "secur[ing]" the fibers between the twisted, helically wound metal wires. Ex. 1116 [Chuter] Abstract, ¶¶17-18, 20, 56-57. Significantly, Chuter's applicant identified attaching fibers via the "twisted strands of the helical wire" to distinguish Chuter from the prior art, characterizing it as a "key element" of the invention. See Ex. 2126 [Chuter-FH] 144, 164-165,

43. Chuter's method of attaching fibers via twisted strands if further shown, *e.g.*, Figs. 7 and 10:



Ex. 1116 [Chuter] Figs. 7, 10; Ex. 2126 [Chuter-FH] 39-40, 43, 144, 164-165.

In contrast, neither of Petitioner's relied-upon frames (Spenser I/Levi) have helically wound wire stents forming loops, much less double wound or twisted wire strands securing fibers therebetween:



Ex. 1116 [Chuter] Figs. 5, 8; Ex. 1010 [Spenser-I] Fig. 44a; Ex. 1008 [Levi] Fig. 20.

I do not believe a POSITA would be motivated to add Chuter's fibers, attached via the twisted strands of a helical loop, to stent frames like those present in Spenser I and Levi that lack both a helical loop and twisted strands. Moreover, even if we assume a POSITA would be inclined to attach the fibers to such a frame, there is no indication of how this would be done nor is it self-evident how a POSITA would accomplish such a thing with a reasonable expectation of success.

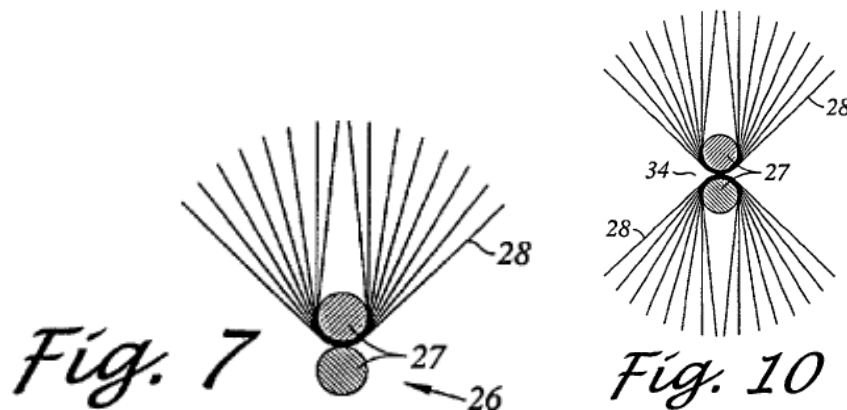
Ex. 2002 [Brecker-Decl.] ¶¶105-109.

Petitioner asserts that the relied-upon frames would nevertheless be

compatible with Chuter's individual extending fibers, contending that POSITAs "would have possessed the knowledge to attach Chuter's fiber pile to Spenser's frame" by unspecified "known ... engineering methods." Pet., 74. But, again, a POSITA would not typically be motivated to combine a reference contrary to its principles of operation, much less by applying a method not taught regarding a "key element" of the reference's invention. *Polaris Indus.*, 882 F.3d at 1069-70; *In re Ratti*, 270 F.2d at 813; *Plas-Pak Indus.*, 600 F.App'x at 759.

Even if we, *arguendo*, assumed that a POSITA would be motivated to attach Chuter's individual occluding fibers to the frame of Spenser I or Levi, critical questions remain unexplained. Per Dr. Brecker:

Chuter depicts its occluding fibers wrapped around, and fanning outwardly from, the twisted wire strands of its helically wound wire frame:



Ex. 1116 [Chuter] Figs. 7, 10. Petitioner does not propose any specific alternative attachment method, which renders the proposed combinations difficult to assess. Even if we assumed that these fibers

could instead be otherwise attached to the frame of Levi or Spenser I, no explanation is given regarding why these fibers would still fan outwardly from the strut as depicted above, instead of being clumped or clustered together where affixed to the frame. These are critical questions which bear directly on whether a POSITA would be motivated to attach Chuter's occluding fibers in this (again, unspecified) manner to produce a transfemorally-deliverable TAVR that effectively seals against PVL.

Ex. 2002 [Brecker-Decl.] ¶113.

A POSITA, moreover, would not be motivated to add Chuter's occluding fibers to the frame of Spenser I or Levi because these are precisely the sort of frames that were distinguished in Chuter's prosecution and disparaged in its specification. As Dr. Brecker explains:

Chuter's applicant noted that the relied-upon occluder embodiments without a backing layer (shown in Figs. 5-10) are directed to a different "species" than its embodiments featuring a backing layer. Ex. 2126 [Chuter-FH] 200 ("Figures 1-4, 11-14, and 26 are directed to one species; [] Figures 5-10 are directed to a second species."). The "species" of Chuter's occluder embodiments lacking a fabric pile backing was further distinguished in prosecution from Callister's tubular stent with struts and cells (alternatively described as "braided," "lattice-like" or having an "open configuration"):

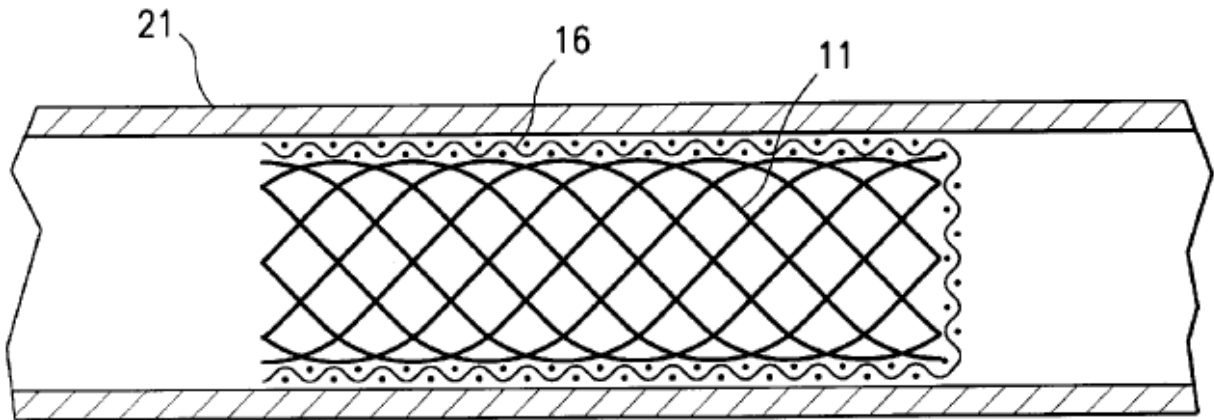
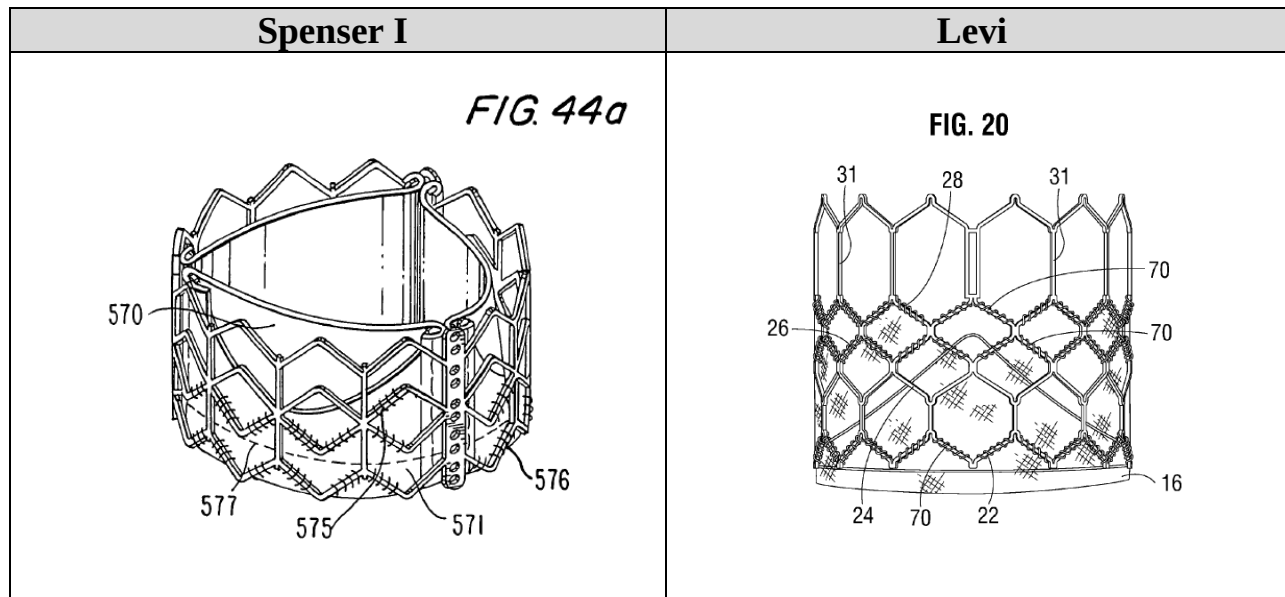


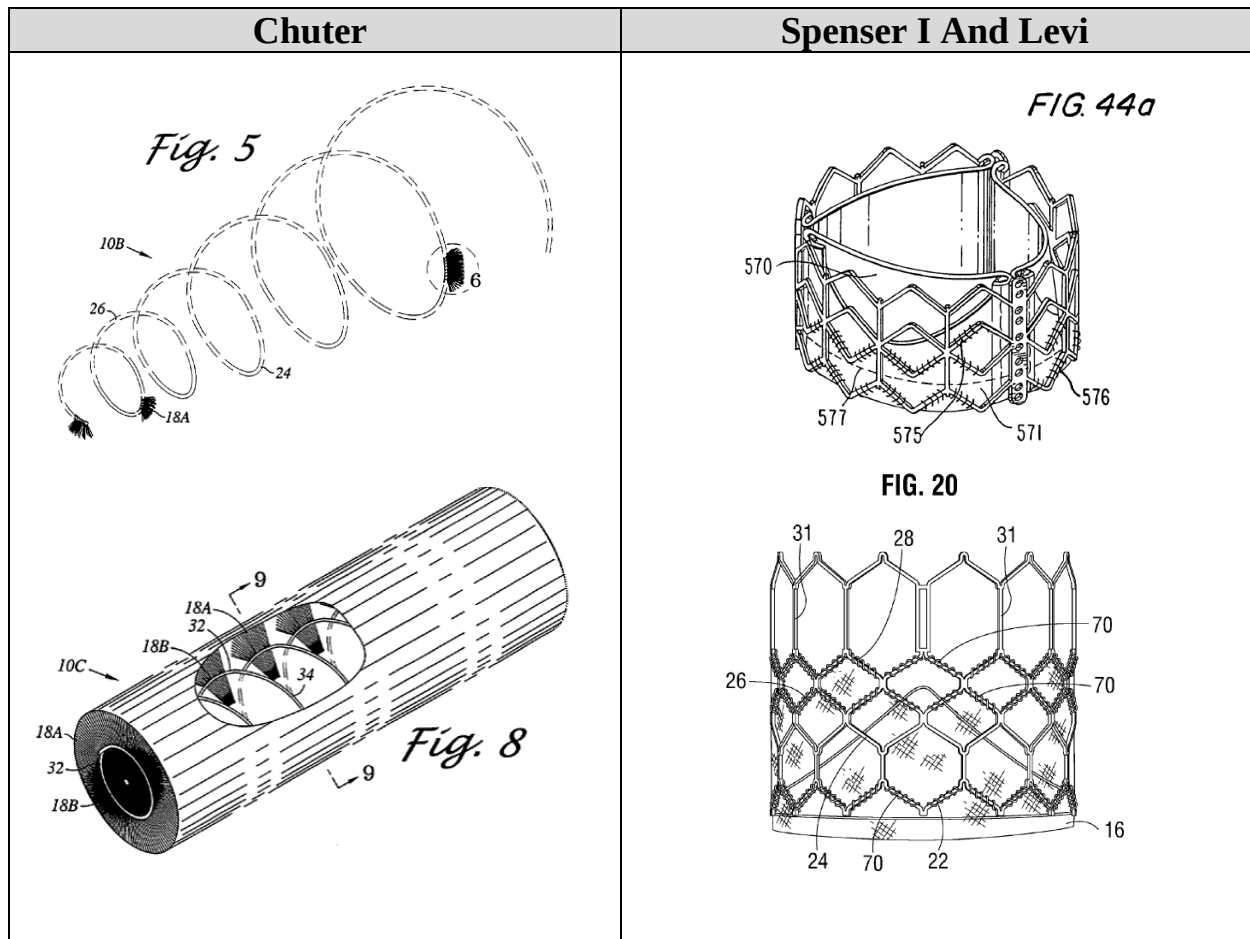
FIG. 11

Ex. 2125 [Callister] Fig. 11, 1:26-30, 2:1-9, 7:13-16, 7:34-38, 8:4-9. In response to the Examiner’s rejections of Chuter over Callister, Chuter’s applicant explained that Callister’s “braided tube” stent “is ***not relevant to the patentability of [the] claimed invention***” because “Applicant’s stent is not a braided tube.” Ex. 2126 [Chuter-FH] 140, 160.

Indeed, Chuter criticizes known stent grafts’ “constant diameter cylindrical profile[s]” which “usually prevent[] the stent-graft from closing off the artery because of the surface irregularities commonly seen in the recipient artery which is already damaged” causing “gaps” and “leakage.”[] Ex. 1116 [Chuter] ¶9. But such “open configuration,” “braided”/“woven” or “lattice-like” stent frames with a “constant diameter cylindrical profile,” are precisely what we see Spenser I’s and Levi’s frames:



Ex. 1010 [Spenser-I] Fig. 44a; Ex. 1008 [Levi] Fig. 20; *see also* Pet., 24 (“Spenser and Levi disclose ‘an outer frame formed from a metallic material and defining an open cell configuration.’”). These frames do not resemble Chuter’s helical loop stent of twisted wires:



The manifest differences between Chuter's twisted wire helical loop frame and the relied-upon lattice-like frames distinguished in prosecution and disparaged in the specification would not motivate POSITAs to make the proposed combinations.

Ex. 2002 [Brecker-Decl.] ¶¶114-116.

Petitioner nevertheless contends that Chuter teaches that its fiber pile “can be adapted” to be compatible with “[v]irtually any expanding stent.” Pet., 73. Petitioner further contends that “Chuter specifically identifies a variety of self-expanding and balloon-expandable frames that can be combined with the fiber pile and ‘employed in the present invention,’ which POSITAs would have understood

to encompass the embodiments ... lacking the ‘backing’ layer ... Thus, while the preferred embodiment in Chuter includes a double-wire frame, Chuter’s invention is not limited to such frames and encompasses many frames.” *Id.*

But, as Dr. Brecker explains, Chuter’s teaching that “[v]irtually any expanding stent may be used” pertains only to Chuter’s backing layer embodiments:

Chuter’s disclosure that “[v]irtually any expanding stent” is compatible with Chuter’s fabric pile is expressly limited to Chuter’s backing layer embodiments. Ex. 1116 [Chuter] ¶¶12-13 (“Virtually any expanding stent can be used ***in this embodiment.***”). Chuter does not suggest that “[v]irtually any expanding stent” is compatible with its embodiments without a backing layer. Indeed, in prosecution, Chuter’s applicant clarified that the relied-upon occluder embodiments without a backing layer are a “different species” from Chuter’s backing layer embodiments, and that Chuter’s individual extending fibers being held between “twisted strands of the helical wire” was a “key element” of Chuter’s invention. Ex. 2126 [Chuter-FH] 200, 144, 164-165. Thus, Chuter in no way suggests its occluding fibers without a backing layer could be added to either Spenser I or Levi’s frame.

Ex. 2002 [Brecker-Decl.] ¶118.

Petitioner nevertheless contends that “adding Chuter’s fiber pile to Spenser’s valves would merely entail applying Chuter’s known technique for reducing PVL

(adding a fabric pile) to Spenser’s known valves” to “yield predictable results.”

Pet., 72-73. Petitioner relies on these same “reasons” regarding Levi. *Id.*, 75. But, as discussed, neither Spenser I nor Levi teach a frame comprising the helically wound twisted wires required for the only attachment “method” taught for Chuter’s fabric pile without a backing layer.

2. Petitioner’s Unspecified Modifications Are Insufficient To Show Its Combinations Meet Each Of The Claims.

Even, *arguendo*, ignoring all of the above, Petitioner fails to demonstrate that the resulting Chuter-occluder combinations could be “deployed endovascularly through a femoral artery of the patient.” Ex. 1001 [’310] cl. 11.

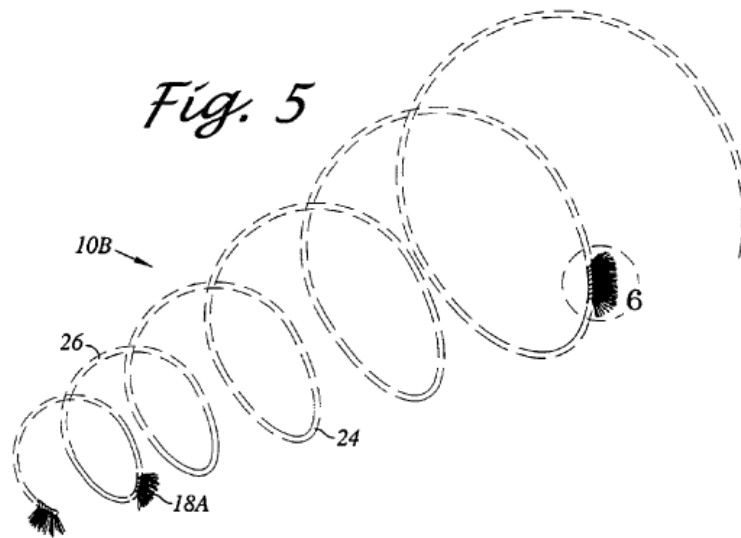
Petitioner argues that “POSITAs would have reasonably expected Chuter’s fabric pile to [] compress when added to Spenser’s or Levi’s valve, allowing for continued endovascular delivery of the valve through the femoral artery.” Pet., 76. Petitioner further contends that Chuter teaches that its “stents are compressed” when placed in a delivery catheter and “the ‘compression compresses the stent and pushes down the fabric pile’ to allow for endovascular delivery.” *Id.* (citing Ex. 1116 [Chuter] ¶62). Dr. Buller asserts that POSITAs “would have understood that Chuter’s fiber pile could have been optimized for delivery through the femoral artery, such as by adjusting the lengths, densities, and distribution of fibers.” Ex. 1003 [Buller-Decl.] ¶244; Pet., 76-77. Petitioner contends that a POSITA would be motivated to combine Chuter’s “fiber pile” with the frame of Spenser I or Levi

to “prevent PVL.” Pet., 72-73, 75, 77.

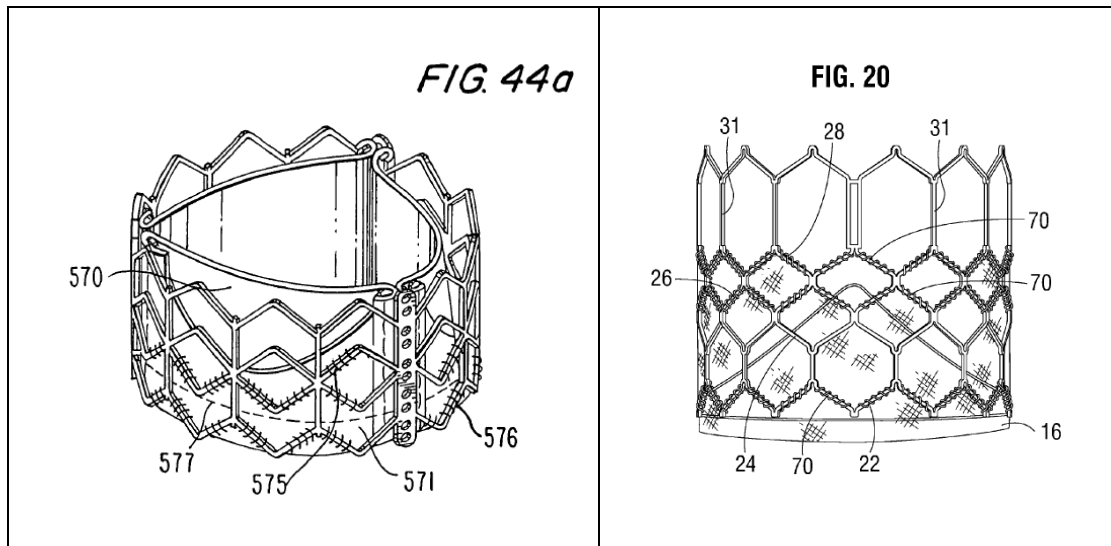
These vague modifications are insufficient to show that a POSITA would reasonably expect to successfully produce a transfemorally-deliverable TAVR by combining Chuter’s occluder embodiments with Spenser I or Levi, as proposed. Indeed, there is no reason to just assume POSITAs would reasonably expect to successfully do so, particularly while “prevent[ing] PVL.” As Dr. Brecker explains:

Petitioner and Dr. Buller do not argue that Chuter’s occluding fibers could simply be added to the frame of Spenser I or Levi and the resulting combination would, without modification, be transfemorally deliverable. Rather, they contend a POSITA “would have understood that Chuter’s fiber pile could have been optimized for delivery through the femoral artery, such as by adjusting the lengths, densities, and distribution of fibers.” Ex. 1003 [Buller-Decl.] ¶244; Pet., 76-77.

I agree that adding Chuter’s occluding fibers to the frame of Spenser I or Levi would not allow for transfemoral delivery. While Chuter’s occluder embodiments without a backing layer are, themselves, delivered endovascularly, Chuter’s dense fibers are accommodated via Chuter’s helical loop frame because, unlike the frame of Spenser I or Levi, there is no valve structure or graft covering housing the native leaflets within the stent to inhibit crimping:



Ex. 1116 [Chuter] Fig. 5. Spenser I and Levi, by contrast, do not just have a hollow frame but, also, a valve, leaflets, and inner skirt/graft that must be accommodated:



Ex. 1010 [Spenser-I] Fig. 44a; Ex. 1008 [Levi] Fig. 20.

Dr. Buller contends that the “lengths, densities, and distribution of fibers” could be altered to facilitate transfemoral delivery, (Ex. 1003 [Buller-Decl.] ¶244) but no specifics are proffered for what modifications would be made or how the resulting combination would

still be transfemorally deliverable. Additionally, no explanation is given for how the so-modified combination would still be dense enough to prevent PVL.

Ex. 2002 [Brecker-Decl.] ¶¶123-125.

Petitioner's vague assertion that some unspecified modifications could be made to Chuter's fibers is insufficient to establish obviousness. *Sisvel Int'l S.A. v. Sierra Wireless, Inc.*, -- 4th --, Slip Op. at 15 (Fed. Cir. Oct. 6, 2023) (rejecting combination that was "too conclusory, lacked clarity, or ... both"); *DSS Tech. Mgmt.*, 885 F.3d at 1376 (rejecting expert's "conclusory statements and unspecific expert testimony") (citation/quotation omitted); *ActiveVideo Networks Inc. v. Verizon Comms., Inc.*, 694 F.3d 1312, 1327 (Fed. Cir. 2012) ("the expert's testimony on obviousness was essentially a conclusory statement that a [POSITA] would have known ... how to combine ... [relied-upon] references to achieve the claimed inventions. This is not sufficient and is fraught with hindsight bias.").

Additionally, while there was a long-felt need for an endovascularly-deliverable TAVR with an effective seal against PVL, Petitioner has not presented any prior art reference disclosing a device comprising a sparse distribution of fibers extending from the frame to form an effective seal against PVL when the valve is expanded. Indeed, both experts testified that they were unaware of any such prior art device with a sparse distribution of fibers like those shown in, *e.g.*, Fig. 9:

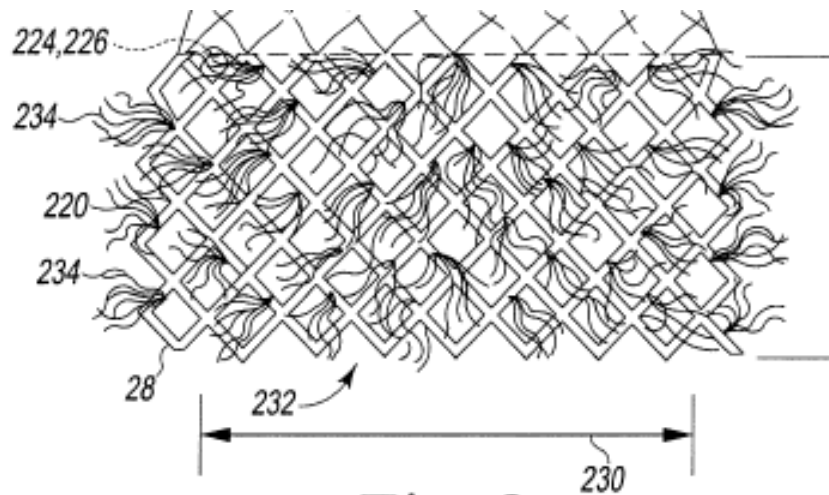


Fig. 9

Ex. 1001 ['310] Fig. 9; Ex. 2052 [Buller-00034-Depo.] 167:10-15, 169:5-25; Ex. 2002 [Brecker-Decl.] ¶126. The Board, moreover, credited Dr. Brecker's testimony that such a "sparse distribution of fibers," when "compressed within the body" would "form a seal is an **unexpected result.**" Ex. 2124 [-00556FWD] 33-34 (quoting Ex. 2103 [Brecker-556-Decl.] ¶160); Ex. 1120 [-00034FWD] 44 (similar). Consequently, relying upon a sparser distribution of fibers, as taught in the '310, is impermissible hindsight. *InTouch Techs., Inc. v. VGo Commc'ns., Inc.*, 751 F.3d 1327, 1351 (Fed. Cir. 2014) (rejecting obviousness theory as hindsight where expert "relied on the [] patent itself as her roadmap for putting what she referred to as pieces of a 'jigsaw puzzle' together.").

Thus, Petitioner fails to show that its proposed addition of Chuter's individual extending fibers without a fabric pile backing would meet each of the

claims. This confirms the overarching error in Petitioner’s analysis, a reliance on impermissible hindsight.

IV. DISCLAIMED CLAIMS 1-10 SHOULD BE TREATED AS THOUGH THEY NEVER EXISTED AND MAY NOT BE A BASIS FOR INSTITUTION UNDER 37 C.F.R. § 42.107(E).

To streamline this proceeding, and in compliance with 37 C.F.R. § 1.321(a), Patent Owner has filed a statutory disclaimer under 35 U.S.C. § 253(a) of claims 1-10 of the ’310 patent (the “Disclaimed Claims”). Ex. 2138 [Disclaimer]. Patent Owner has disclaimed these claims solely in response to the District Court’s construction of “outer frame” (present in the Disclaimed Claims) to reduce the number of issues before the Board. The District Court’s construction, currently on appeal, led the parties to stipulate to non-infringement in prior litigation. (Ex. 2139).

To avoid any doubt, this disclaimer is not a request for adverse judgment. Rather, and as a matter of law, the Disclaimed Claims should be treated as though they never existed. *Baker Hughes LLC v. LiquidPower Specialty Prods., Inc.*, IPR2016-01903, Paper 74, 11-12 (PTAB Mar. 8, 2019) (citing Federal Circuit precedents); *Intel Corp. v. VLSI Technology LLC*, IPR2018-01040, Paper 36, 16 (PTAB Feb. 12, 2020) (similar). Additionally, under the Office’s rules, “[n]o *inter partes* review will be instituted based on disclaimed claims.” 37 C.F.R. § 42.107(e).

V. CONCLUSION

The Petition should be denied.

Respectfully submitted,

/Kenneth J. Weatherwax/

Kenneth J. Weatherwax, Reg. No. 54,528

Nathan N. Lowenstein (*pro hac vice*)

Lowenstein & Weatherwax LLP

Date: November 9, 2023

CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMITS

This Patent Owner Preliminary Response (the “POPR”) consists of 13,584 words, excluding table of contents, table of authorities, certificate of service, this certificate, or table of exhibits. The POPR complies with the type-volume limitation of 14,000 words as mandated in 37 C.F.R. § 42.24. In preparing this certificate, counsel has relied on the word count of the word-processing system used to prepare the paper (Microsoft Word).

Respectfully submitted,

/William Katz/

Date: November 9, 2023

CERTIFICATE OF SERVICE

The undersigned hereby certifies that the following documents were served by electronic service, by agreement between the parties, on November 9, 2023:

PATENT OWNER AORTIC INNOVATIONS LLC'S PRELIMINARY RESPONSE

**EXHIBITS 2002, 2040, 2047, 2051-2052, 2101-2103, 2118, 2122, 2124-2126,
2128-2130, 2132-2139**

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Respectfully submitted,

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Date: November 9, 2023