

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 IPR2023-01325
Patent 11,491,033

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

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2053-2100	Reserved
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2123	Reserved
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I. INTRODUCTION

The Petition should be denied because it fails to demonstrate a reasonable likelihood of prevailing as to any claim. Petitioner's grounds rely upon the addition of either Spenser II or Chuter as satisfying the sealing assembly/spacing limitations to the frame of Spenser I or Levi. Pet., 18. Both grounds fail, however, for the reasons stated in Sections II (Spenser II grounds) and III (Chuter grounds).

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

Grounds 1 and 2 (Spenser II grounds/combinations) propose combining Spenser II's compressible material with Spenser I's or Levi's frame. Petitioner, however, fails to demonstrate that these grounds disclose or render obvious the various "spacings" limitations required by the claims. Spenser II was distinguished in prosecution as not having "spacings," and the Examiner allowed the '033 over each of Spenser II, Levi, and Spenser I once the "spacings" limitations were added. The Applicant's arguments in this regard operate as a disclaimer and, consequently, Spenser II cannot disclose or render obvious the "spacings" limitations. Moreover, under §325(d), the same art and arguments should not be reconsidered. *See* Section II.A. But even were Petitioner's grounds to be reconsidered, they should again be rejected. *See* Section II.B.

A. The Prosecution History Confirms That Spenser II Does Not Disclose “Spacings.”

The claims require a “sealing assembly” including a “plurality of arcuate fibers that extend away from the frame.” Ex. 1001 [’033] cl. 1. The claims further require “spacings extending through a thickness of the sealing assembly...” *Id.* For its Spenser II grounds, Petitioner identifies Spenser II’s compressible material as the “sealing assembly” and the fibers extending outwardly from what Petitioner describes as the compressible material’s “base layer” as the “plurality of fibers.” *See* Pet., 29; Ex. 2136 [-01151-Pet.] 66. Spenser II’s solid, nonporous covering, however, was disclaimed as not disclosing or rendering obvious “spacings” in prosecution. Consequently, and as Petitioner’s district court expert agrees, Spenser II cannot disclose or render obvious the “spacings” limitations. *See* Section II.B.1. The Examiner, moreover, considered each of Spenser II, Spenser I, and Levi, and allowed the claims once amended to include the “spacings” limitations. Therefore, the Board should not reconsider Petitioner’s Spenser II grounds under §325(d). *See* Section II.B.2.

1. The Applicant Disclaimed Spenser II As Not Disclosing “Spacings.”

Petitioner’s Spenser II combinations fail to satisfy the “spacings” limitations because Spenser II, and particularly its compressible material, was expressly distinguished in prosecution of the ’033’s parent (the ’834), as ***lacking*** “spacings.”

The Applicant's statements in this regard operate as a disclaimer such that Spenser II's solid, nonporous covering cannot satisfy the '033's "spacings" limitations. Notably, Petitioner and its district court expert **agree** that Spenser II cannot satisfy the "spacings" limitations in view of the prosecution history.

It is well-established that "an applicant's argument that a prior art reference is distinguishable on a particular ground can serve as a disclaimer of claim scope..." *Saffran v. Johnson & Johnson*, 712 F.3d 549, 559 (Fed. Cir. 2013); *Ekchian v. Home Depot, Inc.*, 104 F.3d 1299, 1304 (Fed. Cir. 1997) ("by distinguishing the claimed invention over the prior art, an applicant is indicating what the claims do not cover..."). The Federal Circuit, moreover, has long recognized that "disclaimer may arise from disavowals made during the prosecution of ancestor patent applications." *Omega Eng'g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1333 (Fed. Cir. 2003) ("an interpretation asserted in the prosecution of a parent application can also affect continuation applications.") (collecting cases). Indeed, imputing disclaimer from related patents is appropriate "[w]hen the application of prosecution disclaimer involves statements from prosecution of a familial patent relating to the same subject matter as the claim language at issue." *Ormco Corp. v. Align Tech., Inc.*, 498 F.3d 1307, 1314-1316 (Fed. Cir. 2007) (statements distinguishing prior art in parent operated as disclaimer in child).

Here, the Applicant's statements in prosecution of the '033's parent operate as a disclaimer such that Spenser II's dense, nonporous covering cannot disclose or render obvious "spacings" in the child. There, the Applicant distinguished both Spenser II's FIG. 22 and Walther (per Dr. Buller, FIG. 22's "real world embodiment," Ex. 2052 [Buller-00034-Depo.] 104:17-105:7) as not disclosing "spacings":

Compare [the claimed spacings] to a very ***tightly knitted outer seal*** made of tightly knitted fibers (such as found in NPL, Walther, of record in the IDS dated July 27, 2021, ***or WIPO Publication 2006005015 A2 to Spenser [i.e., Spenser II], with reference to Figure 22, of record in the IDS dated July 11, 2021), there the lack of "spacings" between some fibers*** would not allow for the compression of the outwardly extending fibers.

Ex. 2140 ['834-FH] 1001; Ex. 2002 [Brecker-Decl.] ¶35.

Significantly, there is no dispute that Patent Owner's statements operated as a disclaimer which also applies to the '033's "spacings." Ex. 2002 [Brecker-Decl.] ¶36. Indeed, on October 27, 2023, Petitioner's district court expert (Dr. Brookstein) declared that the Applicant "argued during prosecution" that the '033's claims "do not include cloths like those described in Walther and Spenser II." Ex. 2141 [Brookstein-Decl.] ¶33; *id.*, ¶40 ('033's claims do not "cover" outer coverings "described in Walther and Spenser II."); *id.*, ¶35 ("Aortic Innovations

argued that the collagen fibers in the Asserted Patents **were distinguishable from the prior art ... (including Walther and Spenser II)**” due to the “lack of ‘spacings’”) (quoting Ex. 2140 [’834-FH] 1001). Thus, Dr. Brookstein, Petitioner’s expert, declared that that the outer coverings disclosed by Spenser II and Walther lack “spacings” and are not covered by the ’033’s claims. *Id.*, ¶¶33, 35, 40; *see also id.*, ¶34.¹

Thus, and as both parties’ experts agree, the Applicant’s specific identification of Spenser II’s compressible material as **not** disclosing “spacings”

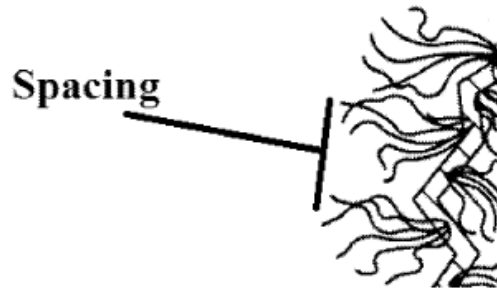
¹ Patent Owner disagrees with Dr. Brookstein’s contentions that the Applicant disclaimed **all** “spacings between fibers that are present in a ‘cloth,’ ‘sleeve,’ ‘graft,’ or ‘graft covering’” (Ex. 2140 [Brookstein-Decl.] ¶33), and that the claims do not cover **any** “distance” between fibers “form[ing] a sleeve, graft covering, or cloth” (*id.*, ¶41). The Applicant clearly disclaimed tightly constructed outer seals, such as Spenser II’s dense, non-porous graft. Ex. 2140 [’834-FH] 1001; Ex. 1002 [Pros.-Hist.] 29-30. The Applicant did not, however, disclaim all sleeves, grafts, or cloths. A loosely woven/knitted cloth with spacings extending through its thickness allowing fluid to pass therethrough in an undeployed state, for example, would satisfy the claims.

operates as a disclaimer. *Saffran*, 712 F.3d at 559; *Ekchian*, 104 F.3d at 1304.

And this is clearly a disclaimer, as the Applicant expressly distinguished Spenser II's compressible material as **not** disclosing the claimed "spacings."

Nor can there be any doubt that Spenser II was correctly identified as lacking "spacings." The Applicant cited FIGS. 11 and 12 as exemplifying the "spacings," which are "not shown in the prior art" of record:

Applicant submits that FIG. 12 of the Application as filed illustrates this spacing. An annotated version is shown below:



And with further reference to annotated FIG. 11:

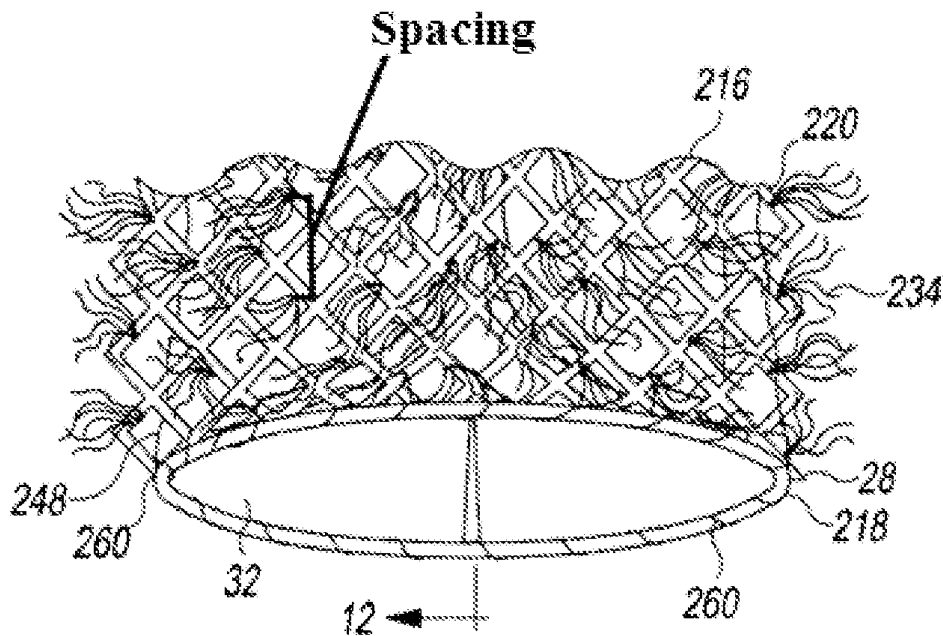


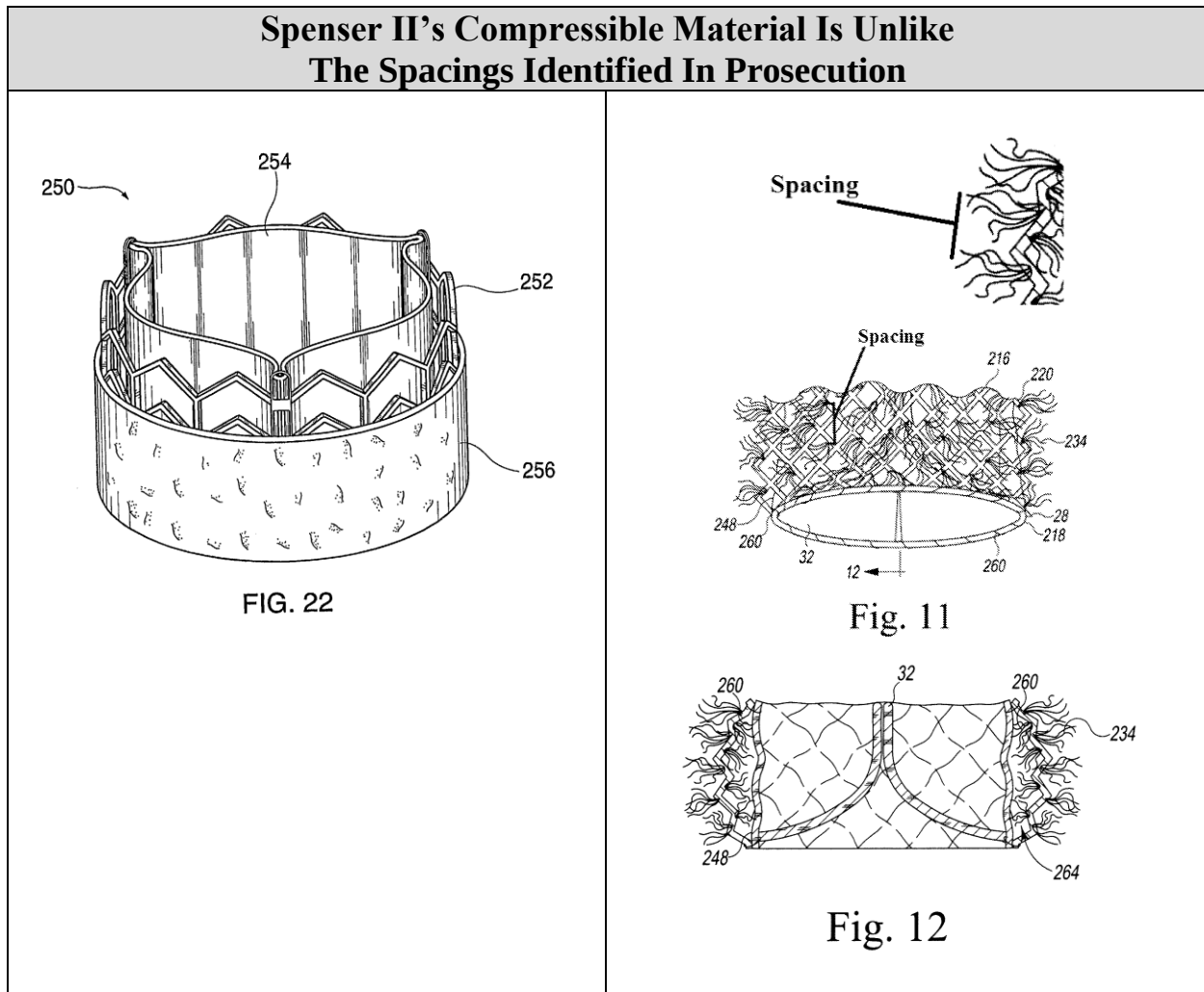
Fig. 11

As the MPEP makes clear, drawings alone may provide a ‘written description’ of an invention as required by Sec. 112. This is the case in this instance ***where the fibers are shown with spacings therebetween. This advantage is not shown in the prior art.***

Ex. 2140 [’834-FH] 1001-2.

The Examiner agreed with the Applicant and, after the claims were amended to require “spacings,” the Examiner’s Reasons for Allowance expressly identified “spacings” as “***not [being] disclose[d] or render[ed] obvious***” by the prior art of record (including Spenser II, Spenser I, and Levi). Ex. 2140 [’834-FH] 850, 995-1002.

The Examiner’s analysis, furthermore, was correct. As the Board found, Spenser II’s compressible material “corresponds to an outer graft covering.” Ex. 2124 [-556-FWD] 29-30; Ex. 1120 [-00034-FWD] 48. The Board, in accord, approvingly cited Dr. Brecker’s description of Spenser II’s compressible material as a “solid, non-porous, graft material.” Ex. 2124 [-00556FWD] 33-34 (quoting Ex. 2103, ¶160); Ex. 1120 [-00034FWD] 44 (similar). Spenser II’s compressible material, moreover, looks nothing like the “spacings” identified in prosecution:



See also Ex. 2002 [Brecker-Decl.] ¶¶39-40.

And, as Petitioner’s expert recognized, the Applicant “**repeatedly** distinguished the claimed ‘spacing(s)’ from spacings between fibers that are present in ... [the] materials disclosed in Walther and Spenser II.” Ex. 2141 [Brookstein-Decl.] ¶¶33, 35 (“Aortic Innovations argued that the collagen fibers in the Asserted Patents **were distinguishable from the prior art ... (including Walther and Spenser II)**” due to the “lack of ‘spacings’”) (quoting Ex. 2140 [’834-FH] 1001).

In accord, the Board credited Dr. Brecker’s testimony distinguishing “the gaps and spaces between the fibers” shown in the ’033’s Fig. 13 with a “solid, non-porous, graft material” as “seen in...Spenser II.” Ex. 2124 [-00556FWD] 33-34 (quoting Ex. 2103 [Brecker-556-Decl.] ¶160); Ex. 1120 [-00034FWD] 44 (similar). Thus, the Applicant rightly disclaimed Spenser II’s compressible material as not satisfying the “spacings” limitations.

And, as Petitioner’s expert agrees, the disclaimer in the ’033’s parent’s prosecution also applies to the ’033. Ex. 2141 [Brookstein-Decl.] ¶¶33, 35, 40. And just so. The ’033, like its parent, requires “spacings” into which extending fibers are compressed to facilitate the creation of a paravalvular seal when the valve is expanded upon deployment, as Dr. Brecker explains:

The '033's claims require "spacings" which "extend[] through a thickness" of a "sealing assembly," that includes a "plurality of [] fibers that extend away from the frame for providing sealing against paravalvular leakage." Ex. 1001 ['033] cl. 1. These "spacings" "allow fluid to pass" through the "sealing assembly" when the valve is in "an undeployed state." *Id.* When the valve is deployed and expanded, the extending fibers are "compresse[d] ... relative to the spacings." *Id.* This compression "relative to the spacings" works "cooperatively" with the expansion of the "polymer covering" to "create a paravalvular seal ... by reducing the spaces in the sealing assembly." *Id.*

The '834 similarly requires a "spacing" that extends through one or two pluralities of fibers and either "to the frame" or "through the ... frame." Ex. 2143 ['834] cls. 2, 17-18. Also similar to the '033, the '834's claims further require that when the valve expands, the extending fibers are "compresse[d] ... relative to the spacing to create a seal thereabout." *Id.*, cls. 17-18. Notably, the '033 and its parent share the same specification and figures. *Compare* Ex. 1001 ['033] *with* Ex. 2143 ['834]. Accordingly, POSITAs reviewing the '033 and the '834 would regard their respective "spacings" limitations, requiring spacings into which extending fibers are compressed when the valve is expanded on deployment to facilitate the formation of a paravalvular seal, as pertaining to this same subject matter.

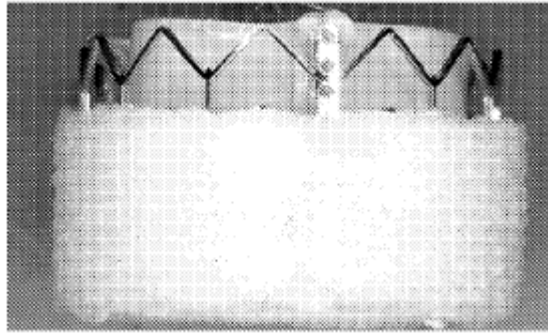
I note that Petitioner's litigation expert, Dr. Brookstein declared that "particularly in view of Aortic Innovations' arguments during prosecution," the '033's "spacings" which "allow fluid to pass" through

the “sealing assembly” “would not have led a POSA to understand that the claims cover” the graft coverings “described in Walther and Spenser II.” Ex. 2141 [Brookstein-Decl.] ¶40. And, notably, the Board credited my testimony describing Spenser II’s outer covering as a “solid, non-porous graft material.” Ex. 2124 [-00556FWD] 33-34 (quoting Ex. 2103 [Breckner-556-Decl.] ¶160); Ex. 1120 [-00034FWD] 44 (similar). Thus, there does not seem to be any dispute that the statements in the prosecution of the ’834 apply equally to the ’033.

Ex. 2002 [Breckner-Decl.] ¶¶43-45.

Thus, the Applicant’s statements operate as a disclaimer of Spenser II’s compressible material as not disclosing or rendering obvious the “spacings” of either the ’033 or ’834. The Applicant’s parallel statements distinguishing Spenser II’s “real-world embodiment” Walther in the ’033’s prosecution as lacking “spacings” further confirms the disclaimer applies to the ’033:

The specification illustrates spacing between fibers that are an intentionally placed spacing, *i.e.*, not just the spacing that may be inherent between radially extending fibers such as those that appear to be found in the Walther reference. Applicant notes that the claims recite spacings extending through a thickness of the sealing assembly that allow fluid to pass therethrough when the prosthetic heart valve assembly is in an undeployed state ... ***These claim limitations are clearly not shown in the Walther reference***, an image of which is reproduced below:



[It] does not appear that any such spacings are visible or disclosed in the Walther reference.

Ex. 1002 [Pros.-Hist.] 29-30; Ex. 1007 [Walther] Fig. 1; Ex. 2052 [Buller-00034-Depo.] 104:17-105:7 (Walther is a “real-world embodiment” of Spenser II). Ex. 2002 [Brecker-Decl.] ¶50.

The Applicant further explained that the claimed “spacings” were “not shown in the references of record,” which notably included Walther, Spenser II, and Levi. See Ex. 1002 [Pros.-Hist.] 30, 135-138. And, like the ’834, the Examiner allowed the claims once they were amended to require “spacings.” *Id.*, 84-85, 96, 46; Ex. 2140 [’834-FH] 850, 995-1002. Indeed, the Examiner’s finding was “confirmed” in a Corrected Notice of Allowability issued in response to the Applicant’s remarks distinguishing Walther and “the references of record” as not showing “spacings.” Ex. 1002 [Pros.-Hist.] 28-30, 15. This confirmation further followed the Applicant identifying, per the Examiner’s request, Walther, Spenser II, and Levi as among the most relevant references of record. Ex. 1002 [Pros.-

Hist.] 86, 93. Consequently, in view of the Applicant’s disclaimer of Spenser II’s and Walther’s solid, non-porous grafts as not disclosing or rendering obvious “spacings,” Petitioner’s Spenser II combinations fail.

2. Under §325(d), Petitioner’s Spenser II Grounds Should Not Be Reconsidered.

Even if the Applicant’s disclaimer could be ignored, the Board should not revisit Petitioner’s Spenser II grounds under §325(d) because the same art and arguments were considered in prosecution.

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) 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 “spacings” limitations played a critical role in prosecution. After an initial rejection, the ’033’s claims were allowed once amended to require “spacings.” See Ex. 1002 [Pros-Hist.] 46, 84-85, 96. It is undisputed that the Examiner allowed the claims after reviewing each reference in

Petitioner's grounds, including Spenser II, Spenser I, Levi, and Chuter. *Id.*, 93, 135; Pet., 81. Indeed, after the Examiner requested that the Applicant identify the most relevant art, the Applicant expressly directed the Examiner's attention to each of Walther, Spenser II, and Levi. Ex. 1002 [Pros.-Hist.] 86, 93.

And similar "spacings" limitations were already a focus in related prosecution. The '033's parent (the '834) was allowed over, *inter alia*, Spenser II, Walther, Spenser I, and Levi precisely because those references did not satisfy similar "spacing" limitations. See Section II.B.1; Ex. 2140 ['834-FH] 850, 995-1002. A §325(d) denial is appropriate where, as here, a reference was distinguished in prosecution of a parent as not meeting "similar limitations." *Motorola Mobility LLC v. Maxell, Ltd.*, IPR2022-01287, Paper 11, 14-22 (Feb. 2, 2023).

After the claims were allowed, the Applicant ensured the Examiner's cognizance of Petitioner's related arguments. The Applicant submitted an IDS including the Institution Decision from IPR2022-00556 ("-00556"), concerning the related '236 patent (Ex. 1002 [Pros.-Hist.] 34, 40), with remarks addressing Petitioner's argument in the -00556 that the '236's "openings" limitations (which the Applicant identified as "parallel" to the '033's "spacings"), would be satisfied by the same combinations raised here. *Id.*, 28-30; IPR2022-00556, Paper 1 (Petition), 52-55, 80-82, 102-104. The Applicant distinguished the '033's

“spacings” as not those which are “inherent between radially extending fibers”:

The specification illustrates spacing between fibers that are an intentionally placed spacing, *i.e., not just the spacing that may be inherent between radially extending fibers ...*”

Ex. 1002 [Pros.-Hist.] 29-30; Ex. 2002 [Brecker-Decl.] ¶50. The Applicant identified “spacings” in the ’033’s Fig. 11, as annotated below:

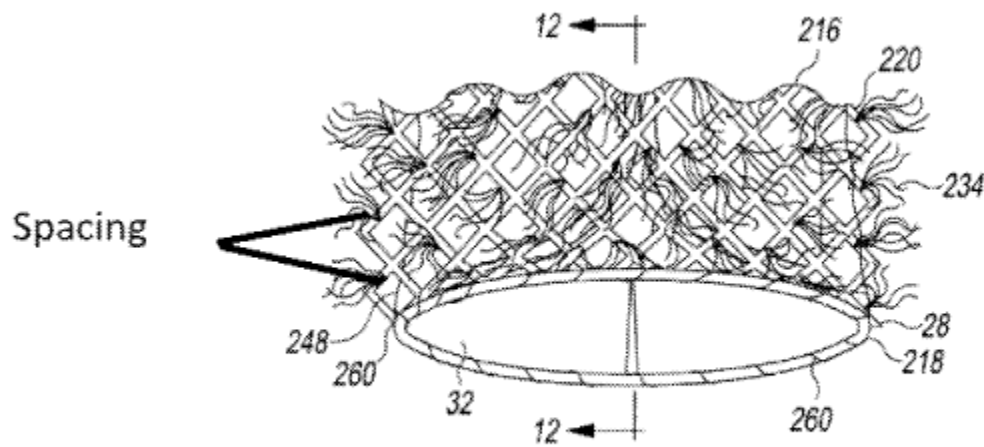


Fig. 11

Id. The Applicant further distinguished Walther, an admitted “real-world embodiment” of Spenser II (Ex. 2052 [Buller-00034-Depo.] 104:17-105:7), and the other “references of record” as lacking “spacings.” *Id.* (“[it] does not appear that any such spacings are visible or disclosed in the Walther reference.”).

In response, the Examiner “confirmed” “the allowability of [the] claims,” as “[n]othing cited on the newly presented IDS altered the previous determination of allowable subject matter.” Ex. 1002 [Pros.-Hist.] 15. Thus, the same art and

arguments were considered by the Examiner, who found that Spenser II, Walther, and other references did not disclose or render obvious the claimed “spacings” of either the ’033 or its parent.

As to the second prong, Petitioner has not shown any material error by the Examiner. Petitioner argues institution should not be denied “based on the inclusion of Spenser, Spenser II, Chuter, and Levi on an IDS” because the Examiner allegedly “never applied” them. Pet., 81. But, the Federal Circuit has long recognized that “[i]t is reasonable to infer, absent an indication to the contrary, that an examiner will consider an IDS when determining whether to allow the claims.” *Ekchian*, 104 F.3d 1299 at 1303-1304.

Petitioner’s argument that the Office merely considered an IDS is also wrong. The IDS identifying Spenser II was submitted after the Examiner agreed that Spenser II did not satisfy the related “spacings” limitation of the ’834. And, as discussed, the Examiner also considered Petitioner’s argument that Spenser II discloses “openings” from IPR2022-00556 and the Applicant’s argument that Walther (Spenser II’s “real-world” embodiment) similarly did not disclose “spacings.”

Petitioner further contends the Examiner erred by allowing the claims because the prior art would not be transfemorally deliverable. Pet., 82 (citing Ex. 1002 [Pros-Hist.] 93-98, 167-180). Not so. The claims were allowed only after

they were amended to include the “spacings” limitations. Ex. 1002 [Pros.-Hist.] 46, 93-96 165-173. With that amendment, the Examiner dismissed the Applicant’s transfemoral arguments as “moot.” *Id.*, 96, 167-180, 186-190.

Petitioner further contends the Examiner erred because the Board allegedly found allegedly “highly similar” claims with “no material difference” in “scope” to those challenged here to be unpatentable in related IPRs. Pet., 81, 83. This is absurd. The Board did not find “spacings” to be disclosed or rendered obvious in the prior IPRs. Petitioner, however, does not explain why there is no “material difference between the scope of [] claims” which do or do not require “spacings.” What is more, the Board has twice found that Petitioner failed to prove that Spenser II’s compressible material is “free of an outer graft covering.” Thus, the Board’s prior decisions reinforce the Examiner’s conclusion. Ex. 2002 [Brecker-Decl.] ¶40.

Finally, Petitioner argues that “the challenged claims would have been obvious ... for the reasons explained” in its grounds. Pet., 81. But, as discussed, Spenser II was distinguished as lacking “spacings.” See Section II.A.1. And, here, too, Petitioner fails to show that its Spenser II combinations disclose or render obvious “spacings.” See Section II.B.

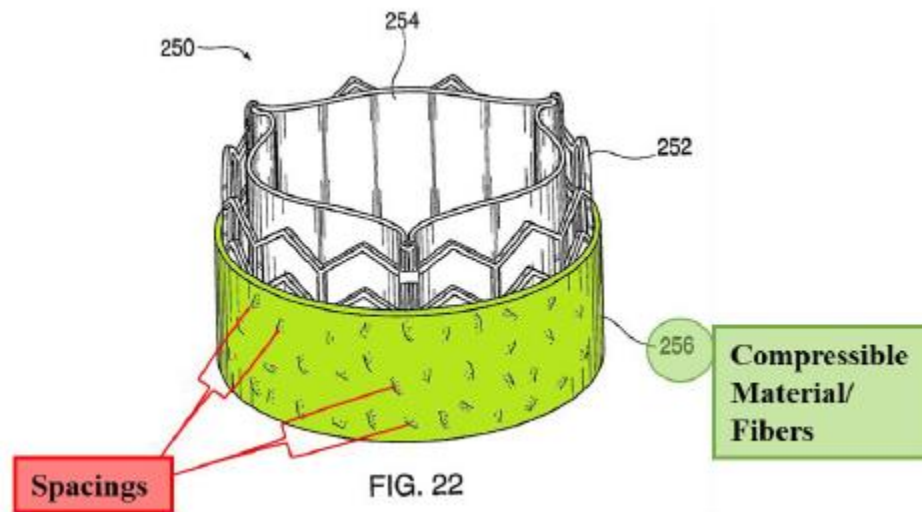
Thus, both *Advanced Bionics* prongs are met and the Board should reject Petitioner’s Spenser II grounds under §325(d).

B. Petitioner Fails To Show That Its Spenser II Combinations Disclose Or Render Obvious “Spacings” (All Claims).

Even were they to be reconsidered, Petitioner fails to prove that its Spenser II combinations satisfy the “spacings” limitations for three independently sufficient reasons. First, Petitioner fails to show that Spenser II discloses or renders obvious “spacings extending through a thickness” of its compressible material (relied-upon “sealing assembly”). See Section II.B.1. Second, Petitioner fails to show that the alleged spacings would “allow fluid to pass” through the compressible material “in an undeployed state.” See Section II.B.2. Finally, Petitioner fails to show that the “compression of the plurality of fibers” and the “expansion of the polymer covering” “cooperatively create a paravalvular seal ... by reducing the spaces in the sealing assembly.” See Section II.B.3.

1. Petitioner Fails To Show That Spenser II’s Compressible Material Includes “Spacings Extending Through A Thickness Of The Sealing Assembly.”

The claims require “*spacings* extending through a thickness of the sealing assembly.” Ex. 1001 [’033] cl. 1. Petitioner contends that Spenser II’s Fig. 22 “illustrates ‘spacings’ between the [extending] fibers” which “extend ‘through a thickness of the sealing assembly,’ where the ‘thickness’ is at least the length of the fibers”:



Pet., 46 (Petitioner’s annotation).

Undisputedly, however, Spenser II was disclaimed as not disclosing or rendering obvious “spacings.” See Section II.A.1. Petitioner’s district court expert declared that “Aortic Innovations argued that the collagen fibers in the Asserted Patents *were distinguishable from the prior art ... (including Walther and Spenser II)*” due to the “lack of ‘spacings.’” Ex. 2141 [Brookstein-Decl.] ¶35 (quoting Ex. 2140 [’834-FH] 1001). Petitioner’s expert further declared that the “*Aortic Innovations clearly argued during prosecution*” that the “cloths ... *described in Walther and Spenser II ... were not covered*” by the ’033’s claims. *Id.*, ¶40, ¶33 (similar); see also Ex. 2002 [Brecker-Decl.] ¶53.

Thus, as both parties’ experts agree, Spenser II does not disclose or render obvious the claimed “spacings.” What is more, and notwithstanding its duty of candor, Petitioner has not disclosed its contrary position to the Board. *Facebook*,

Inc. v. Sound View Innovations, LLC, IPR2017-01002, Paper 13, 17-18 (Sept. 5, 2017) (“Instead, Petitioner left it to Patent Owner to advise us of Petitioner’s differing claim construction arguments to the district court ... At the very least, Petitioner’s failure to inform us of its differing claim construction arguments before the district court raises the specter of lack of candor.”) (denying institution).

But even if Petitioner’s undisclosed, unreconciled, contradictory positions were tolerated, Petitioner’s contention that Spenser II’s FIG. 22 “illustrates” “spacings extending through a thickness of the sealing assembly” that “is at least the length of the fibers” (Pet., 46) is, at best, unclear. To the extent that Petitioner is arguing that the required “spacings” allegedly illustrated in Spenser II’s FIG. 22 may extend only the distance between the tips of Spenser II’s extending fibers and the outer surface of the compressible material’s base layer, this is further inconsistent with its position in IPR2023-01232 that Spenser II “discloses” that its extending fibers are “in contact with the frame” when the valve is in either the “radially compressed” or “radially expanded” orientation. Ex. 2144 [-01232-Pet.] 44, 47.

Thus, Petitioner’s position in IPR2023-01232 indicates an understanding that the spacings would extend “the length” of Spenser II’s fibers, through the compressible material’s base layer to the frame. But, it is well-settled that no such “spacings” are disclosed by Spenser II. Rather, the Board found that Spenser II’s

compressible material “corresponds to an outer graft covering,” which “covers” both the frame’s struts and the interstices therebetween (Ex. 2124 [-556-FWD] 29-30; Ex. 1120 [-00034-FWD] 48), and further credited Dr. Brecker’s testimony describing Spenser II’s compressible material as a “***solid, non-porous, graft material***” (Ex. 2124 [-00556FWD] 33-34 (quoting Ex. 2103 [Brecker-556-Decl.] ¶160); Ex. 1120 [-00034FWD] 44 (similar)). Nothing about such a structure suggests “spacings extending through a thickness of the sealing assembly.” Ex. 2002 [Brecker-Decl.] ¶55; Ex. 2128 [Buller-556-Decl.] ¶60 (exemplary graft covering is a “low-porosity woven fabric.”) (citing Ex. 2144 [Leonhardt] 3:53-55).

Thus, Petitioner fails to show that Spenser II discloses “spacings extending through a thickness of the sealing assembly.”

2. Petitioner Does Not Demonstrate The Spacings Would “Allow Fluid To Pass” Through The “Sealing Assembly” “In An Undeployed State.”

Even if we were to assume, *arguendo*, that “spacings” existed in Spenser II’s compressible material, Petitioner still fails to show that those “spacings ... ***allow fluid to pass [through]***” the “sealing assembly” when the “prosthetic heart valve assembly is in an undeployed state.” Ex. 1001 [’033] cl. 1. Petitioner contends this limitation is inherently disclosed and, alternatively, that a POSITA would be motivated to modify Spenser II to achieve the limitation. Both arguments fail.

a. *Petitioner's Inherency Argument Fails.*

Petitioner does not argue that Spenser II expressly discloses “spacings ... that allow fluid to pass” through its compressible material “in an undeployed state.” Rather, Petitioner relying upon inherency, argues that POSITAs allegedly “**would have understood**” that Spenser II discloses this limitation because the compressible material allegedly “**must have spacings** extending through a thickness of the material” which “also mean[s] that the material is porous and would permit the flow of fluid therethrough.” Pet., 47-49 (“**POSITAs would have understood** that fluid can pass through Spenser II’s compressible material when the prosthetic heart valve assembly is in an undeployed state.”).

Petitioner further contends that “POSITAs **would have understood** that fluid can pass through Spenser II’s compressible material when the prosthetic heart valve assembly is in an undeployed state” to “compress,” “fill[] the gaps” between the frame and native tissue, “encourage the coagulation of blood” and “promote tissue ingrowth.” Pet., 47-49 (“**POSITAs would have understood** that promoting blood coagulation and tissue ingrowth into the compressible material would have only been possible, and necessary, if the material were porous and did not, on its own, prevent the flow of fluid therethrough”). Petitioner also contends that “**POSITAs would have understood** that the spacings necessary to promote tissue ingrowth into a fibrous material were in the range of 40-100 μm , far larger than the

size of a spacing necessary to allow passage of fluid therethrough.” *Id.*, 48-49 (citing Ex. 1003 [Buller-Decl.] ¶156; Ex. 1106 [Estridge] 158).

These foregoing arguments, each concerning what POSITAs 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. 2023) (arguments that POSITAs “would understand this [limitation] is present” invoke inherency). Proving obviousness by inherency requires 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 well short of demonstrating that “spacings ... that allow fluid to pass” through Spenser II’s compressible material in “an unexpanded state” are “necessarily” present. As Dr. Brecker explains:

Compressible material 256 is described as a “layer,” “sleeve,” “cloth,” or “fabric.” Again, no mention is made of any “spacings” therein, much less ones “that allow fluid to pass” through the compressible material in “an unexpanded state.” Nor are such “spacings” suggested by Spenser II’s FIG. 22, which depicts a thick, opaque, seal without any spacings extending through the compressible material/graft:

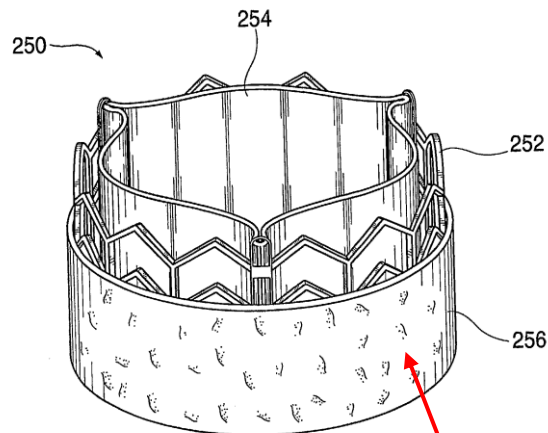
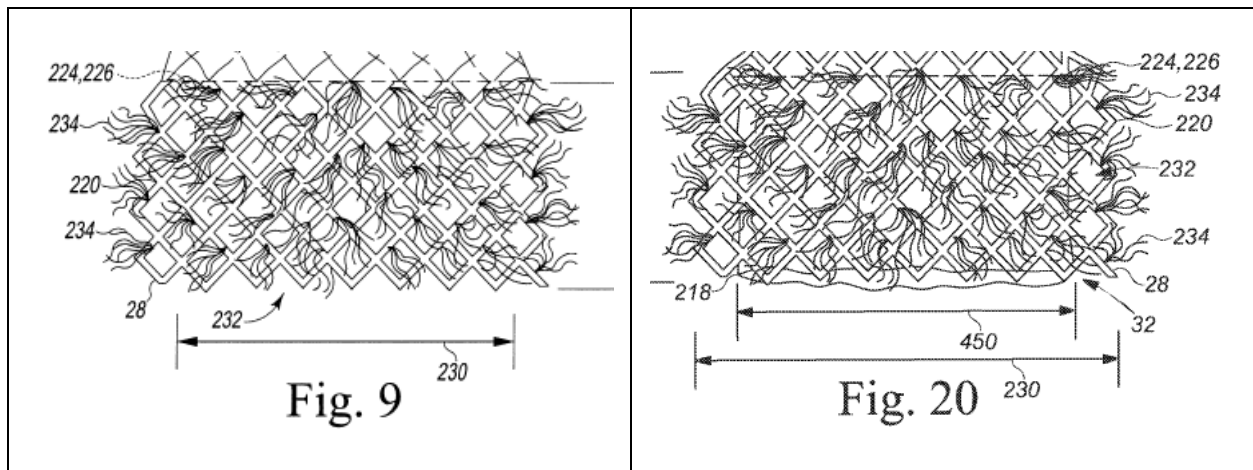


FIG. 22

No Spacings

In this regard, Spenser II's FIG. 22 stands in stark contrast with the fibers with spaces therebetween illustrated in the '033's figures, which would allow blood to pass through in an undeployed state:



Ex. 1001 ['033] Figs. 9, 20; see also *id.*, Figs. 8, 11-16, 21-22.

Moreover, even if some “spacings” were imagined, there is nothing in FIG. 22 or its corresponding description indicating that any unmentioned, hypothetical “spacings” would further “extend” through

the material's thickness "that allow fluid to pass" through Spenser II's graft in "an undeployed state."

Indeed, as the Board (rightly, in my opinion) found, Spenser II's compressible material "corresponds to an outer graft covering." Ex. 2124 [-00556FWD] 38; Ex. 1120 [-00034FWD] 48 (same). The Board also credited my testimony describing Spenser II's compressible material as a "solid, **non-porous**, graft material." Ex. 2124 [-00556FWD] 33-34 (quoting Ex. 2103 [Brecker-556-Decl.] ¶160); Ex. 1120 [-00034FWD] 44 (similar). A "non-porous graft covering," however, would not allow, much less necessarily permit, "fluid to pass therethrough" in "an undeployed state." See Ex. 2122 [Buller-556-Reply-Depo.] 20:2-21:3 ("nonporous" means "impermeable to fluid."). In the TAVR context, blood is the relevant fluid which TAVRs must form a seal against to prevent paravalvular leaks.

In accord, Dr. Buller similarly testified that Spenser II's compressible material would be "**sufficiently dense** to prevent blood from leaking through the cloth/fabric." Ex. 2128 [Buller-556-Decl.] ¶222. I agree that POSITAs would understand that the compressible material would be "sufficiently dense" to prevent blood from leaking because that is its principal purpose. This indicates a "non-porous graft covering," a favored solution to prevent PVL.

Nor do the materials used in the compressible material suggest that is porous. Spenser II teaches that the compressible material is "prefer[ably]...formed of polyethylene terephthalate (PET)," a type of polyester. But a thick, sleeve-like PET layer as depicted in FIG. 22

would not suggest, much less necessarily indicate, a “porous” covering. Indeed, the ’033 repeatedly describes standard polyester, low-profile polyester, and ePTFE as “covering materials” that “prevent[] blood from passing through the [] surface.” Ex. 1001 [’834] 7:30-36, 8:51-55, 9:35-38; 13:35-38, 13:61-67, 15:60-65, 17:6-10, 19:17-20.

Petitioner, moreover, proposed claims in Spenser II’s European prosecution requiring that “the compressible material is a *fluid impermeable membrane*.” Ex. 2040 [Spenser-II-European-Proceeding] 2087-2093. A “fluid impermeable membrane” would not “allow fluid to pass therethrough,” much necessarily do so.

Quite simply, Spenser II’s FIG. 22 and description thereto provide no basis to conclude that “spacings” that would “allow fluid to pass” through the compressible material in “an undeployed state” are “necessarily” present.

Ex. 2002 [Brecker-Decl.] ¶¶59-65.

Petitioner’s and Dr. Buller’s opposite conclusion does not pass muster.

Here, Petitioner’s analysis is based upon the unsubstantiated premise that Spenser II’s compressible material is “porous” and “*must* have spacings” that “would permit the flow of fluid therethrough.” Pet., 47-49. But Spenser II’s compressible material is not described as “porous.” Instead, the Board approvingly cited Dr. Brecker’s description of Spenser II’s compressible material as a “solid, non-porous, graft material.” Ex. 2124 [-00556FWD] 33-34 (quoting Ex. 2103

[Brecker-556-Decl.] ¶160); Ex. 1120 [-00034FWD] 44 (similar); *see also* Ex. 2122 [Buller-556-Reply-Depo.] 20:2-21:3 (“nonporous” means “impermeable to fluid.”). And Dr. Buller’s position here is at-odds with his prior position that the compressible material would be “**sufficiently dense** to prevent blood from leaking through the cloth/fabric” (Ex. 2128 [Buller-556-Decl.] ¶222), and Petitioner’s proposed claims in Spenser II’s European prosecution requiring that “the compressible material is a **fluid impermeable** membrane” (Ex. 2040 [Spenser-II-European-Proceeding] 2087-2093). Ex. 2002 [Brecker-Decl.] ¶¶62-64.

Petitioner does not attempt to reconcile its position here with its prior positions and presents no evidence that “spacings” extending through Spenser II’s compressible material which “allow fluid to pass therethrough” are **required** for Spenser II’s material to be compressible, fill gaps, encourage blood coagulation or promote tissue ingrowth. Certainly, this is not suggested by Petitioner’s real-world products. Walther’s outer cloth “promotes tissue ingrowth,” “fill[] little gaps,” and, per Petitioner, is “highly compressible” and “clots” blood. *See* Ex. 1007 [Walther] 1, 7; IPR2022-00556, Paper 22 (Reply) 8 (“Walther’s outer cloth is highly compressible”); Ex. 1128 [Buller-556-Depo.] 72:8-9 (“blood clots” in Walther’s outer cloth). Yet, Walther does not reveal any “spacings” extending through its outer cloth, much less ones further allowing “fluid to pass therethrough.” Ex. 2002 [Brecker-Decl.] ¶66.

Additionally, Spenser II's compressible material, like Walther's outer cloth, is designed to prevent paravalvular **leakage**. Ex. 1011 [Spenser-II] ¶145; Ex. 1007 [Walther] 1. To that end, per Dr. Buller, POSITAs would understand the material would be "sufficiently dense" to prevent blood from leaking through the cloth. Ex. 2128 [Buller-556-Decl.] ¶222. Accordingly, Spenser II addresses PVL via a "solid, non-porous, graft material." Ex. 2124 [-00556FWD] 33-34 (quoting Ex. 2103 [Brecker-556-Decl.] ¶160); Ex. 1120 [-00034FWD] 44 (similar); Ex. 2040 [Spenser-II-European-Proceeding] 2087-2093 (compressible material is "a fluid impermeable membrane").

Further, as Dr. Brecker explains:

Petitioner's and Dr. Buller's posited goals—filling gaps, encouraging blood coagulation, and promoting tissue ingrowth—are each addressed via the fibers extending from Spenser II's compressible material, and do not require any "spacings" which "allow fluid to pass" through the "thickness" of the compressible material/graft. The extending fibers "fill the gaps between the stented valve and the surrounding tissue" and, "[a]ccordingly, the compressible material creates a mechanical seal that prevents paravalvular leakage." Ex. 1011 [Spenser-II] ¶145. Spenser II tells us directly that it is "the fibers" that "encourage coagulation of blood to further fill the gaps and prevent leakage." *Id.* These teachings refer to the filling of gaps between the outer surface of the compressible material's base layer and the "surrounding tissue," and do not indicate that fluid could pass through the thickness of the compressible

material/graft in “an undeployed state.” In accord, Spenser II further teaches that a growth factor may be applied “along the outer surface of the compressible material,” *i.e.*, where the extending fibers are, and may promote tissue ingrowth on the outer side of the valve where the cloth attaches to the vessel wall. *Id.*, ¶¶145, 55. This is consistent with Dehdashtian’s teaching that extending fibers facilitate tissue ingrowth. Ex. 2101 [Dehdashtian] 3:7-16, 3:37-41 (describing a graft with floaters that “promote tissue ingrowth where they are placed along the exterior of the graft body”)[]. None of this suggests the compressible material must allow fluid to pass through in an undeployed state.

Ex. 2002 [Brecker-Decl.] ¶69.

Petitioner’s additional contentions that promoting tissue ingrowth and blood coagulation requires “spacings ... that allow fluid to pass [through]” the compressible material also fail. Even if “spacings” between the extending ***fibers*** (which address tissue ingrowth and blood coagulation) were assumed, this would not suggest that fluid could pass through the “***sealing assembly***” in an undeployed state, given the presence of a non-porous graft material/“fluid impermeable membrane.” Ex. 2002 [Brecker-Decl.] ¶70. Thus, regardless of whether any spaces exist between fibers, that would not indicate that fluid may pass through the undeployed sealing assembly.

Even considering only the extending fibers, Petitioner’s argument does not hold. Petitioner contends that “spacings” allegedly “far larger than the size of a

spacing necessary to allow passage of fluid” are required for promoting tissue ingrowth. *Id.*, 48-49 (citing Ex. 1003 [Buller-Decl.] ¶156; Ex. 1106 [Estridge] 158). The evidence Petitioner relies upon, however, does not even speak to fluid permeability. As Dr. Brecker explains:

The relied-upon Estridge article does not mention fluid permeability. See Ex. 1106 [Estridge] 157-158. Instead, Estridge appears to be referring to “healing porosity” (pertaining to tissue ingrowth), not “bleeding porosity” (pertaining to fluid permeability). See Ex. 1106 [Estridge] 157 (“there is little information about the design criteria that could lead to optimal tissue ingrowth into [] porous materials.”); Ex. 2122 [Buller-556-Reply-Depo.] 43:8-45:12 (healing porosity refers to “the ability of tissue to ... grow through the fabric,” not “the passage of fluids” therethrough). Yet, Petitioner’s own evidence confirms that sufficient healing porosity need not come at the expense of bleeding porosity. See Ex. 1110 [Pourdeyhimi] 172 (“the use of bulk texturized yarns has led to a reduction in porosity (increasing healing porosity) without adversely affecting permeability (bleeding porosity).”); Ex. 1129 [Chu] 7. Thus, Petitioner fails to substantiate its position that spacings allowing for tissue ingrowth would be “far larger than ... necessary to allow passage of fluid therethrough.”

Ex. 2002 [Brecker-Decl.] ¶72.

Petitioner alternatively contends that the claimed “spacings” may be the “inherent spacings between fibers.” Pet., 51. The Applicant, however, clearly

distinguished the claimed “spacings” from the “inherent” spaces between fibers as shown in Walther (Spenser II’s real-world embodiment):

The specification illustrates spacing[s] between fibers that are an intentionally placed spacing, *i.e.*, ***not just the spacing that may be inherent between radially extending fibers*** such as those that appear to be found in the Walther reference.

Ex. 1002 [Pros.-Hist.] 29; Ex. 2002 [Brecker-Decl.] ¶74. This statement operates as a disclaimer of the mere inherent spacing between fibers as sufficient to satisfy the “spacings” limitation. *Saffran*, 712 F.3d at 559.

Indeed, Petitioner’s district court expert agreed that the claimed spacings are not the “inherent” spacings between fibers. Ex. 2141 [Brookstein-Decl.] ¶36 (recognizing Applicant’s statement distinguishing the claimed “spacings” from “the spacing that may be inherent between radially extending fibers...” (quoting Ex. 1002, 29). Notwithstanding its own expert’s testimony, Petitioner now argues precisely the opposite; that the Applicant’s statement distinguishing inherent spacings is “unsupported by the intrinsic record” and further “improperly attempts to inject an intent element into the construction,” and is “vague,” leaving POSITAs “no meaningful definition to apply.” Pet., 50-52. Thus, what its own expert recognized as a disclaimer, Petitioner contends is “unsupported by the intrinsic record.” Moreover, the Applicant did not “inject” any “intent element” into the

meaning of “spacings.” Rather, the Applicant made clear it was not claiming the “the *spacing that may be inherent between radially extending fibers.*” Ex. 1002 [Pros.-Hist.] 29. In fact, Petitioner’s interpretation, which includes inherent spacings between fibers, would read “spacings” out of the claims. The claims already require a “plurality of fibers” that “extend away from the frame.” Ex. 1001 [’033] cl. 1. Claiming “spacings” inherent to this already-claimed feature would, accordingly, render “spacings” superfluous. Ex. 2002 [Brecker-Decl.] ¶75.

Consequently, Petitioner fails to show that Spenser II inherently discloses “spacings ... that allow fluid to pass []through” the “sealing assembly” when the valve is undeployed.

b. *Petitioner Fails To Prove A POSITA Would Be Motivated To Modify Spenser II’s Outer Covering.*

Petitioner argues in the alternative that “POSITAs would have been motivated to use, and expected success in using, a porous fabric or cloth, such as a knitted or woven velour-like fabric, as the compressible material taught by Spenser II ... because they were known to be compressible, stretchable, and provide enhanced tissue ingrowth.” Pet., 49 (citing Ex. 1003 [Buller-Decl.] ¶157).

Petitioner’s argument, rooted in abject hindsight, fails.

The benefits Petitioner alleges would motivate POSITAs to modify Spenser II’s compressible material are already disclosed by Spenser II (compressibility and

promoting tissue ingrowth) and/or are not shown to either enhance the compressible material's performance or to even result from Petitioner's proposed modifications (stretchability).

Petitioner contends that POSITAs would modify the compressible material to provide compressibility and enhance tissue ingrowth. Pet., 49. But Spenser II's **compressible** material is already compressible, as Petitioner has repeatedly recognized. See, e.g., Pet., 47 ("Spenser II describes a '**compressible** material'") (emphasis in Petition); Ex. 2136 [-01151-Pet.] 49 ("Spenser II expressly describes the material as 'compressible.'"). Spenser II's compressible material, moreover, may already promote tissue ingrowth. See Ex. 1011 [Spenser-II] ¶145 ("a tissue growth factor may be applied ... for promoting the growth of tissue into the material."); Ex. 2002 [Brecker-Decl.] ¶79. There is no motivation to modify Spenser II to provide these benefits already expressly disclosed therein. *Apple Inc. v. Cellular Comm'ns Equipment, LLC*, IPR2015-00576, Paper 7, 12 (June 12, 2015) ("Petitioner...fails to provide a specific explanation why [reference] did not already accomplish [the asserted benefits] by itself.") (denying institution); *Norman Int'l, Inc. v. Hunter Douglas, Inc.*, IPR2014-00282, Paper 8, 16 (June 20, 2014) ("Petitioner has not explained adequately why a [POSITA] would have had a reason to modify Todd's device to include Strahm's one-way brake mechanism in

the manner required by [the] challenged claims...because Todd's device already includes brake/clutch mechanism 28.”).

Petitioner further contends that POSITAs would be motivated to modify Spenser II to provide “stretchability.” Pet., 49 (citing Ex. 1003 [Buller-Decl.] ¶157). But Petitioner neither explains why a POSITA would be motivated to make Spenser II's compressible material “stretchable” nor demonstrates that the compressible material is insufficiently stretchable to achieve an unidentified purpose. Ex. 2002 [Brecker-Decl.] ¶80. Consequently, Petitioner fails to show that its POSITAs would have found it obvious to modify Spenser II's compressible material to “allow fluid to pass therethrough.”

Even if POSITAs were motivated to make Spenser II's compressible material “stretchable,” Petitioner's relied-upon evidence does not even substantiate its contention that this aim would be achieved by making Spenser II's compressible material porous. Petitioner relies upon Dr. Buller's testimony which in turn relies upon Hall (Ex. 1007), Estridge (Ex. 1006) and Pourdeyhimi (Ex. 1110). See Pet., 49 (citing Ex. 1003 [Buller-Decl.] ¶157). These documents, however, neither mention “stretchability” nor any benefits thereof, much less establish that a porous velour fabric is desirably more stretchable than a nonporous velour. See Ex. 1006 [Estridge]; Ex. 1007 [Hall]; Ex. 1110 [Pourdeyhimi]; Ex. 2002 [Brecker-Decl.] ¶81. Thus, Petitioner not only fails to prove that a POSITA

would be motivated to make Spenser II's compressible material more stretchable, it also fails to prove its proffered modification would achieve that end.

Petitioner also fails to prove that POSITAs would be motivated to make Spenser II's compressible material porous. Spenser II's compressible material is intended to address paravalvular leakage and uses a non-porous graft covering, or, per Petitioner, a "fluid impermeable membrane" to do so. Ex. 2040 [Spenser-II-European-Proceeding] 2087-2093; Ex. 2002 [Breckler-Decl.] ¶82. Petitioner's *ex post facto* argument that a POSITA would be motivated to modify the compressible material to "allow fluid to pass therethrough" when the valve is "undeployed" is rank hindsight, using the claim limitations as a roadmap. *TQ Delta, LLC v. Cisco Sys.*, 942 F.3d 1352, 1361 (Fed. Cir. 2019) (rejecting "the impermissible *ex post* reasoning and hindsight bias" caused by "the use of the challenged patent as a roadmap to reconstruct the claimed invention using disparate elements from the prior art.")).

But it is not just hindsight. Modifying Spenser II's compressible material to have "spacings" that "allow fluid to pass therethrough" would further be inconsistent with Dr. Buller's previous testimony that the compressible material would be "**sufficiently dense** to prevent blood from leaking through the cloth/fabric." Ex. 2128 [Buller-556-Decl.] ¶222. Again, Petitioner identified Spenser II's compressible material as a "fluid impermeable membrane." Ex. 2040

[Spenser-II-European-Proceeding] 2087-2093. Such a structure, however, would not allow “fluid to pass therethrough,” as required.

3. Petitioner Does Not Attempt To Show How The “Polymer Covering” Assists In “Reducing The Spaces In The Sealing Assembly.”

The claims require that the “plurality of fibers” and “polymer covering” “cooperatively create a paravalvular seal **by reducing the spaces in the sealing assembly.**” Ex. 1001 [’033] cl. 1. Thus, it is not enough that the plurality of fibers create a “paravalvular seal.” The fibers must work “cooperatively” with the “polymer covering” to create that seal “by reducing the spaces in the sealing assembly.” Petitioner, however, makes no attempt to prove this limitation is met.

Fatally, Petitioner does not argue that the inner skirts of Levi or Spenser I (the alleged “polymer covering”) assist in “reducing the spaces in the sealing assembly.” Rather, Petitioner merely states that these elements are present, again invoking inherency, assuring us that POSITAs “would have understood” the limitation is met. Pet., 60. Inherency requires proving the limitation is necessarily met, yet Petitioner provides only *ipse dixit*. This is insufficient.

Petitioner also relies upon improper incorporation by reference. Only Dr. Buller contends that “the polymer covering would prevent blood from leaking through the open cells of the frame and the compressible material would prevent blood from leaking around the outside of the THV, between the frame and the

patient's native tissue." Ex. 1003 [Buller-Decl.] ¶171. This should not be considered. 37 C.F.R. § 42.6(a)(3). Even if it were, it is irrelevant, as Dr. Buller does not even contend that the polymer covering would "cooperatively ... reduc[e] the spaces in the sealing assembly." Ex. 2002 [Brecker-Decl.] ¶86.

Nor does Petitioner provide any basis to assume the polymer covering would "cooperatively" reduce spaces in Spenser II's compressible material. Notably, Petitioner has no argument for how this would be achieved given the dense, nonporous graft covering and struts of the metal frame between the extending fibers and the "polymer covering" in the Spenser II combinations. As Dr. Brecker explains:

It is unclear how Petitioner's Spenser II combinations would satisfy the claims' requirement that the expansion of the "polymer covering" works "*cooperatively*" with the extending fibers' compression "to create a paravalvular seal ... *by reducing the spaces in the sealing assembly.*" Ex. 1001 ['033] cl. 1. The inner skirts of Spenser I/Levi (relied-upon "polymer covering") are positioned inside the frame. Pet., 27-28 (citing Ex. 1010 [Spenser-I] Fig. 44b; Ex. 1007 [Levi] Fig. 2). Spenser II's compressible material 256 (relied-upon "sealing assembly") including its base layer, is outside the frame. Therefore, at least the bars of the metal frame and the compressible material's base layer would be between the extending fibers and the "polymer covering." While the struts of the frame would not preclude the polymer covering from assisting in "reducing the spaces in the sealing

assembly” through the frame’s open cells, the dense base layer of the “fluid impermeable membrane” (Ex. 2040 [Spenser-II-European-Proceeding] 2087-2093) compressible material would span across those open cells. Petitioner, however, does not explain how the polymer covering nevertheless assists in reducing the spaces in view of these intervening elements. Moreover, per Dr. Buller, the compressible material must “be sufficiently dense” to prevent leakage therethrough. Ex. 2128 [Buller-556-Decl.] ¶222. The solid, dense, graft covering of the outer seal, particularly when coupled with the struts of the metal frame[], may hinder the polymer covering from assisting in “reducing the spaces in the sealing assembly.” How this limitation could nevertheless be met by Petitioner’s Spenser II combinations is unexplained.

Ex. 2002 [Breckner-Decl.] ¶88.

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. Pet, 68. The second concerns Chuter’s occluder embodiment without a backing layer where fibers are secured between twisted strands of a helically wound wire stent. *Id.*, 67-68. Petitioner, however, fails to demonstrate that the Chuter grounds render any claim obvious under either

embodiment.

A. Petitioner’s Chuter Combinations Should Not Be Reconsidered (All Claims).

As a threshold matter, the Board should not even consider the Petitioner’s Chuter combinations in view of the prosecution history because “the same or substantially the same art or arguments were previously presented to the Office.” 35 U.S.C. §325(d).

As to the first *Advanced Bionics* prong, the Applicant disclosed each of the references in the Chuter grounds (Chuter, Spenser I, and Levi) to the Examiner. Ex. 1002 [Pros.-Hist.] 93, 135; Pet., 81. The Examiner confirmed these documents were “considered by the Examiner.” *Id.*, 93, 135-138, 46, 84-85, 96. And, indeed, after the Applicant submitted remarks specifically distinguishing Walther and “the references of record” as not showing “spacings,” the Examiner issued a Corrected Notice of Allowability. *Id.*, 28-30, 15.

Even ignoring, *arguendo*, Chuter’s direct consideration, Chuter’s backing layer embodiments, described as a “graft” or “sleeve,” are cumulative of Spenser II’s solid, nonporous, “sleeve”-like compressible material that the Board found “corresponds to an outer graft covering.” Ex. 2124 [-00556FWD] 38; Ex. 1120 [-00034FWD] 48 (same); *compare* Ex. 1116 [Chuter] ¶25 (“[t]he stents of the present invention that employ a **graft** ... The **graft** pouch, sock, or **sleeve** can

extend beyond one end or both ends of the stent.”) *with* Ex. 1011 [Spenser-II] ¶145 (describing compressible material as a “sleeve.”); Ex. 2002 [Breckler-Decl.] ¶96. Notably, Spenser II was disclaimed in prosecution as not disclosing or rendering obvious “spacings” (Section II.A.1) and this disclaimer applies to Chuter’s backing layer embodiments (Section III.B.1).

As to the second prong, Petitioner has not shown any material error by the Examiner. Petitioner argues that institution should not be denied, notwithstanding “the inclusion of Spenser, Spenser II, Chuter, and Levi on an IDS,” because the Examiner allegedly “never applied” these references. Pet., 81. But, the Examiner repeatedly confirmed that Chuter was considered. *See* Ex. 1002 [Pros-Hist.] 93, 135-138. And, “[i]t is reasonable to infer, absent an indication to the contrary, that an examiner will consider an IDS when determining whether to allow the claims.” *Ekchian*, 104 F.3d 1at 1303-1304.

Petitioner further contends that the Examiner materially erred because the Board has found in related IPRs that Petitioner’s same grounds render allegedly “highly similar” claims with “no material difference” in scope from the challenged claims obvious. Pet., 81, 83. Petitioner further contends the Examiner erred by allowing the claims because the prior art would not be transfemorally deliverable. *Id.*, 82. These arguments fail for the same reasons discussed in Section II.A.2.

Finally, Petitioner argues that “the challenged claims would have been

obvious ... for the reasons explained” in its grounds. Pet., 81. But, as discussed, the Applicant disclaimed Spenser II’s nonporous, “sleeve”-like graft as not disclosing or rendering obvious “spacings.” Chuter, however, discloses the same sort of tight outer seal in its backing layer embodiments, which are similarly described as a “graft” or “sleeve.” And, here, too, Petitioner fails to show that its Chuter backing layer combinations disclose or render obvious “spacings.” See Section III.B. Similarly, Petitioner fails to show that POSITAs would be motivated to combine Chuter’s occluders with Spenser I/Levi with a reasonable expectation of success and further fails to show that such a combination would meet each of the claims. See Section III.C.

Thus, both *Advanced Bionics* prongs are met, and the Board should accordingly reject Petitioner’s previously considered grounds under §325(d).

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

Even if Petitioner’s Chuter backing layer combinations were considered, they fail for three independently sufficient reasons. First, the backing layer combinations rely upon the same sort of tight outer seal, nonporous “graft” or “sleeve” that was disclaimed in prosecution as not disclosing or rendering obvious “spacings.” See Section III.B.1. Second, Petitioner fails to show that these grounds disclose or render obvious “spacings ... that allow fluid to pass []through”

the “sealing assembly” in “an undeployed state.” See Section III.B.2. Third, Petitioner makes no attempt to show how the “polymer covering” and “plurality of fibers” “cooperatively create a paravalvular seal ... by reducing the spaces in the sealing assembly.” See Section III.B.3.

1. The Applicant Disclaimed Tight Outer Seals Like Chuter’s Backing Layer Embodiments.

Petitioner’s Chuter’s backing layer combinations cannot satisfy the “spacings” limitations because Chuter’s backing layer embodiments disclose the same sort of tight outer seal that was disclaimed in prosecution as not disclosing or rendering obvious “spacings.”

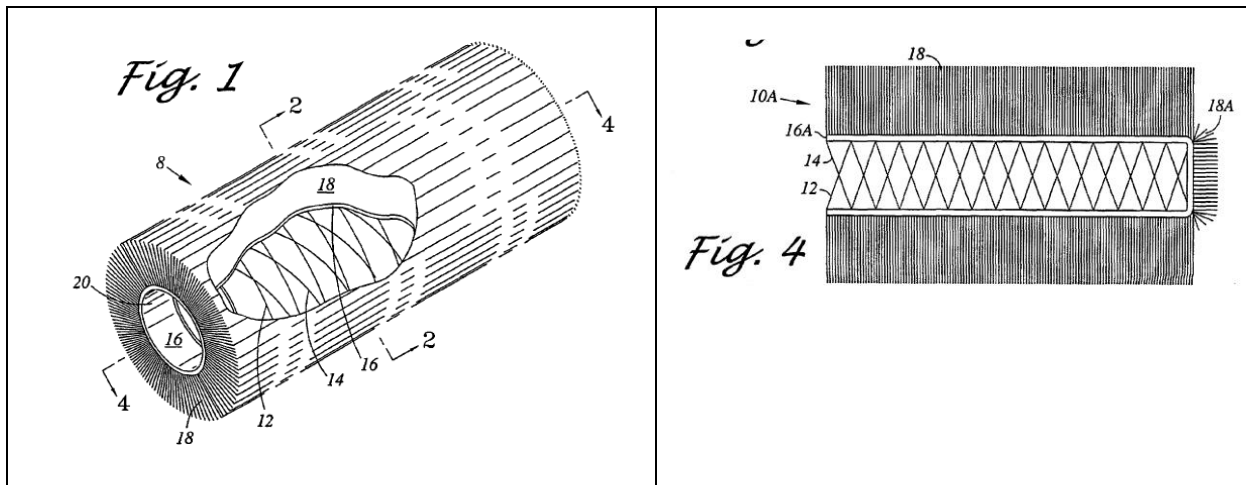
As discussed, the Applicant distinguished both Spenser II (and particularly FIG. 22) and Walther (FIG. 22’s “real world embodiment”) as not disclosing “spacings” in prosecution of the ’033’s parent, the ’834. See Section II.A.1.; Ex. 2140 [’834-FH] 1001 (distinguishing Walther and Spenser II as disclosing “tightly knitted outer seal[s]” that “lack [] ‘spacings.’”). And, as discussed in Section II.A.1, the parties’ experts agree that the Applicant’s arguments operate as a disclaimer applicable to the ’033. Petitioner’s district court expert declared that the Applicant “argued during prosecution” that the ’033’s claims “do not include cloths like those described in Walther and Spenser II” (Ex. 2141 [Brookstein-Decl.] ¶33), and that “Aortic Innovations argued that the collagen fibers in the

Asserted Patents *were distinguishable from the prior art ... (including Walther and Spenser II)* due to the “lack of ‘spacings’” (*id.*, ¶35 (quoting Ex. 2140 [’834-FH] 1001)). See also *id.*, ¶40 (the ’033’s claims do not “cover” the outer coverings “described in Walther and Spenser II.”). But, just as Spenser II’s compressible material, which the Board found “corresponds to an outer graft covering” (Ex. 2124 [-556-FWD] 29-30; Ex. 1120 [-00034-FWD] 48) and is described as a “sleeve” (Ex. 1011 [Spenser-II] ¶145), Chuter’s backing layer is also described as a “graft” and “sleeve.” Ex. 1116 [Chuter] ¶25 (“[t]he **graft** pouch, sock, or **sleeve** can extend beyond one end or both ends of the stent.”). Chuter, moreover, relies upon a nonporous backing layer extending over at least one open end of the stent to form an occluder blocking all blood flow. Ex. 1116 [Chuter] ¶¶5, 12, 25, 55, Figs. 4, 11. Chuter thus describes a dense, nonporous sleeve/graft just like Spenser II’s compressible material which, per Petitioner’s expert, cannot satisfy the “spacings” limitations. Ex. 2002 [Breckers-Decl.] ¶¶97-98.

Indeed, the similarities between Chuter’s backing layer embodiments and Spenser II’s FIG. 22 confirm that the Applicant’s disclaimer of Spenser II’s compressible material applies to Chuter’s graft. As Dr. Brecker explains:

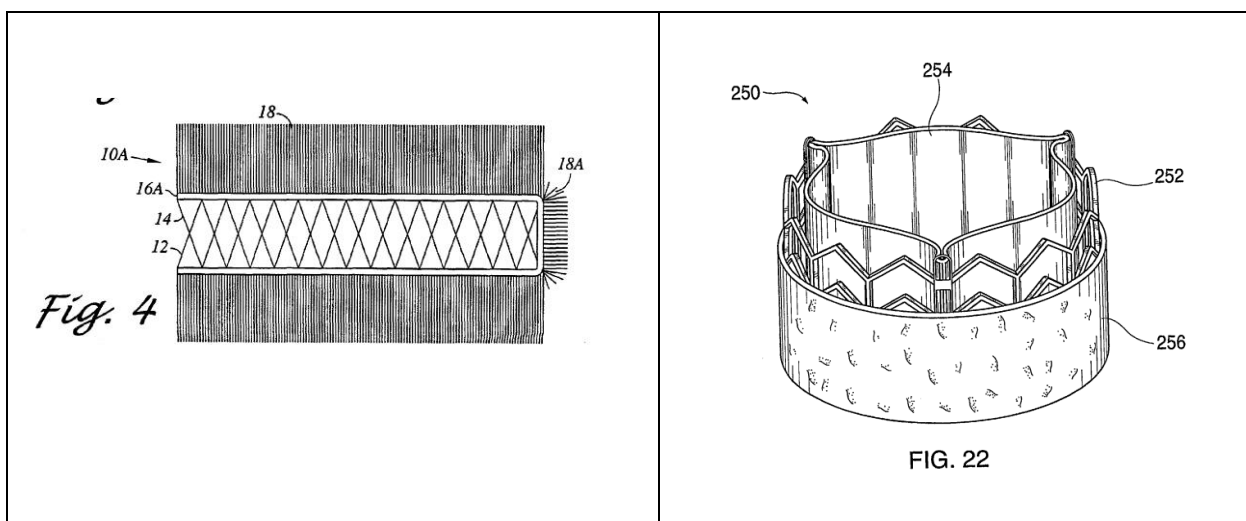
Chuter discloses embodiments comprising individual fibers extending outwardly from fabric pile backing 16 (“backing layer”). Chuter’s backing layer embodiments are clearly depicted as lacking any

“spacings extending through a thickness” of Chuter’s fiber pile (alleged “sealing assembly”), including the fiber pile’s backing layer, much less “spacings” “that allow fluid to pass [t]hrough” the graft’s thickness in an undeployed state:

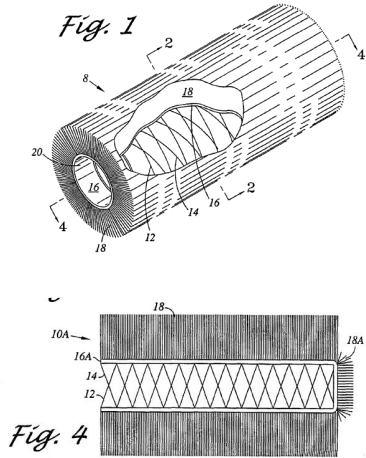
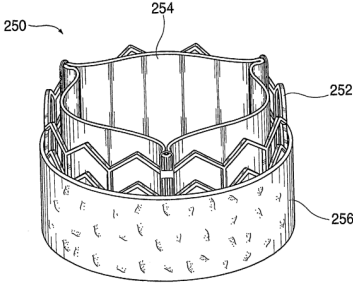
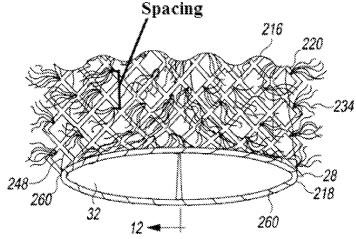


Ex. 1116 [Chuter] Figs. 1, 4, ¶¶54-55; see also Fig. 2.

Chuter does not disclose or suggest any “spacings” extending through this backing layer. Rather, like Spenser II’s FIG. 22, Chuter’s figures depict a tight outer seal without such “spacings”:



Certainly, neither Chuter’s fabric pile backing layer nor Spenser II’s compressible material resemble the ’033’s figures identified as showing “spacings” in prosecution:

Chuter	Spenser II	’834
 Fig. 1 Fig. 4	 FIG. 22	 Fig. 11

Nor are any “spacings” in the backing layer described. To the contrary, Chuter describes these embodiments as a “graft pouch, sock or sleeve,” mirroring Spenser II’s description of its compressible material as a “sleeve.” Ex. 1116 [Chuter] ¶25; Ex. 1011 [Spenser-II] ¶145. Thus, Chuter’s description of its backing layer embodiments mirrors that of Spenser II’s compressible material, which the Applicant expressly distinguished as lacking “spacings.” See Ex. 2140 [’834-FH] 1001; Ex. 2141 [Brookstein-Decl.] ¶35 (“Aortic Innovations argued that the collagen fibers in the Asserted Patents *were distinguishable from the prior art ... (including Walther and Spenser II)*” due to the lack of “spacings”); *id.*, ¶¶33, 40.

Ex. 2002 [Brecker-Decl.] ¶¶100-101.

Petitioner further fails to show that the Chuter backing layer embodiments disclose or render obvious “spacings ... that allow fluid to pass [t]hrough” the “sealing assembly” when the valve is in “an undeployed state.”

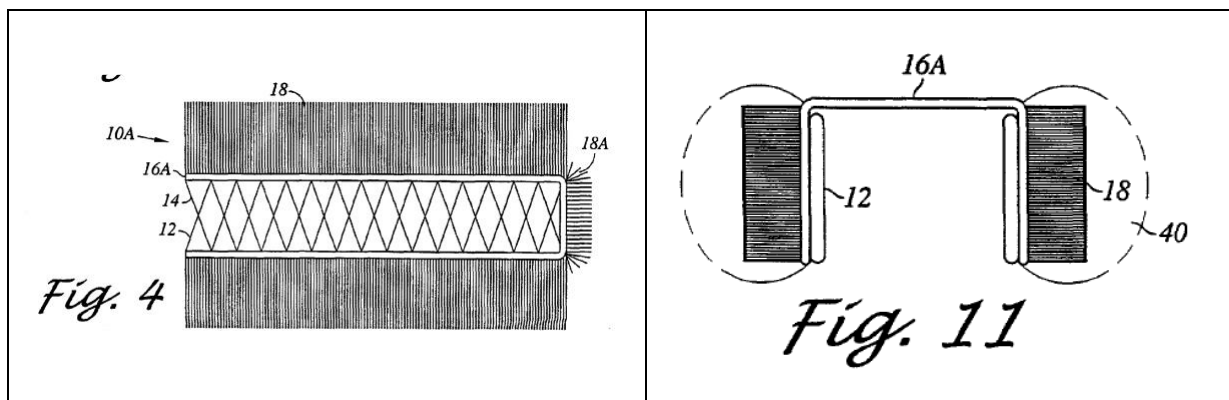
Id., 76 (Petitioner’s annotations).

Chuter, however, neither suggests nor discloses “spacings...that allow fluid to pass []through” its backing layer/graft. As Dr. Brecker explains:

There is no reason to conclude, from Chuter’s disclosure, that its backing layer embodiments disclose “spacings...that allow fluid to pass []through” the “sealing assembly.” Chuter does not describe these embodiments as “allow[ing] fluid to pass therethrough” when undeployed. Rather, Chuter discloses that its fabric pile backing is used as either a stent graft or an occluder. Ex. 1116 [Chuter] ¶¶12-16, 25, 54-55, 64. Similar to TAVRs, which are designed to allow blood flow exclusively through the valve, stent grafts are designed to allow blood to flow only inside the channel formed by the inner surface of the stent. *Id.*, ¶54. Chuter teaches that stent grafts had the known requirement of “damming off or wall[ing] off” any “gap between the exterior surface of the stent-graft and the interior arterial wall” to prevent blood leaking therebetween. Ex. 1116 [Chuter] ¶9. Such leaking “frequently leads to complications resulting either from clot formation in the gap which escape ... and enter the lungs or delamination of the interior arterial wall surface.” *Id.*, see also *id.*, ¶4 (similar). Were there “spacings ... allowing fluid to pass []through” the backing layer, blood may leak through the graft into such “gap[s].” Ex. 1116 [Chuter] ¶9. Accordingly, Chuter operates from the premise that stent grafts must prevent leaks through the wall of the graft (backing layer) when implanted, which does not suggest that the graft would not also prevent fluid from passing therethrough when undeployed. Nowhere does

Chuter suggest that the stent graft allows fluid to pass therethrough in a free air or undeployed state, much less that “spacings” allowing fluid to pass through its graft’s thickness are reduced upon deployment to create a paravalvular seal.

Chuter also teaches its backing layer being used in an occluder as a “pouch” or “sock” graft extending over at least one end of the stent to occlude—i.e., prevent blood from passing through—the vessel:



Id., Figs. 4, 11, ¶¶12, 25, 55. Because the fabric pile backing is utilized to occlude the blood vessel, this further indicates that fluid may not pass therethrough. *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.”). Notably, in these embodiments where a portion of the backing covers an open end of the stent, that portion is not compressed against any solid surface. But, even in the absence of compression, blood is prevented from passing therethrough. This suggests that, similarly, when the backing layer is in an undeployed state, it too would prevent blood/fluid from “passing therethrough.”

Additionally, Chuter teaches that its backing layer may be polyester. Ex. 1116 [Chuter] ¶22. The '033, again, identifies “polyester” as a material that “prevents blood from passing through the [] surface.” Ex. 1001 ['033] 7:30-36, 8:51-55, 13:35-38, 13:61-67, 15:60-65, 17:6-10, 19:17-20.

In accord, Dr. Buller recognizes that Chuter’s backing layer may prevent fluid from passing in an undeployed state, arguing in connection with Chuter’s occluder embodiments that the **absence** of a backing layer “traversing the openings between the struts” would “necessarily” indicate “spacings” that “would allow fluid to pass” through the “sealing assembly.” Ex. 1003 [Buller-Decl.] ¶216. But, assuming the absence of a backing layer would allow fluid to pass, the backing layer’s presence would indicate the opposite.

Accordingly, nothing in Chuter teaches or suggests “spacings” that “allow fluid to pass []through” its graft in an “undeployed state.” If anything, Chuter suggests the opposite.

Ex. 2002 [Brecker-Decl.] ¶¶105-109.

3. Petitioner Does Not Attempt To Show How The “Polymer Covering” Assists In “Reducing The Spaces In The Sealing Assembly.”

The claims require that the “plurality of fibers” and “polymer covering” “cooperatively create a paravalvular seal by reducing the spaces in the sealing assembly.” Ex. 1001 ['033] cl. 1. As with its Spenser II grounds, however, Petitioner makes no attempt to prove this limitation is met. Indeed, Petitioner’s

argument fails for much the same reasons stated in Section II.A.3.

As with Spenser II, Petitioner again does not argue that the inner skirts of Levi or Spenser I (alleged “polymer covering”) assist in “reducing the spaces in the sealing assembly.” Rather, Petitioner merely states that these elements are present, again invoking the language of inherency, assuring us that POSITAs “would have understood” the limitation is met. Pet., 78. But, as with Spenser II, Petitioner provides nothing more than *ipse dixit*.

Petitioner, again as with Spenser II, relies upon improper incorporation of Dr. Buller’s testimony (absent from the Petition) that “the polymer covering would prevent blood from leaking through the open cells of the frame and the fiber pile would prevent blood from leaking around the outside of the THV, between the frame and the patient’s native tissue.” Ex. 1003 [Buller-Decl.] ¶223. But even were this testimony considered, it is irrelevant because Dr. Buller does not contend that the “polymer covering” assists in “reducing the spaces” in the fiber pile. See Ex. 2002 [Brecker-Decl.] ¶111.

Nor does Petitioner provide any reason to assume the polymer covering would assist in “reducing” the alleged “spaces” in Chuter’s backing layer. Notably, Petitioner has no argument for how this would be achieved given the presence of a dense, nonporous graft covering and the struts of the metal frame between the extending fibers and the “polymer covering” in the backing layer

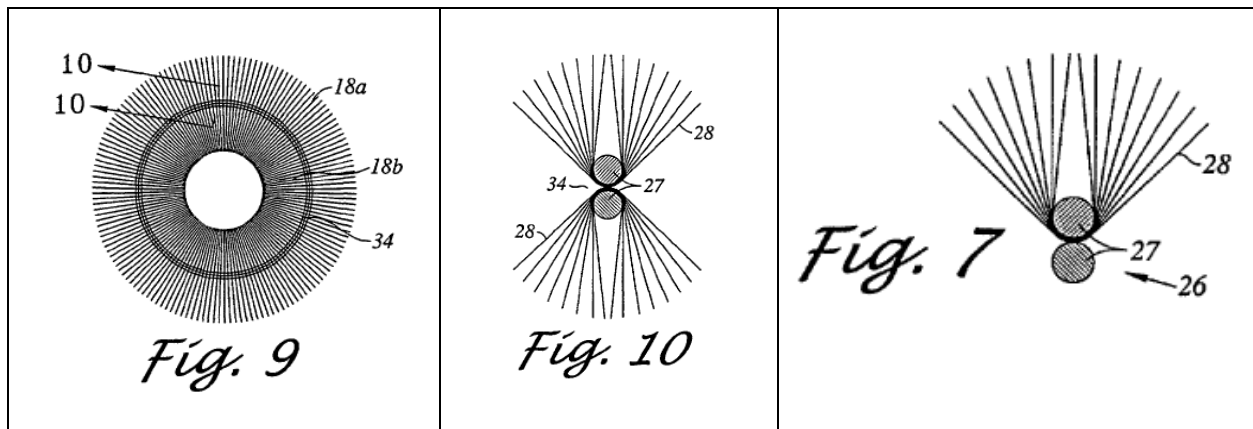
combinations. As Dr. Brecker explains:

As with Spenser II, at least the struts of the metal frame and Chuter's dense backing layer would be between the extending fibers and the "polymer covering." As discussed, while the struts of the frame would not preclude the polymer covering from assisting in "reducing the spaces in the sealing assembly" through the frame's open cells, Chuter's dense backing layer would "travers[e] the openings between the struts," as Dr. Buller recognizes. Ex. 1003 [Buller-Decl.] ¶216. Indeed, as with Spenser II, Chuter's solid, dense, graft covering, particularly when coupled with the struts of the metal frame[], may hinder the polymer covering from assisting in "reducing the spaces in the sealing assembly." Petitioner, however, again fails to explain how the polymer covering nevertheless assists in reducing the spaces in view of these intervening elements.

Ex. 2002 [Brecker-Decl.] ¶114.

C. 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., 67-69, 72-75; Ex. 1116 [Chuter] Figs. 7, 9-10. Petitioner alleges that Chuter’s fiber pile represents the “sealing assembly” and that the individual extending fibers correspond to the “plurality of fibers.” Pet., 67-69.

Petitioner’s arguments, however, fail to show that POSITAs would be either motivated to make the proposed Chuter-occluder combinations or could do so with a reasonable expectation of success. Section III.C.1. Even if this could be overlooked, Petitioner fails to show the resulting combinations would satisfy the claims. Section III.C.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.] ¶119.

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.] ¶120.

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.] ¶121.

In accord, a POSITA would not be motivated to make a combination that "would run contrary to [the primary reference]'s stated purposes." *Polaris Indus., Inc. v. Arctic Cat, Inc.*, 882 F.3d 1056, 1069-70 (Fed. Cir. 2018); *In re Ratti*, 270 F.2d 810, 813 (CCPA 1959) (combination improper where it would change a reference's basic principle of operation); *Plas-Pak Indus., Inc. v. Sulzer Mixpac AG*, 600 F.App'x 755, 759 (Fed. Cir. 2015) (similar). 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., 80. 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 “lacking the fabric pile backing.” See, e.g., Pet., 69. 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.] ¶123.

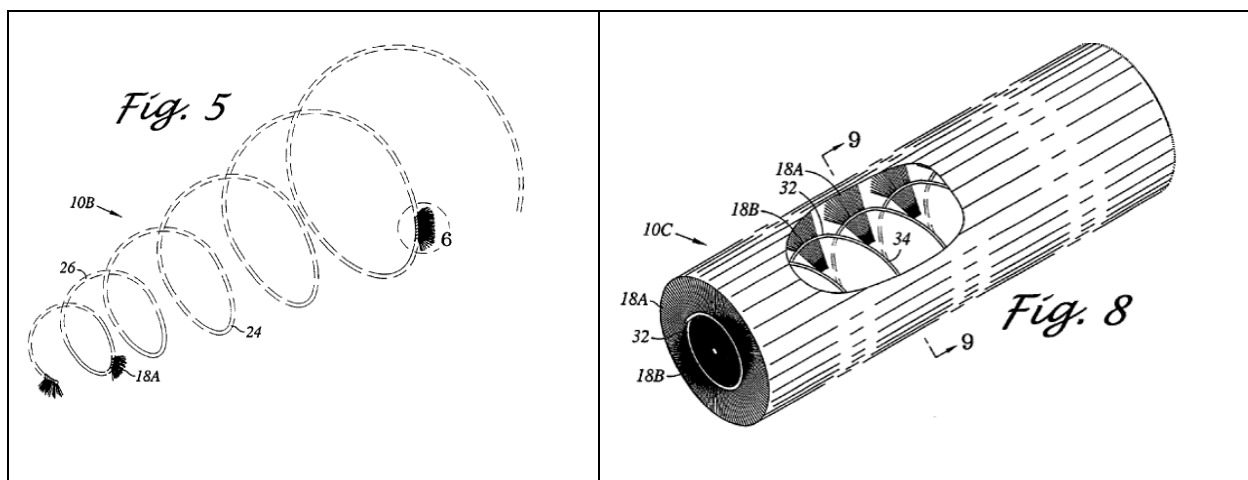
Petitioner nevertheless contends that POSITAs “would have been motivated

to attach the fiber pile to Spenser's or Levi's frames *in the same way they are attached to Chuter's frame.*" *Id.*, 76-77, 74-75 (similar). But, 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 with a reasonable expectation of success, much less "in the same way" as Chuter teaches its occluding fibers attach to its frame.

Chuter's occluding fiber pile, importantly, 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:

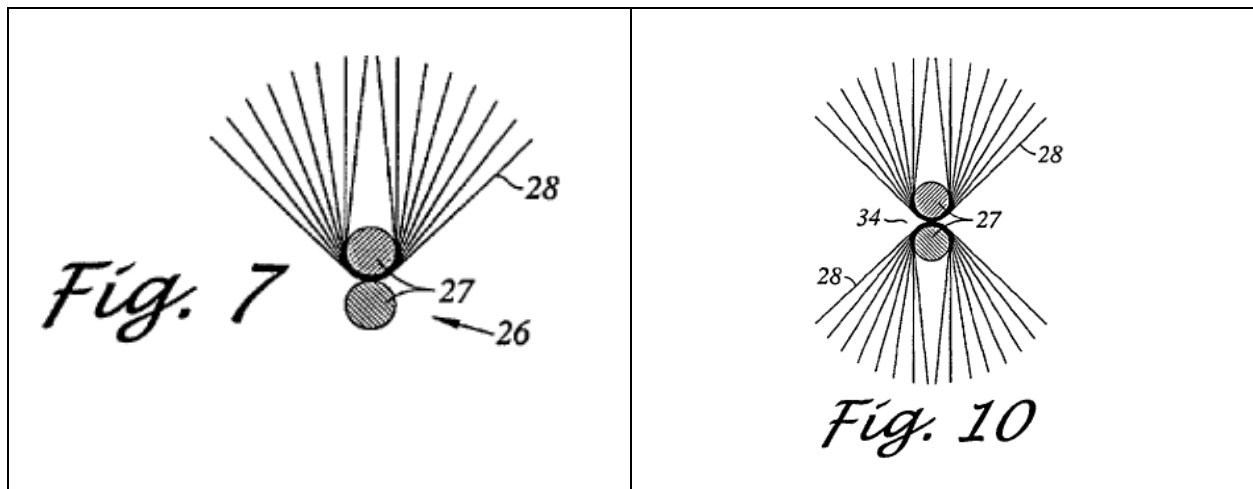
Chuter's attachment method relies upon placing and securing fibers between the "twisted strands" of "helically wound wire." Such twisted strands, however, are not present in the frames of Levi and Spenser I. In my opinion, even if we were to assume that a POSITA would be inclined to add an occluder's fibers to a TAVR, it 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, much less "in the same way" as Chuter teaches given the absence of "twisted strands" of "helically wound wire" in the frames of Levi and 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:



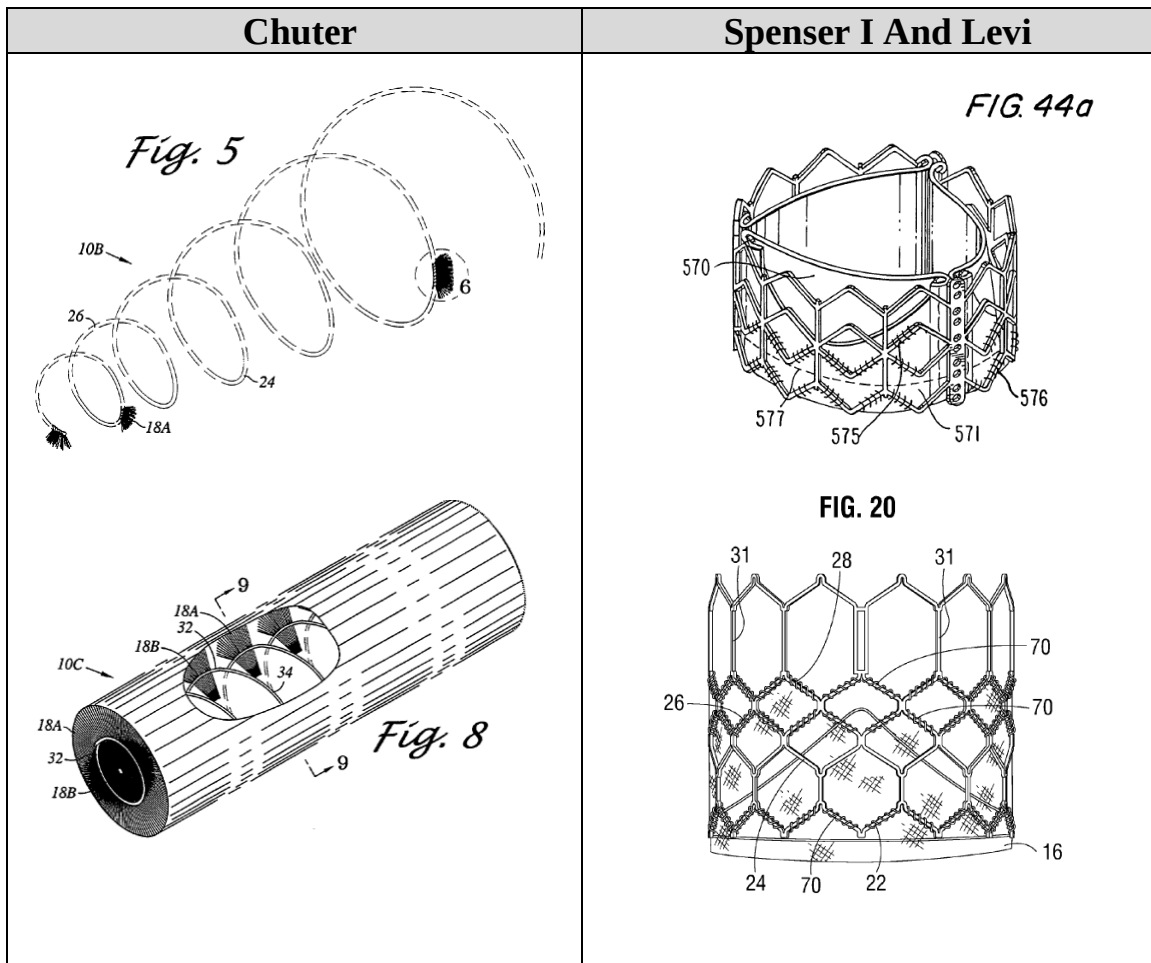
Ex. 1116 [Chuter] Figs. 5, 8; Ex. 2126 [Chuter-FH] 34-40.

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. There is no suggestion in Chuter, Spenser I, or Levi to support Petitioner's contention that a POSITA could or would attach Chuter's extending fibers to the frame of Spenser I/Levi "in the same way" as in Chuter's occluder embodiments. Pet., 76-77, 74-75 (similar). Moreover, even if we assume a POSITA would be inclined

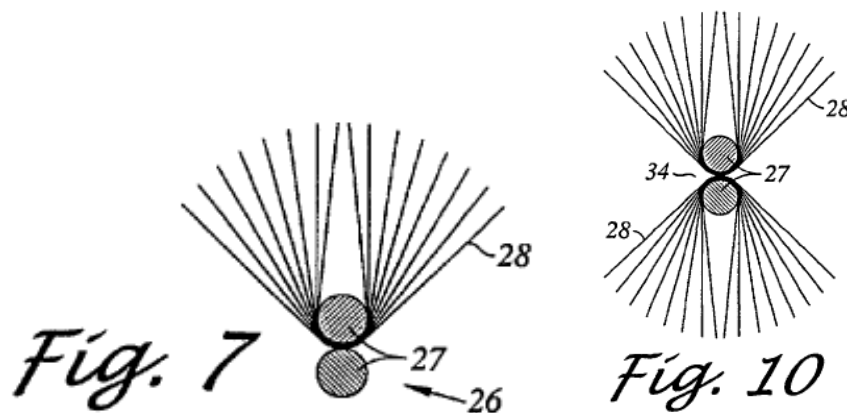
to attach the fibers to such a frame by some other method, there is no indication of how this would be done nor is it self-evident how a POSITA would accomplish such a thing with a reasonable expectation of success.

Ex. 2002 [Brecker-Decl.] ¶¶125-129.

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., 70-71. 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.] ¶133.

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"):

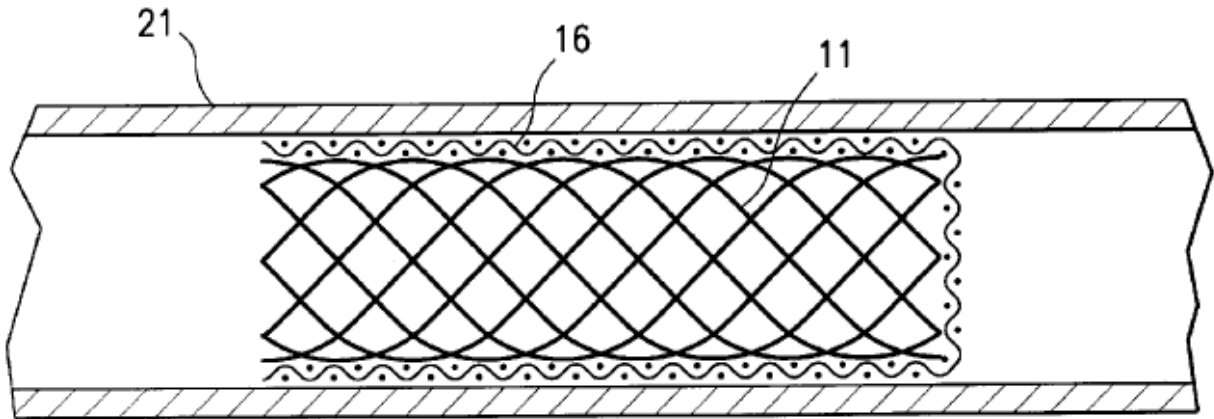
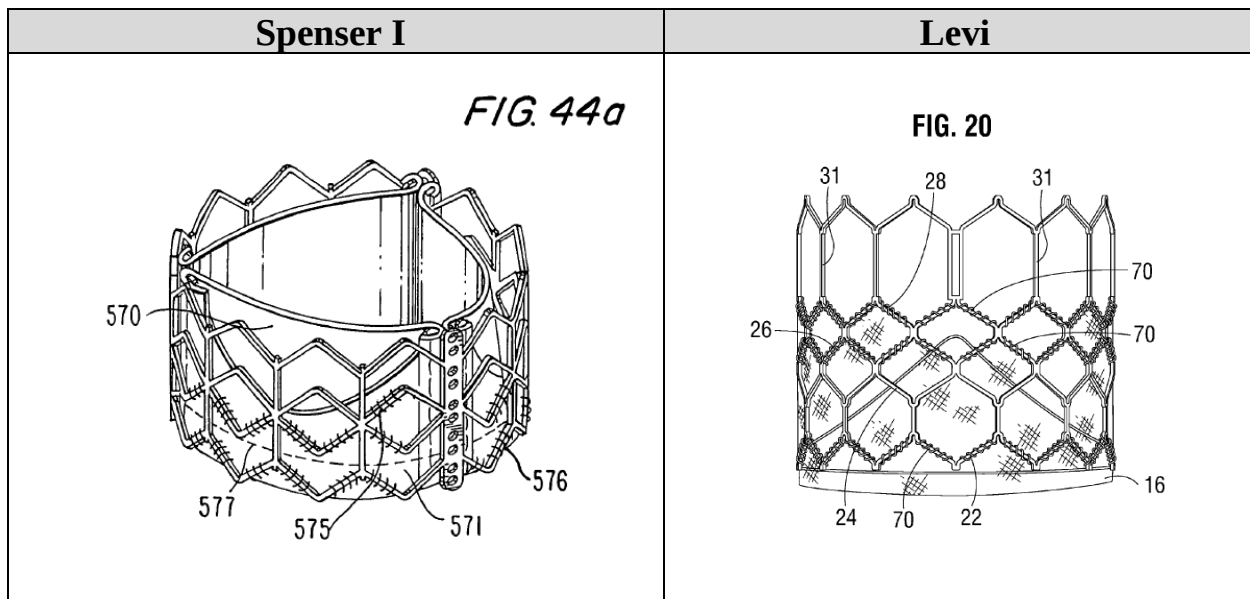


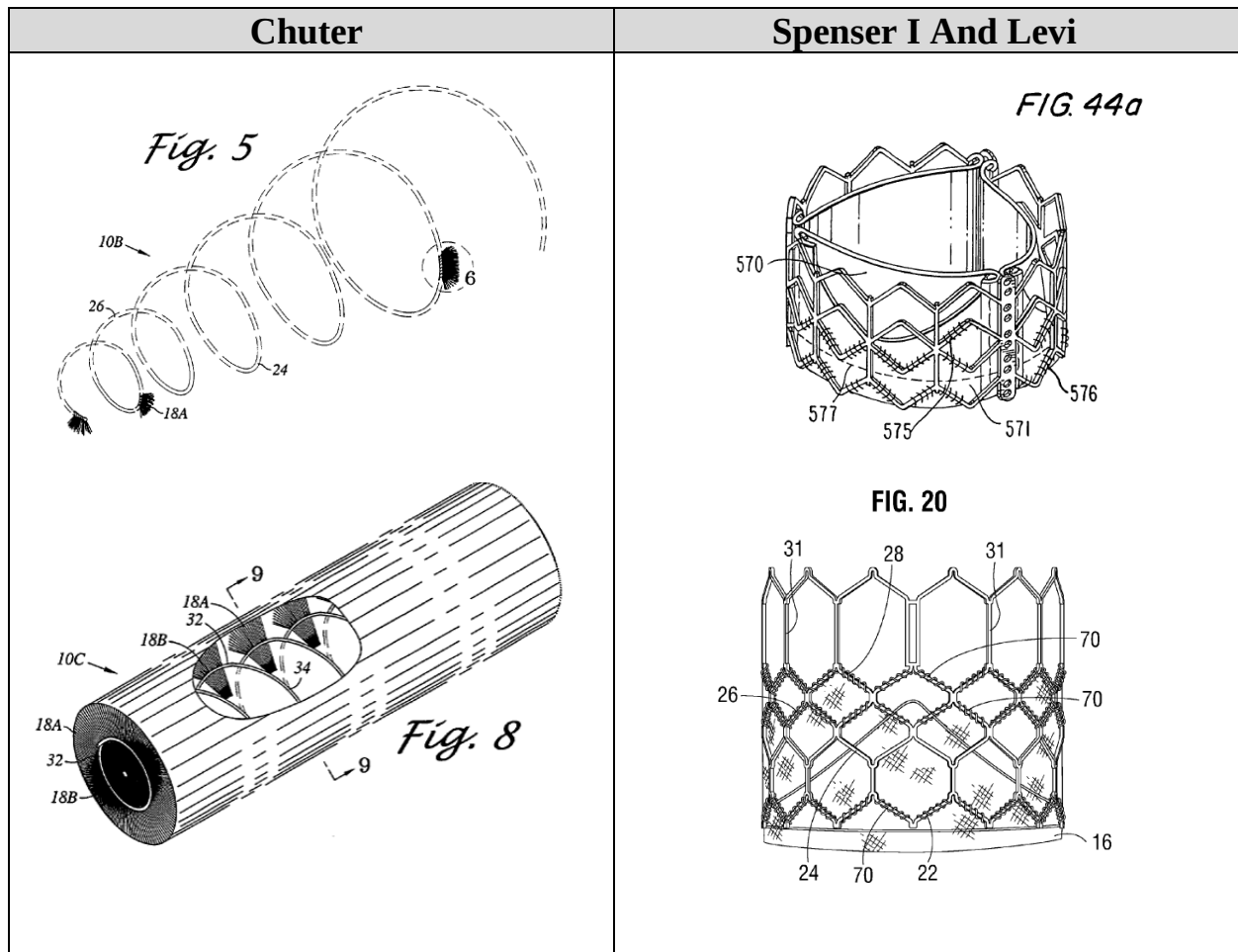
FIG. 11

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.] ¶¶134-136.

Petitioner nevertheless contends that Chuter teaches its fiber pile “can be adapted” to be compatible with “[v]irtually any expanding stent.” Pet., 70.

Petitioner further contends that “Chuter specifically identifies a variety of self-expanding and balloon-expandable frames that can be combined with the fiber pile

... 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.] ¶138.

Petitioner nevertheless contends that "adding Chuter's fiber pile to Spenser's valves would merely entail applying Chuter's known technique for reducing leaks around a frame (adding a fabric pile) to Spenser's known frames" to "yield

predictable results.” Pet., 69. Petitioner relies on these same “reasons” regarding Levi. *Id.*, 71. 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 [’033] cl. 1.

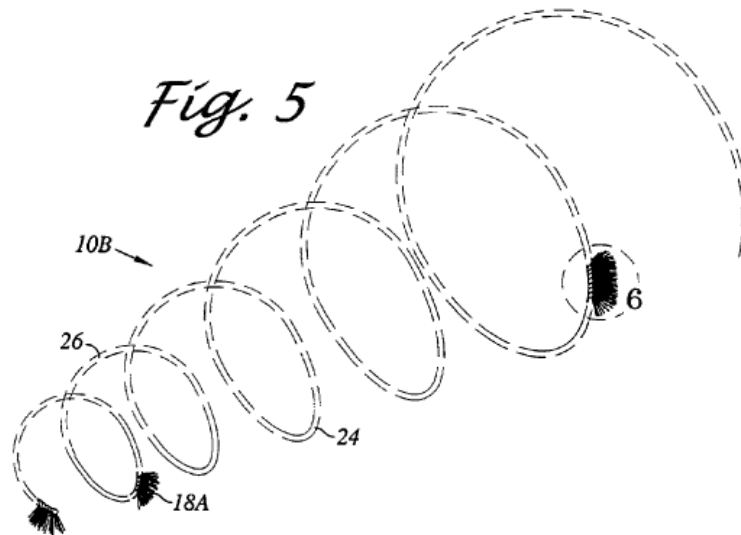
Petitioner argues that “POSITAs would have reasonably expected Chuter’s fabric pile to [] compress when added to Spenser’s or Levi’s valve, allowing for continued endovascular delivery of the valve through the femoral artery.” Pet., 75-76. Petitioner further contends that Chuter teaches that its “stents 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.*, 75 (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.] ¶212; Pet., 76. 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., 66, 69, 71, 77.

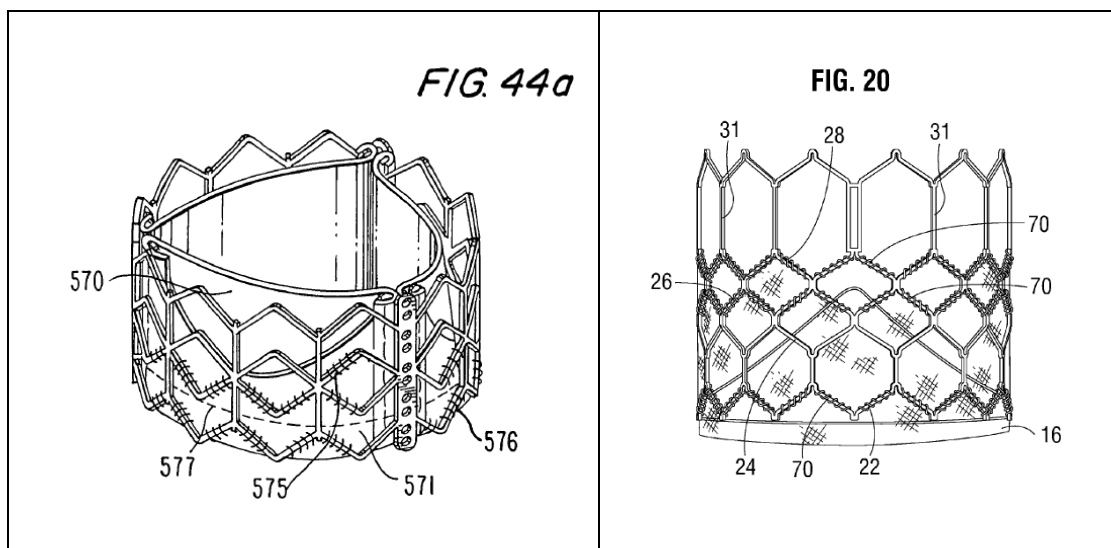
These vague modifications are insufficient to show that a POSITA would reasonably expect to successfully produce a transfemorally-deliverable TAVR by combining Chuter’s occluder embodiments with Spenser I or Levi, as proposed. Indeed, there is no reason to just assume POSITAs would reasonably expect 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.] ¶212; Pet., 66, 69, 71, 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.] ¶212) 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.] ¶¶143-145.

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., 2023 U.S. App. LEXIS 26590 *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:

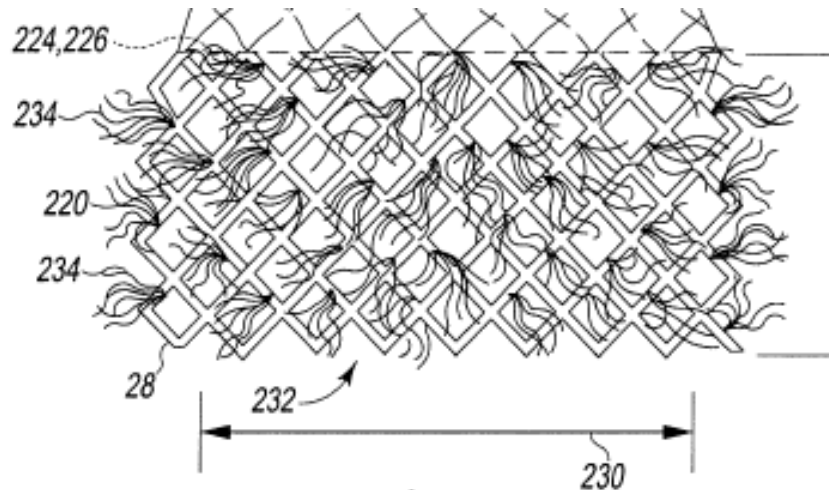


Fig. 9

Ex. 1001 [’033] Fig. 9; Ex. 2052 [Buller-00034-Depo.] 167:10-15, 169:5-25; Ex. 2002 [Brecker-Decl.] ¶146. 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 ’033, 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.”).

Petitioner further fails to show that its Chuter occluder combinations would

satisfy the claimed “spacings ... that allow fluid to pass []through” the “sealing assembly” in “an undeployed state.” Ex. 1001 [’033] cl. 1. Petitioner contends its occluder combinations “disclose” this limitation because “spacings” are allegedly illustrated in Chuter’s FIG. 7. Pet., 76 (citing Ex. 1003 [Buller-Decl.] ¶216). Dr. Buller, invoking inherency, contends that “POSITAs would have understood” that “there would necessarily be spacings” allowing fluid to pass through the “sealing assembly.” Ex. 1003 [Buller-Decl.] ¶216. Petitioner, however, fails to show this limitation is necessarily met. As Dr. Brecker explains:

I see no basis upon which to conclude that Chuter’s fibers would necessarily “allow fluid to pass therethrough” in “an undeployed state.” As noted, Chuter’s occluding fibers must have high density to plug the blood vessel, indicating Chuter’s fibers would not allow fluid to pass. This is further confirmed by Chuter’s inwardly-extending fibers (made of the same material as the outwardly-extending fibers), which must be densely arranged to “occlude the inner bore of the stent” and “plug” the blood vessel without pressing against any solid surface. See Ex. 1116 [Chuter] ¶¶18, 57. Again, in Chuter’s occluder embodiments without inwardly-extending fibers, the outwardly-extending fibers must be dense enough to achieve the same purpose.

Dr. Buller contends that POSITAs “**would have understood**” that, in Petitioner’s occluder combinations, “**there would necessarily be spacings ... that span at least the width of the open cells**” of the frame and “allow fluid to pass therethrough” due to the lack of a backing layer

“traversing the openings between the struts.” Ex. 1003 [Buller-Decl.] ¶216. But, this does not account for Chuter’s densely arranged, outwardly-extending occluding fibers, which Petitioner identifies as “arcuate.” Such a dense arrangement of outwardly extending, “arcuate,” fibers would be unlikely to “allow fluid to pass therethrough,” much less necessarily do so.

Ex. 2002 [Brecker-Decl.] ¶¶150-151.

IV. 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 29, 2023

CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMITS

This Patent Owner Preliminary Response (the “POPR”) consists of 13,992 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 29, 2023

CERTIFICATE OF SERVICE

The undersigned hereby certifies that the following documents were served by electronic service, by agreement between the parties, on November 29, 2023:

PATENT OWNER AORTIC INNOVATIONS LLC'S PRELIMINARY RESPONSE

**EXHIBITS 2001-2002, 2040, 2052, 2101-2103, 2122, 2124-2126, 2128, 2136,
2140-2141, 2143-2144**

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