

**COMMUNICATION TO THE UNITED STATES PATENT AND TRADEMARK
OFFICE**

Application No. : 17/469,391 Confirmation No.: 5834
Applicant : Aortic Innovations, LLC
First Named Inventor : Ali Shahriari
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Examiner : Shipmon, Tiffany
Docket No. : 426/2/24 UTIL
Customer No. : 175373

Title of Invention: TRANSCATHETER VALVE REPAIR HAVING IMPROVED
PARAVALVULAR SEAL

Via EFS-Web
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RESPONSE TO OFFICE ACTION DATED NOVEMBER 30, 2021

Amendments to the Claims begin on page 2 of this paper.

Remarks begin on page 5 of this paper.

Amendments to the Claims:

The claims are amended as follows and will replace all previous versions and listings of claims:

Listing of Claims:

1. (Currently Amended) A transcatheter aortic heart valve assembly comprising:
 ~~an inner frame comprising~~ a graft covering housing ~~[[a]]~~ prosthetic heart valve leaflets,
wherein the graft covering extends ~~around~~ about the prosthetic heart valve leaflets for providing
sealing thereto to the heart valve;
 ~~an outer~~ a frame formed from a metallic material and defining a plurality of continuously
extending struts that extend through a circumference of the frame, the struts cooperatively
forming an open cell gridded configuration, and the frame being secured to the graft covering by
stitching a plurality of stitches; and
 ~~a sealing material positioned externally to the outer frame for providing sealing between~~
~~the outer frame and a patient's anatomical wall to prevent paravalvular leaks, wherein the sealing~~
~~material includes a plurality of radially extending fibers that extend outwardly of the outer frame;~~
 wherein the graft covering is made of polyester, polytetrafluoroethylene, expanded
polytetrafluoroethylene, or a polymer,
 wherein the transcatheter aortic heart valve assembly has a radially compressed
orientation and a radially expanded orientation,
 a first plurality of fibers positioned radially outwardly of the frame that is configured to
form a first sealing interface against native valve leaflets of a patient when the first plurality of
fibers is compressed thereagainst, wherein the first plurality of fibers extends radially outwardly
of the frame; and
 a second plurality of fibers carried by the frame that is configured to form a second
sealing interface that includes spacings between fibers to form a mesh network against the frame,
 wherein the first plurality of fibers and the second plurality of fibers are in overlapping
radial alignment,
 wherein, in operation the heart valve assembly is deployed endovascularly through a
femoral artery of the patient after obtaining access to the femoral artery.

2. (Currently Amended) The valve assembly of claim 1, wherein the second plurality of fibers extend from ~~[[cover]]~~ at least two circumferentially extending rows of ~~grids~~ cells formed in the ~~gridded~~ open cell configuration.
3. (Canceled)
4. (Currently Amended) The valve assembly of claim 1, wherein the ~~outer~~ frame extends distally further than the prosthetic heart valve leaflets.
5. (Currently Amended) The valve assembly of claim 1, wherein the ~~outer~~ frame is a singular, integral component.
6. (Currently Amended) The valve assembly of claim 1, wherein the ~~outer~~ frame and the graft covering are attached by ~~stitches~~ stitching at a top and bottom portion of the graft covering.
7. (Canceled)
8. (Canceled)
9. (Canceled)
10. (Original) The valve assembly of claim 1, wherein the valve assembly is balloon expandable.
11. (Canceled)
12. (Canceled)

13. (New) The valve assembly of Claim 1, wherein the graft covering forms an inner frame for housing the prosthetic heart valve leaflets.
14. (New) The valve assembly of Claim 1, wherein the first plurality of fibers are in contact with the frame.
15. (New) The valve assembly of Claim 1, wherein the valve assembly is configured for being received within a catheter that is delivered through the femoral artery of the patient.
16. (New) The valve assembly of Claim 1, wherein the first plurality of fibers and the second plurality of fibers are collagen fibers.
17. (New) The valve assembly of Claim 1, wherein a row of cells distal to the graft covering is uncovered by the graft covering and the first plurality of fibers and the second plurality of fibers.
18. (New) The valve assembly of Claim 1, wherein the second plurality of fibers extend radially inwardly from the frame.

REMARKS

This is in response to the Office Action dated November 30, 2021.

Claims 1-12 stand rejected under 35 USC 103(a) as being unpatentable over Spenser (USPN 7,510,575) in view of Dehdashtian (WO 2006/005015).

A double patenting rejection is also made, and a terminal disclaimer is submitted herewith to address that rejection.

Applicant has amended the claims to recite patentable features over the references of record.

AMENDMENT PRESENTED TO CLAIM 1

Amended Claim 1 recites:

A transcatheter aortic heart valve assembly comprising:

a graft covering housing prosthetic heart valve leaflets, wherein the graft covering extends about the prosthetic heart valve leaflets for providing sealing thereto;

a frame formed from a metallic material and defining a plurality of continuously extending struts that extend through a circumference of the frame, the struts cooperatively forming an open cell configuration, and the frame being secured to the graft covering by stitching; and

wherein the graft covering is made of polyester, polytetrafluoroethylene, expanded polytetrafluoroethylene, or a polymer,

wherein the transcatheter aortic heart valve assembly has a radially compressed orientation and a radially expanded orientation,

a first plurality of fibers positioned radially outwardly of the frame that is configured to form a first sealing interface against native valve leaflets of a patient when the first plurality of fibers is compressed thereagainst, wherein the first plurality of fibers extends radially outwardly of the frame; and

a second plurality of fibers carried by the frame that is configured to form a second sealing interface that includes spacings between fibers to form a mesh network against the frame,

wherein the first plurality of fibers and the second plurality of fibers are in overlapping radial alignment,

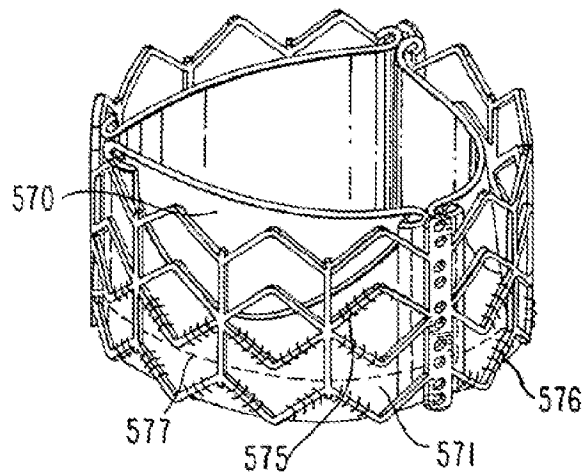
wherein, in operation the heart valve assembly is deployed endovascularly through a femoral artery of the patient after obtaining access to the femoral artery.

(claim presented in clean form, underlining emphasis added)

PRIOR ART REJECTION OF CLAIM 1

The USPTO relies on FIG. 44a of Spenser in forming the prior art rejections:

FIG. 44a



And FIG. 22 of Dehdashtian:

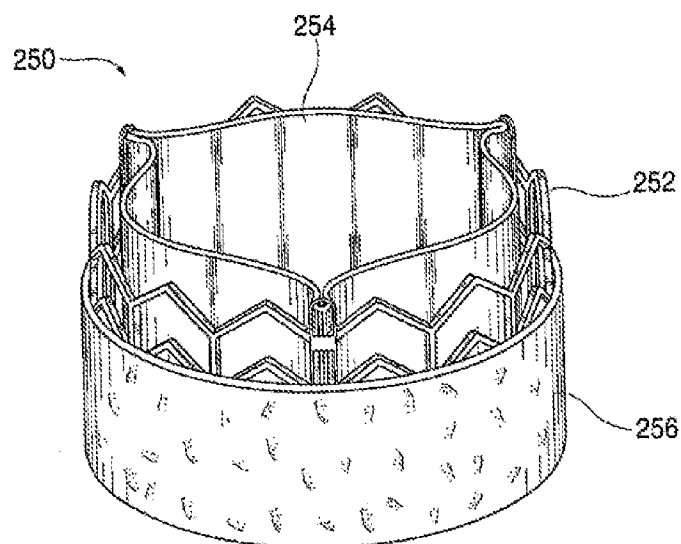


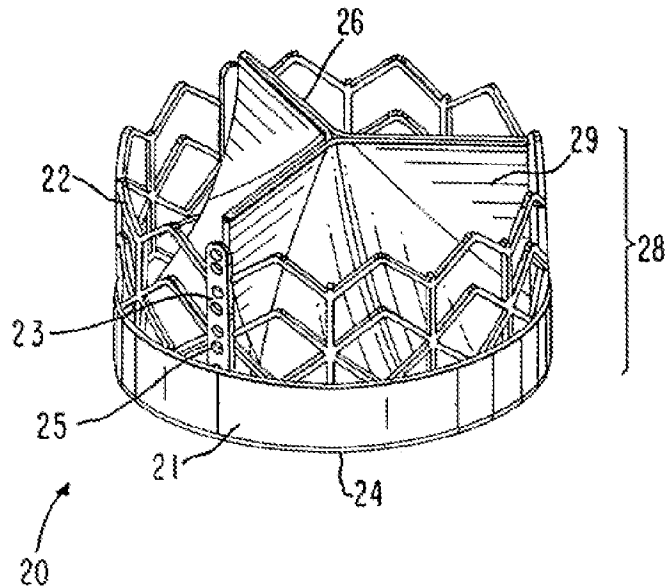
FIG. 22

Applicant notes that Spenser and Dehdashtian share three of the same four inventors.

According to the USPTO:

7. It would have been obvious to a person of ordinary skill in the art at the time of the invention to modify the heart valve assembly of Spenser et al. to include a sealing member positioned externally to an outer frame as taught in Dehdashtian et al. in order to provide additional sealing against leakage. Additionally, Spenser et al. teaches an outer sealing member (21) in the embodiment of Fig. 1.

FIG. 1



**AMENDED CLAIM 1 IS PATENTABLE OVER THE REFERENCES OF RECORD
BECAUSE THE REFERENCES OF RECORD ARE NOT CAPABLE OF MEETING
THE GENERAL LIMITATIONS OF ENDOVASCULAR DELIVERY THROUGH THE
FEMORAL ARTERY**

The amended claims generally require that the transcatheter valve assembly is configured for endovascular delivery through the femoral artery.

The primary reference, Spenser, discloses:

*A typical size of an aortic prosthetic valve is from about 19 to about 25 mm in diameter. **A maximal size of a catheter inserted into the femoral artery should be no more than 8 mm in diameter.** The present invention introduces a device, which has the ability to change its diameter from about 4 mm to about 25 mm. Artificial valves are not new; however, artificial valves in accordance with the present invention possess the ability to change shape and size for the purpose of delivery and as such are novel. These newly designed valves*

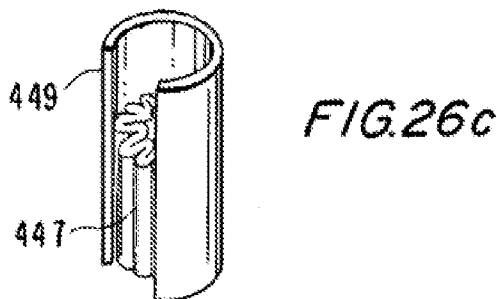
require new manufacturing methods and technical inventions and improvements, some of which were described herein.

(Emphasis added)

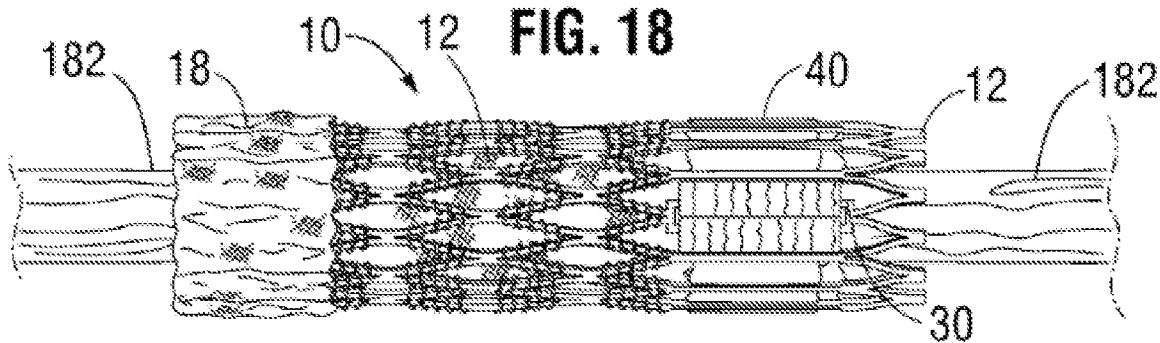
Valve crimp profile is of significant importance in transcatheter valves as Spenser recognizes. The crimp profile impacts not only the delivery route, but the ability to cross the native leaflets of the aorta for deployment. And each of the claims require some general limitation of endovascular deployment through the femoral artery.

It is bedrock analysis that if the proposed combination from the USPTO is incapable of meeting the claim limitations (in this instance, endovascular deployment through the femoral artery), then the proposed combination is not proper for rejecting the claims under 35 USC 103. Catheter size is typically expressed in terms of French numbers, where each millimeter of catheter diameter equates to a 3F increase in French size. Thus, an 8.00 mm diameter catheter would be expressed as a 24F system. Spenser states that an 8.00 mm diameter catheter is the maximal for femoral access, and thus a 24F catheter would be the maximum as well. Thus, if the proposed combination by the USPTO of Spenser and other references would yield a valve having a crimp profile greater than a 24F catheter size, then, according to the majority of the inventors of the primary references, the proposed combination cannot meet the claim limitation of endovascular deployment through the femoral artery.

Adding an outer seal to a valve structure such as Spenser is not trivial, and the results are not necessarily expected because of the aforementioned crimp profile concerns. Crimping of the valve necessarily creates “bunching” on the outside of the Spenser valve. This is well-illustrated in FIG. 26c of Spenser.



Additionally, other art of record shows this same behavior. For example, US Patent No. 9393110 to Levi illustrates bunching of seal 18 in the compressed orientation in FIG. 18:



As illustrated, addition of an outer seal necessarily adds significantly to the crimp profile, and further restricts full crimping of the valve. This is even more pronounced with the proposed combination by the USPTO, where adding the outer “band” of Dehdashtian is likely to significantly add to crimped profile such that the crimped profile will exceed the “maximal size [of]..... 8 mm in diameter.”

Assuming *arguendo* that Spenser is capable of reaching a crimp profile of 4.00 mm as stated in Spenser, the addition of the minimal size thickness outer band as stated in Dehdashtian of 1.00 mm would result in a crimped profile that would not fit within a catheter with a maximum outer diameter of 8.00 mm.

This is not only well-illustrated with reference to the bunching shown in Fig. 26c of Spenser, but it is further well described with reference to simple calculations.

A catheter of 4.0 mm in outer diameter, assuming an infinitely thin wall thickness, necessarily has a crimped cross-area of:

$$A = \pi * (2.0 \text{ mm})^2 = 12.56 \text{ mm}^2$$

Addition of a 1.0 mm outer seal to a 25 mm valve as disclosed by Spenser and Dehdashtian potentially creates an increase in cross-area of:

$$A = \pi * (13.5 \text{ mm})^2 - (12.5 \text{ mm})^2 = 81.64 \text{ mm}^2$$

Dehdashtian does teach that the band is a “layer of compressible material 256,” so some amount of compression is expected. However, nowhere does Dehdashtian teach that the layer is compressible by over 600 percent to be able to go from a non-compressed area size of 81.64 mm² to a crimped area size of 12.56 mm² (this analysis entirely ignores the thickness of the stent frame itself; inclusion of the thickness of the stent frame for these calculations would further emphasize the mathematical impossibility presented by the proposed combination by the USPTO).

Applicant submits that a much larger catheter would be required in order to accommodate the proposed combination by the USPTO. And the much larger catheter would not be able to meet the claim limitation of “deployed endovascularly through a femoral artery of the patient.”

**THE NON-PATENT LITERATURE OF RECORD SUPPORTS APPLICANT POSITION
THAT THE PROPOSED COMBINATIONS CANNOT MEET THE LIMITATIONS OF
CLAIM 1 RELATED TO ENDOVASCULAR DELIVERY THROUGH THE
TRANSFEMORAL ARTERY**

The same Dehdashtian that is an inventor on one of the primary references collaborated with Walther to make a valve having the same general construction as the proposed combination used by the USPTO. This is shown in the Walther non-patent literature submitted herewith. The Walther non-patent literature indicates that the proposed combination cannot be deployed endovascularly through a femoral artery of the patient.

In the NPL of Walther, Dehdashtian and others reported on a mitral valve replacement similar to that which is shown in Figure 22 of Dehdashtian.

The similarity in the valve illustrated in the patent application of Dehdashtian and the publication by Dehdashtian and Walther is striking:

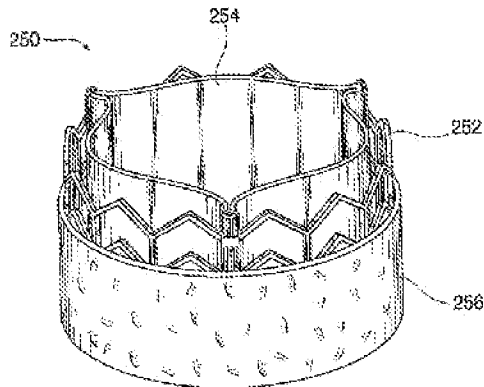
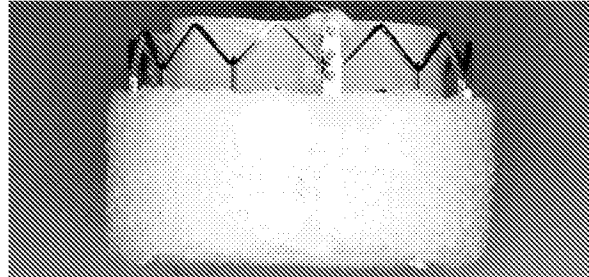


FIG. 22



In the Walther NPL, just as in the Dehdashtian Patent, a “cloth” valve is disclosed. (Described as a cloth valve in Walther, and described in Dehdashtian as “the compressible material 256 may resemble a cloth or fabric having small fibers extending from the surface of the material.”) And Walther makes clear that a substantially larger catheter was required to deploy the cloth valve in a benchtop testing of a second implant, mitral valve in surgical valve deployment. In Walther, a 33F catheter was required for -use, having a profile of 11.0 mm, far greater than the 8.0 mm that Spenser indicates is a maximal diameter. (“A maximal size of a catheter inserted into the femoral artery should be no more than 8 mm in diameter” per Spenser, whereas Walther discloses “The SAPIEN valves were deployed inside various CEP valves (see Figs. 2 and 3) via the 33F Ascendra system”). The 11.00 mm 33F catheter allows for an area size of almost 95 mm² (again, assuming an infinitesimally small catheter wall thickness), which is needed to accommodate the additional profile size of the cloth seal of Walther and Dehdashtian.

This valve may have been suitable for benchtop testing as shown in the Walther NPL, or for surgical implantation in a valve-in-valve procedure where leaflets have already been removed from the patient, however, the valve is not suitable for endovascular deployment through the femoral artery, a requirement of the claims. And one of ordinary skill would not necessarily further modify the cloth of Dehdashtian to be of a smaller thickness because Dehdashtian utilizes “expan[sion] after deployment at a treatment site” and “as the compressible material expands, it fills the gaps between the stented valve and the surrounding tissue.” And Dehdashtian also

discloses “a cloth or fabric having small fibers extending from the surface of the material” and thus requires two distinct elements: the cloth base material, plus fibers extending from the cloth base material. Thus, when considering that a certain amount of material must be present for the expansion of the compressible material, and that the seal has two distinct elements, it would not be routine to further reduce the thickness of the cloth material until a sufficient profile is reached.

Thus, Applicant has shown that not only does the proposed combination not teach the claim limitation of “deployed endovascularly through a femoral artery of the patient” but that such a combination, even if it taught all elements of the claim, would be inoperable. MPEP 2143 makes clear that:

If a proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. In re Gordon, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984)

THE COMBINATION OF CLAIM LIMITATIONS OF A FIRST PLURALITY OF FIBERS CONFIGURED TO FORM A FIRST SEALING INTERFACE AGAINST NATIVE VALVE LEAFLETS OF THE PATIENT, AND A SECOND PLURALITY OF FIBERS CARRIED BY THE FRAME THAT INCLUDES SPACINGS BETWEEN FIBERS TO FORM A MESH NETWORK COOPERATIVELY FORM THE IMPROVEMENTS NOT SHOWN IN THE PRIOR ART OF RECORD

The Amended claims recite:

a first plurality of fibers positioned radially outwardly of the frame that is configured to form a first sealing interface against native valve leaflets of the patient when the first plurality of fibers is compressed thereagainst, wherein the first plurality of fibers extend radially outwardly of the frame; and

a second plurality of fibers carried by the outer frame that is configured to form a second sealing interface that includes spacings between fibers to form a mesh network against the frame,

These limitations thus provide a low profile needed for endovascular delivery, yet a large enough sealing surface area to seal against paravalvular leak. By having the first plurality of fibers into engagement with the native leaflets, and a second plurality of fibers defining spacing therebetween to form a mesh network, the overall fiber construction is loosely structured (compared to a band/sleeve/cloth as shown in Dehdashtian). This loosely structured arrangement allows for sufficient crimping of the valve to reach a desired delivery profile, while also providing sufficient surface area to allow for tissue ingrowth and thrombosis to create a seal. Indeed, the patent application discloses deployment of the valve assembly through a catheter that is passed through the femoral artery after obtaining percutaneous access. This lower density seal doesn't increase crimp profile significantly because the valve can still be sufficiently crimped due to compressibility of the low density fiber arrangement, yet the increased surface area of fibers (as compared to a graft covering or other outer seal) allows for sufficient sealing once the seal is formed upon compression of the fibers. Compare this to the illustrated high density seal of Dehdashtian where subsequent clinical attempts to use a thick, highly dense outer cloth did not result in a valve with a sufficiently small enough crimp profile for endovascular delivery.

This aspect is well illustrated in FIG. 11 of the Application as filed:

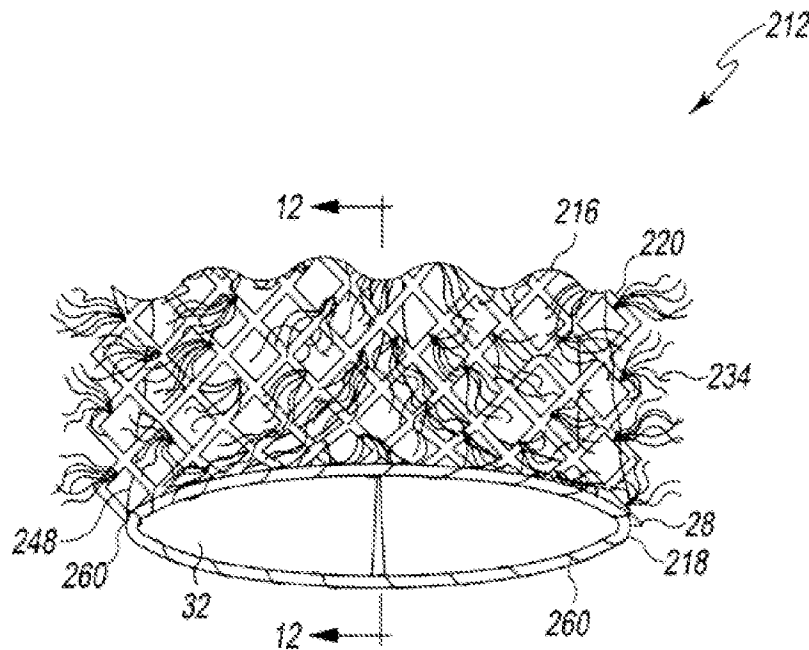
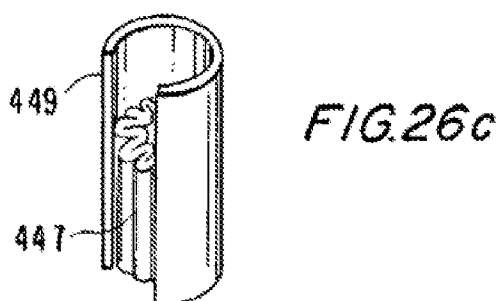


Fig. 11

The loosely packed arrangement of the fibers and spacings defined therebetween allow for a low density, high surface area seal that allows for tissue ingrowth and compressibility. This loosely packed structure of the fibers illustrated in FIG. 11 allows for a far lower crimping profile when the valve assembly is crimped into a delivery system sheath compared to conventional transcatheter valves with dense outer seals such as Dehdashtian. During crimping into a delivery sheath, the loosely packed fibers will be compressed into close proximity of each other and avoid the folding and bunching that is observed with outer cloth and fabric seals disclosed by the prior art, specifically Spenser FIG. 26, reproduced again below for reference:



**FEDERAL CIRCUIT PRECEDENT IN THE SAME FIELD OF ART IS
CONTROLLING IN THIS MATTER**

Finally, the Federal Circuit has spoken to this exact issue in the exact same field of art. In *Snyders Heart Valve LLC v. St. Jude Medical, LLC*¹, the Federal Circuit determined that the prior art of Bessler (USPN 5,855,601) did not anticipate claim limitations in USPN 6,821,297 that the transcatheter valve had a “frame sized and shaped for insertion in [a plurality of cusps of the damaged heart valve.” Bessler taught a valve where a cutting tool first excised the native leaflets

¹ https://cafc.uscourts.gov/opinions-orders/19-2111.OPINION.10-5-2021_1844521.pdf

of a patient to provide sufficient room for deployment of the Bessler valve. The claimed invention of the '297 thus required that the native leaflets remain in place.

Here, just as similar language was used in *Snyders*, the claims require that the heart valve assembly is configured to be deployed endovascularly through a femoral artery of the patient. As already discussed, the prior art is incapable of meeting these limitations, and just as in *Snyders*, when the prior art is incapable of meeting the claim limitations in this technical space, an anticipation rejection on that prior art is improper. Put simply, as Spenser recites, a 24F catheter size is the maximal size of an endovascular deployment through the femoral artery.

Furthermore, the claims each require expansion of the heart valve assembly from the radially compressed orientation to the radially expanded orientation is configured to press the radially extending fibers into engagement with native leaflets of the aorta of a patient. Applicant submits that the prior art of record, as proposed to be combined by the USPTO, is not capable of meeting these claim limitations.

The parallels to *Snyders* are striking. In *Snyder* the claims were construed in a manner consistent with Applicant's claim language--- that the expansion of the valve pressed into engagement with native leaflets of the aorta of a patient. However, in *Snyders*, the primary reference taught removing the native leaflets in order to provide sufficient space for delivery in the annulus. In determining that the Bessler reference did not anticipate the claims, the Board stated "*Of particular note, the specification expressly describes Bessler as presenting problems that the Snyders invention overcomes, stating that the procedure disclosed in Bessler is too invasive because it "includes excision, vacuum removal of the native valve, cardiopulmonary bypass and backflushing of the coronary arterial tree."* (emphasis added).

Just as in *Snyders*, the references of record proposed by the USPTO, when put into practice as shown in the NPL of Walther and Russel, all required removal of the native leaflets. Put simply, the proposed combination by the USPTO was too large to be deployed within the native leaflets of the aorta and the scientific papers presented herein show that to be the case.

Thus, it is clear that the proposed combination by the USPTO is incapable of meeting the claim limitation of expansion of the heart valve assembly from the radially compressed orientation to the radially expanded orientation is configured to press the radially extending fibers into engagement with native leaflets of the aorta of a patient. As such, the claims are patentable for at least this reason.

Applicant submits that the claims are patentable over the references of record as presented herein.

35 USC 112 SUPPORT

The amendment of the independent claims to recite that the inner frame is a graft covering is well supported in paragraph [0089] of the application as filed:

In the illustrative embodiment, the outer surface 248 of the stent 244 is covered with low-profile polyester, ePTFE, or other nonporous covering material 250 that prevents fluid from passing through the outer surface 248. However, it should be appreciated that the stent 244 may be covered with standard polyester, ePTFE or other nonporous materials.

Additionally, FIG. 11 of the Application as filed clearly shows a graft covering inwardly of the metallic/outer frame.

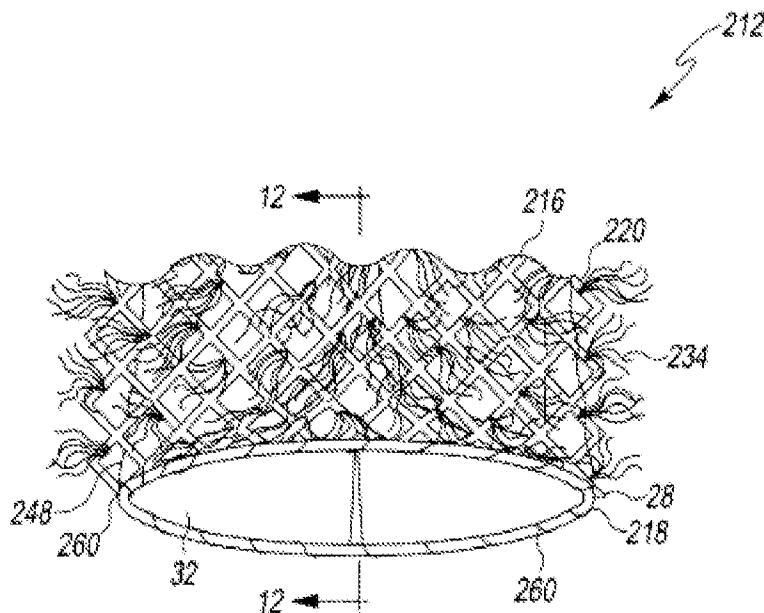


Fig. 11

Applicant has amended the claims to recite spacings, along with other limitations directed towards a mesh network. Applicant submits that the figures clearly display the “spacings” limitations.

MPEP 2163 requires:

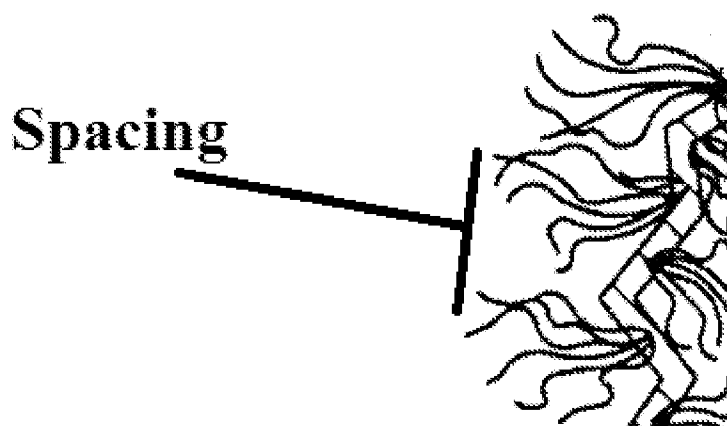
*An applicant may show possession of an invention by disclosure of drawings or structural chemical formulas that are sufficiently detailed to show that applicant was in possession of the claimed invention as a whole. See, e.g., Vas-Cath, 935 F.2d at 1565, 19 USPQ2d at 1118 ("**drawings alone may provide a 'written description' of an invention as required by Sec. 112**"; In re Wolfensperger, 302 F.2d 950, 133 USPQ 537 (CCPA 1962) (the drawings of applicant's specification provided sufficient written descriptive support for the claim limitation at issue); Autogiro Co. of Am. v. United States, 384 F.2d 391, 398, 155 USPQ 697, 703 (Ct. Cl. 1967) ("In those instances where a visual representation can flesh out words, drawings may be used in the same manner and with the same limitations as the specification."); Eli Lilly, 119 F.3d at 1568, 43 USPQ2d at 1406 ("In claims involving chemical materials, generic formulae usually indicate with specificity what the generic claims encompass. One skilled in the art can distinguish such a formula from others and can identify many of the species that the claims encompass. Accordingly, such a formula is normally an adequate description of the claimed genus."). The description need only describe in detail that which is new or not conventional. See Hybritech v. Monoclonal Antibodies, 802 F.2d at 1384, 231 USPQ at 94. This is equally true whether the claimed invention is directed to a product or a process.*

What the Applicant is claiming is the spacing between segments of some fibers. (to mimic the general language of the claims, "the second plurality of fibers.... includes spacings between fibers to form a mesh network against the frame). The spacing allows for inward deflection and compression of the fibers when the frame is expanded to fill any voids within the native leaflets and the seal formed by the fibers. This is well-illustrated in the images showing the deployed device. The collection of fibers and spacing between the fibers thus forms a mesh network. See related application No. 17/327,673 for further reference.

Compare this to a very tightly knitted outer band made of tightly knitted fibers (such as found in NPL, Walther, of record in the IDS dated July 27, 2021, or WIPO Publication 2006005015A2 to Spenser, with reference to FIG. 22, of record in the IDS dated July 11, 2021), where the lack of "spacings" between some fibers would not allow for compression of the outwardly extending fibers. Additionally, the further advantages of the spacings allowing for expansion and contraction of the stent frame compared to a tight outer seal such as a graft. The spacing provides a lesser rigidity than a graft covering (as one example, a graft covering cannot foreshorten during crimping expansion to the same degree as a loosely defined fiber structure),

which allows for both an advantageous crimp profile and tissue ingrowth in response to the overall increased surface area.

Applicant submits that FIG. 12 of the Application as filed illustrates this spacing (shown relative to the first plurality of fibers for simplicity purposes). An annotated version is shown below:



And with further reference to annotated FIG. 11:

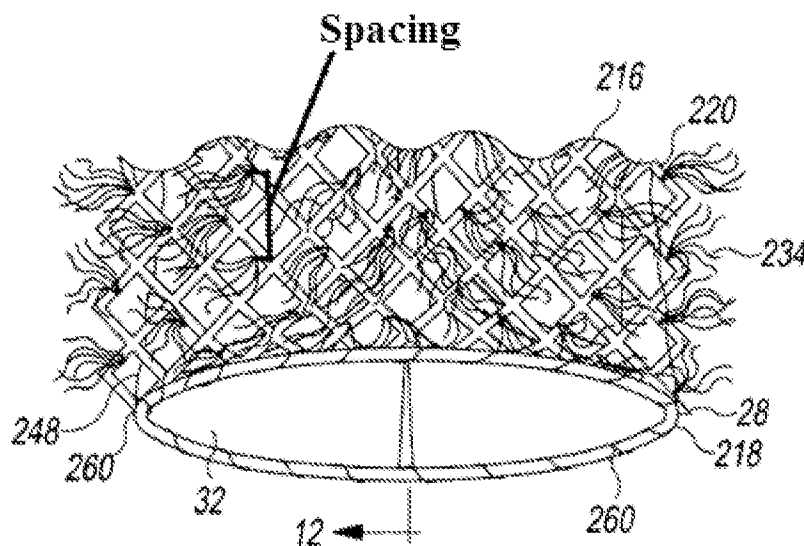


Fig. 11

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

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Amdt. dated: January 4, 2022

with spacings therebetween. This advantage is not shown in the prior art. The advantage provides a low density seal with high surface area to address PVL.

DEPOSIT ACCOUNT

The Commissioner is hereby authorized to charge any otherwise unpaid fees associated with the filing of this correspondence to Deposit Account No. **50-6191**.

Respectfully submitted,

Date: January 4, 2022

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