

**COMMUNICATION TO THE UNITED STATES PATENT AND TRADEMARK
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Applicant	:	Aortic Innovations		
First Named Inventor	:	Ali Shahriari		
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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 8/11/2021

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

Remarks begin on page 7 of this paper.

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Document Description		Start	End
Amendment/Req. Reconsideration-After Non-Final Reject		1	1
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Applicant Arguments/Remarks Made in an Amendment		8	29

Warnings:

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New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

Amendments to the Claims:

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

Listing of Claims:

1-10 (Canceled)

11. (Currently Amended) An endovascular prosthetic heart valve for use in a patient, comprising:

a frame formed of a plurality of struts that cooperate to form a plurality of cells, wherein the frame is radially expandable from a radially compressed orientation to a radially expanded orientation;

a leaflet assembly within the frame;

~~an inner skirt~~ a polymer covering, wherein the polymer covering is attached to the leaflet assembly and positioned radially inwardly of the frame and radially outwardly of the leaflet assembly;

~~an outer seal that extends radially outwardly of the frame;~~

~~wherein the outer seal comprises a~~ first array plurality of fibers that extend away from the frame, ~~[[and]]~~

wherein the first array plurality of fibers ~~[[are]]~~ is configured for being pressed against native leaflets of the patient when the prosthetic heart valve is endovascularly deployed to the radially expanded orientation within a native heart valve annulus of the patient,

a second array of fibers that is positioned radially inwardly from the first array of fibers,

wherein the second array of fibers is in direct contact with the frame.

12. (Canceled)

13. (Currently Amended) The prosthetic heart valve of claim ~~[[12]]~~ 11, wherein the second ~~plurality array~~ of fibers defines an opening extending through a thickness thereof that is created by spacing formed between adjacent fibers, wherein the opening extends to the frame.

14. (Currently Amended) The prosthetic heart valve of claim 11, wherein the ~~inner skirt~~ polymer covering extends proximally further than a proximal scalloped ~~end~~ of the leaflet assembly.
15. (Currently Amended) The prosthetic heart valve of claim 11, wherein a distance that the first array of fibers of the outer seal extends from a centerline extending longitudinally through the frame varies along a length of the centerline.
16. (Currently Amended) The prosthetic heart valve of claim 11, wherein the plurality of cells defines at least two rows of cells at an inflow end of the frame, wherein the ~~outer seal~~ first array of fibers extends over ~~covers~~ each of the at least two rows of cells.
17. (Currently Amended) The prosthetic heart valve of claim 11, wherein the first array plurality of fibers and the second array of fibers of the outer seal are non-metallic.
18. (Currently Amended) The prosthetic heart valve of claim 11, wherein the first array plurality of fibers and the second array of fibers of the outer seal are collagen fibers.
19. (Previously Presented) The prosthetic heart valve of claim 11, wherein the cells formed in the frame are gridded.
20. (Currently Amended) The prosthetic heart valve of claim 11, wherein the ~~outer seal~~ prosthetic heart valve is free of a non-porous graft covering between the first array plurality of fibers of the outer seal and the frame and the second array of fibers and the frame.
21. (Currently Amended) The prosthetic heart valve of claim 11, wherein the ~~inner skirt~~ polymer covering is stitched to the frame.
22. (Currently Amended) The prosthetic heart valve of claim 11, wherein the frame extends distally further than the leaflet assembly.

23. (Currently Amended) The prosthetic heart valve of claim 11, wherein the ~~inner skirt~~ polymer covering and the first array of fibers and the second array of fibers ~~outer seal~~ are distinct elements.

24. (Currently Amended) The prosthetic heart valve of claim 11, wherein the prosthetic heart valve is balloon expandable and expansion of the prosthetic heart valve is configured to press some of the first array ~~plurality of fibers of the outer seal~~ against native leaflets of an aorta of the patient.

25. (Currently Amended) The prosthetic heart valve of claim 11, wherein the ~~inner skirt~~ polymer covering extends beyond a proximal end of the frame and over the proximal end thereof to cover the proximal end of the frame.

26. (Currently Amended) The prosthetic heart valve of claim 11, wherein the first array ~~plurality of fibers of the outer seal~~ defines an opening that extends through a thickness thereof that is created by spacing formed between adjacent fibers thereof.

27. (New) The prosthetic heart valve of claim 11, wherein the frame is radially expandable from the radially compressed orientation to the radially expanded orientation along a length of the frame extending from a proximal end thereof to a distal end thereof.

28. (New) An endovascular prosthetic heart valve for use in a patient, comprising:

- a frame formed of a plurality of struts that cooperate to form a plurality of cells, wherein the frame is radially expandable from a radially compressed orientation to a radially expanded orientation;
- a leaflet assembly within the frame;
- a polymer covering carrying the leaflet assembly and positioned radially inwardly of the frame and radially outwardly of the leaflet assembly;
- a first array of fibers that extend away from the frame, wherein the first array of fibers is configured for being pressed against native leaflets of the patient when the prosthetic heart valve is endovascularly deployed to the radially expanded orientation within a native heart valve annulus of the patient;
- a second array of fibers that is positioned radially inwardly from the first array of fibers, wherein the second array of fibers is in direct contact with the frame, wherein the prosthetic heart valve defines openings extending through a thickness of the first array of fibers that is created by spacing formed between adjacent fibers thereof, through a thickness of the second array of fibers created by spacing formed between adjacent fibers thereof, and through the plurality of cells of the frame,
- wherein, compression of the first array of fibers and the second array of fibers in response to expansion of the prosthetic heart valve compresses the first array of fibers relative to the openings to create a seal thereabout.

29. (New) An endovascular prosthetic heart valve for use in a patient, comprising:

- a frame formed of a plurality of struts that cooperate to form a plurality of cells, wherein the plurality of cells defines at least two rows of cells at an inflow end of the frame,
- wherein the frame is radially expandable from a radially compressed orientation to a radially expanded orientation;
- a leaflet assembly within the frame;
- a polymer covering carrying the leaflet assembly and positioned radially inwardly of the frame and radially outwardly of the leaflet assembly;
- an array of fibers that extend away from the frame,

wherein the array of fibers is configured for being pressed against native leaflets of the patient when the prosthetic heart valve is endovascularly deployed to the radially expanded orientation within a native heart valve annulus of the patient;

wherein the prosthetic heart valve defines openings extending through a thickness of the array of fibers that is created by spacing formed between adjacent fibers thereof through the plurality of cells of the frame,

wherein, compression of the array of fibers in response to expansion of the prosthetic heart valve compresses the array of fibers relative to the openings to create a seal thereabout,

wherein the array of fibers extends over each of the at least two rows of cells.

REMARKS

This is in response to the Office Action dated August 11, 2021.

Without acquiescing to the 112 rejections in the matter, Applicant has amended the claims to address the 112 rejections.

CLAIM 11

Claim 11 has been amended to recite:

*An endovascular prosthetic heart valve for use in a patient, comprising:
a frame formed of a plurality of struts that cooperate to form a plurality of cells,
wherein the frame is radially expandable from a radially compressed orientation to a
radially expanded orientation;
a leaflet assembly within the frame;
~~an inner skirt~~ a polymer covering, wherein the polymer covering is attached to the leaflet
assembly and positioned radially inwardly of the frame;
~~an outer seal that extends radially outwardly of the frame,~~
~~wherein the outer seal comprises a first array~~ plurality of fibers that extend away from
the frame, [[and]]
wherein the first array ~~plurality~~ of fibers [[are]] is configured for being pressed against
native leaflets of the patient when the prosthetic heart valve is endovascularly deployed to the
radially expanded orientation within a native heart valve annulus of the patient,
a second array of fibers that are positioned radially inwardly from first array of fibers,
wherein the second array of fibers is in direct contact with the frame.*

Applicant has amended “inner skirt” to recite “polymer covering.” This 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.

Applicant has amended “outer seal” to recite first array of fibers and second array of fibers to address the 112 rejections. While “array” is not used verbatim in the specification, array is used herein to represent a grouping of fibers that cooperate to form a structure, namely an array. Applicant submits this is well-supported by at least the drawings. Applicant may be their own lexicographer, and submits that the claim language clearly claims the invention.

CLAIM 12

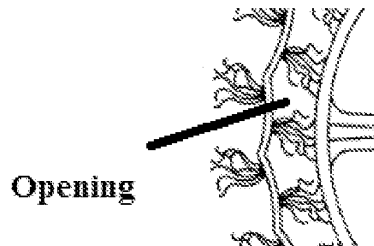
Claim 12 is canceled.

CLAIM 13

Claim 13 recites:

The prosthetic heart valve of claim 11, wherein the second array of fibers defines an opening extending through a thickness thereof that is created by spacing formed between adjacent fibers, wherein the opening extends to the frame.

This claim is well illustrated with reference to the annotated, partial view of FIG. 13:



The advantage of this limitation is that the opening reduces restrictions on expansion and contraction of the stent frame (as opposed to a solid, outer graft), and encourages thrombosis of the fibers by allowing blood flow therethrough.

CLAIM 14

Claim 14 recites:

The prosthetic heart valve of claim 11, wherein the polymer covering extends proximally further than a proximal end of the leaflet assembly.

This is well illustrated in FIG. 12:

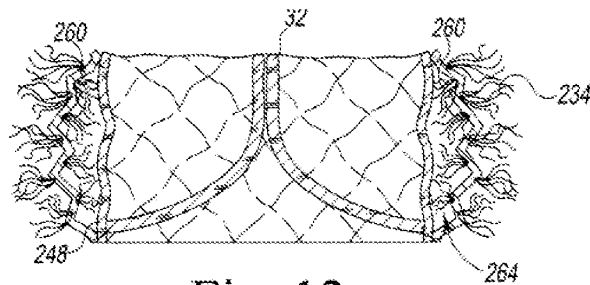


Fig. 12

CLAIM 15

Claim 15 recites:

The prosthetic heart valve of claim 11, wherein a distance that the first array of fibers extends from a centerline extending longitudinally through the frame varies along a length of the centerline.

This is well illustrated with annotated FIG. 12:

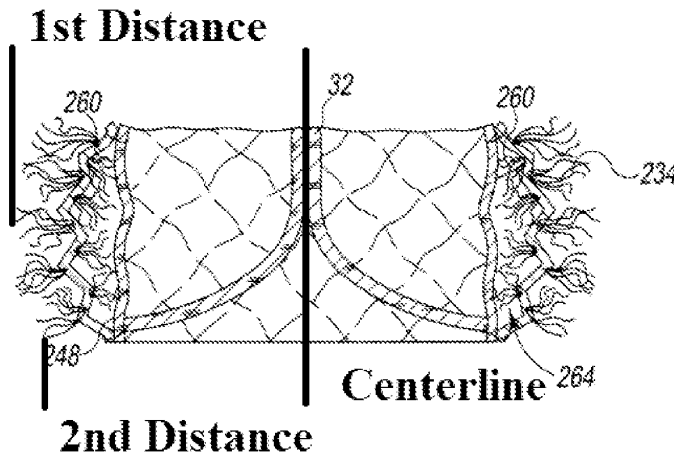


Fig. 12

The advantage of this limitation is that differing sealing profiles are applied against the native annulus, to thereby vary the sealing profile and decrease paravalvular leakage.

CLAIM 16

Claim 16 recites:

The prosthetic heart valve of claim 11, wherein the plurality of cells defines at least two rows of cells at an inflow end of the frame, wherein the first array of fibers extends over each of the at least two rows of cells.

The claims have been amended to recite that the first array of fibers extends over each of the at least two rows of cells.

CLAIM 17

Claim 17 recites:

The prosthetic heart valve of claim 11, wherein the first array of fibers and the second array of fibers are non-metallic.

CLAIM 18

Claim 18 recites:

The prosthetic heart valve of claim 11, wherein the first array of fibers and the second array of fibers are collagen fibers.

CLAIM 19

Claim 19 recites:

The prosthetic heart valve of claim 11, wherein the cells formed in the frame are gridded.

CLAIM 20

Claim 20 recites:

The prosthetic heart valve of claim 11, wherein the prosthetic heart valve is free of a non-porous graft covering between the first array of fibers and the frame and the second array of fibers and the frame.

This so-called negative limitation has been discussed in related applications. MPEP 2173 is controlling on the use of support for negative limitations:

Any negative limitation or exclusionary proviso must have basis in the original disclosure. If alternative elements are positively recited in the specification, they may be explicitly excluded in the claims. See In re Johnson, 558 F.2d 1008, 1019, 194 USPQ

187, 196 (CCPA 1977) ("[the] specification, having described the whole, necessarily described the part remaining."). See also Ex parte Grasselli, 231 USPQ 393 (Bd. App. 1983), aff'd mem., 738 F.2d 453 (Fed. Cir. 1984). The mere absence of a positive recitation is not basis for an exclusion. Any claim containing a negative limitation which does not have basis in the original disclosure should be rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. Note that a lack of literal basis in the specification for a negative limitation may not be sufficient to establish a prima facie case for lack of descriptive support. Ex parte Parks, 30 USPQ2d 1234, 1236 (Bd. Pat. App. & Inter. 1993).

Additionally, the Federal Circuit has clarified the standards for negative limitations as well. The Federal Circuit has held that a negative limitation has written description support when the specification "describes a reason to exclude the relevant limitation." *Santarus, Inc. v. Par Pharm., Inc.*, 694 F.3d 1344, 1351 (Fed. Cir. 2012). That standard is easily satisfied with the disclosure. Such written description support need not rise to the level of disclaimer. In fact, it is possible for the patentee to support both the inclusion and exclusion of the same material. The specification discloses multiple embodiments of a heart valve, and some of the embodiments show a design with an outer graft covering, and some of the other embodiments show a design that is free of an outer graft covering. The inclusion of an embodiment that includes an outer graft covering, and an embodiment without an outer graft covering provides support for the negative limitations disclosed herein. The specification even states "It should be appreciated that in other embodiments the outer frame 216 may be covered with hydrogel or other sealing materials," implying that alternate sealing materials, such as a non porous graft covering may or may not be provided.

CLAIM 21

Claim 21 recites:

The prosthetic heart valve of claim 11, wherein the polymer covering is stitched to the frame.

Claim 21 has been amended consistent with the base claim. The stitch is visible in FIG. 12.

CLAIM 22

Claim 22 recites:

The prosthetic heart valve of claim 11, wherein the frame extends distally further than the leaflet assembly.

Applicant submits that this improves hemodynamic performance.

CLAIM 23

Claim 23 recites:

The prosthetic heart valve of claim 11, wherein the polymer covering and the first array of fibers and the second array of fibers are distinct elements.

This is well-illustrated throughout the drawings.

CLAIM 24

Claim 24 recites:

The prosthetic heart valve of claim 11, wherein the prosthetic heart valve is balloon expandable and expansion of the prosthetic heart valve is configured to press some of the first array of fibers against native leaflets of an aorta of the patient.

This is well-illustrated throughout the drawings.

CLAIM 25

Claim 25 recites:

The prosthetic heart valve of claim 11, wherein the polymer covering extends beyond a proximal end of the frame and over the proximal end thereof to cover the proximal end of the frame.

Claim language similar to this has been presented in related applications, with reference to 218 extending over a proximal end of the frame as illustrated in FIG. 11:

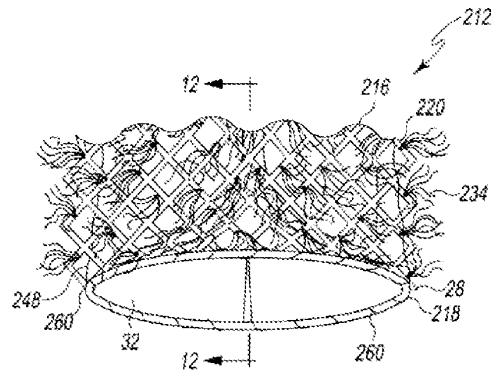


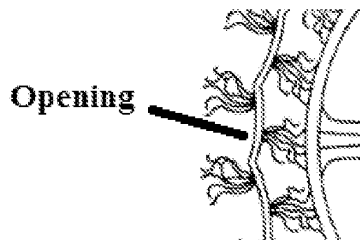
Fig. 11

CLAIM 26

Claim 26 recites:

The prosthetic heart valve of claim 11, wherein the first array of fibers defines an opening that extends through a thickness thereof that is created by spacing formed between adjacent fibers thereof.

Similar to claim 13, annotated, partial view of FIG. 13 illustrates this limitation:



CLAIM 27

Claim 27 recites:

The prosthetic heart valve of claim 11, wherein the frame is radially expandable from the radially compressed orientation to the radially expanded orientation along a length of the frame extending from a proximal end thereof to a distal end thereof.

These claim limitations generally recite that the length of the TAVR is radially compressible and expandable.

CLAIM 28

New claim 28 recites:

An endovascular prosthetic heart valve for use in a patient, comprising:
a frame formed of a plurality of struts that cooperate to form a plurality of cells,
wherein the frame is radially expandable from a radially compressed orientation to a radially expanded orientation;
a leaflet assembly within the frame;
a polymer covering carrying the leaflet assembly and positioned radially inwardly of the frame and radially outwardly of the leaflet assembly;
a first array of fibers that extend away from the frame,
wherein the first array of fibers is configured for being pressed against native leaflets of the patient when the prosthetic heart valve is endovascularly deployed to the radially expanded orientation within a native heart valve annulus of the patient;
a second array of fibers that is positioned radially inwardly from first array of fibers,
wherein the second array of fibers is in direct contact with the frame,
wherein the heart valve defines openings extending through a thickness of the first array of fibers that is created by spacing formed between adjacent fibers thereof, through a thickness of the second array of fibers created by spacing formed between adjacent fibers thereof, and through the plurality of cells of the frame,
wherein, compression of the first array of fibers and the second array of fibers in response to expansion of the heart valve compresses the first array of fibers relative to the openings to create a seal thereabout.

The claim recites that the openings extend through a thickness of the first second array of fibers and into a cell of the plurality of cells. This is illustrated with reference to annotated FIG. 12, FIG. 13, and FIG. 21:

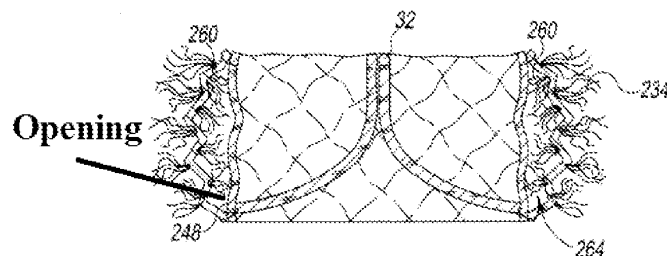


Fig. 12

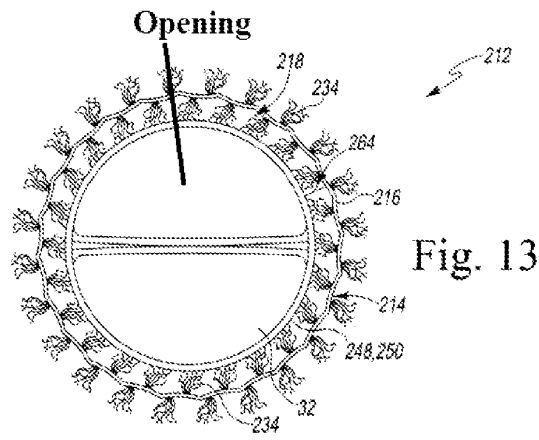


Fig. 13

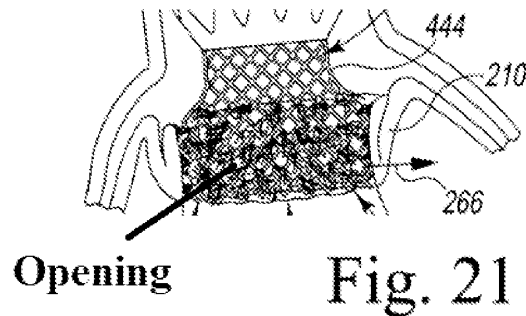


Fig. 21

The advantage of this claim limitation is the ability for thrombosis of the array of fibers about the frame to thereby seal the frame after compression of the fibers, while the lower overall fiber density of the claimed invention (as compared for example with a stent graft) allows for proper expansion of the valve without the disadvantages associated with a stent graft such as restrained valve foreshortening, under expansion, and increased valve profile size.

New claim 29 recites similar limitations, however, only recites an array of fibers, and further recites that the array of fibers extends over each of the at least two rows of cells.

PROBLEMS WITH EXISTING TAVR DEVICES

TAVR devices have competing design forces at all times. The TAVR must maximize valve leaflet size, provide sealing characteristics to reduce PVL and PVR¹, yet, must maintain a small overall crimped profile as the compressed TAVR must be delivered endovascularly

¹ <https://www.acc.org/latest-in-cardiology/articles/2017/02/02/08/25/transcatheter-management-of-paravalvular-leaks>

through an access artery and cross the native heart valve of the patient², maintain appropriate asymmetric foreshortening characteristics³, and maintain appropriate hoop stresses and forces so that undue pressure is not required to inflate the balloon for balloon expandable valves or for self-expansion for self-expanding valves, or underexpansion of the valve assembly can occur⁴.

US Patent Publication No. 20120123529 (“Levi”), which is discussed further herein, well describes this problem of crimp profile with respect to the inner skirt:

[0066] Known fabric skirts comprise a weave of warp and weft fibers that extend perpendicular to each other and with one set of fibers extending perpendicularly to the upper and lower edges of the skirt. When the metal frame, to which the fabric skirt is secured, is radially compressed, the overall axial length of the frame increases. Unfortunately, a fabric skirt, which inherently has limited elasticity, cannot elongate along with the frame and therefore tends to deform the struts of the frame and prevents uniform crimping.

While this was in reference to the inner skirt, the same concerns are presented with an outer skirt where conformability to the native annulus is even more pronounced. Thus, it should be evident that an expandable outer frame (which is thus subject to higher compressive forces) having an outer graft covering of sufficient height, along with an inner graft covering, presented significant engineering design challenges. This is partly why Levi teaches a billowing outer skirt that does not tightly fit against the frame. Designing an outer seal that would effectively seal and limit PVL for an expandable frame is thus desirable.

The issue with the outer seal is particularly relevant because paravalvular leaks and regurgitation are a persistent problem with TAVR. For example, a recent study found that the CoreValve prosthesis, one of the few available TAVR devices in the United States market, had moderate or severe PVR of 11.4% and 9.0% at 30 days. From the study involving 60 patients:

The primary efficacy endpoint was defined as the proportion of patients with less-than-mild prosthetic valve regurgitation at 30 days and amounted to 72.4%, with no patient showing evidence for moderate or severe regurgitation. Of the patients without a pacemaker at baseline, 11.8% required implantation of a permanent pacemaker within 30 days after TAVR. The mean transprosthetic gradient was low with 6.4 mm Hg as

² <https://www.sciencedirect.com/science/article/pii/S2666084919304760>

³ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6551197/>

⁴ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5300953/>

typical for a supra-annular valve design, though acknowledging that no patient requiring a 23-mm device was included. The pre-defined primary safety endpoints, all-cause mortality and disabling stroke at 30 days, amounted to 1.7% each in a patient population with a mean Society of Thoracic Surgeons score of 6.4%. Thirty-day rates of major vascular complications and life-threatening or disabling bleeding were 10.0% and 11.7%, respectively.

The presented data are promising and support the concept to mimic surgical-like outcomes as it relates to PVR by the addition of an external seal that compensates for incomplete stent-landing zone apposition...

<http://interventions.onlinejacc.org/content/jint/11/2/169.full.pdf>

From another study:

Moderate to severe regurgitation after TAVR confers a poor prognosis and is associated with an increased risk of all-cause mortality. Even mild PVL has been shown to have a negative impact on survival. Kodali et al reported on the outcomes of patients who underwent TAVR from the randomized cohorts of the PARTNER trial and continued access registries. Data were analyzed from a total of 2,434 patients. PVL was reported as mild in 38% and moderate/severe in 9.1% of patients after TAVR. There was no difference in 30-day mortality. Instead, the adverse effect was expressed later with a significant increase in 1-year all-cause and cardiac mortality and repeat hospitalization in those with worsening PVL.

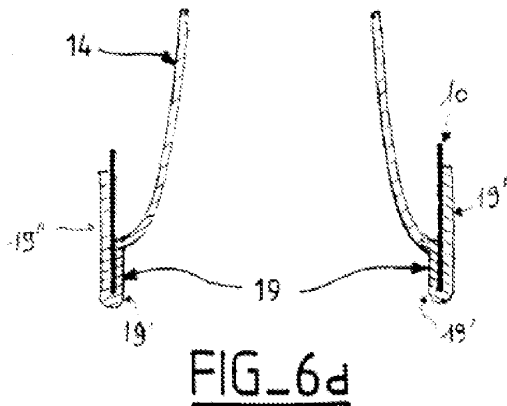
<https://citoday.com/articles/2015-july-aug/managing-paravalvular-leaks-after-tavr>

Thus, as these studies show, PVL is a long-felt problem and a method of addressing this problem has been needed. Studies show high one year mortality and rehospitalization rates of 35% and 31% may be attributed to PVL, and reducing PVL will thus reduce mortality and rehospitalization rates. According to this study, an external seal helps to address PVL and PVR. Surgical valves, as will be discussed herein, did not traditionally have significant PVL concerns because the valve leaflets were removed from the patient, and a sealing ring or similar could be stitchably engaged with the aorta in an open heart procedure. However, a robust outer seal system on a TAVR presents problems with expansion forces, foreshortening, underexpansion,

and crossing of the aorta. Applicant submits that the claimed invention addresses these problems.

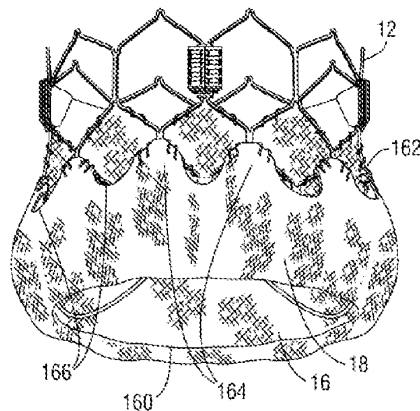
**A DISCUSSION OF SOME OF THE PRIOR ART FOLLOWS:
TRANSCATHETER VALVE TECHNOLOGY**

An example of a transcatheter valve having an inner and outer seal is shown in at least WO98/29057 (“Cribier”). See for example FIG. 6D that shows a cover extending from an inner surface to an outer surface of the stent frame.



Similarly, US Patent Publication No. 20120123529 (“Levi”) appears to teach an inner and outer seal in FIG. 42.

FIG. 42



WO2006/005015 (“Spenser”) appears to teach a thick band with fibers emanating therefrom in FIG. 22. Spenser or a valve similar to Spenser appears to be shown in the NPL Walther, submitted in the information disclosure statement dated July 27, 2021. Additionally, Spenser is unable to substantially foreshorten (see commissure supports that restrict length of stent) and thus, the issue of valve foreshortening and creating a compliant outer seal that does not restrict foreshortening would not have been apparent. The thick outer seal of Spenser adds to valve profile size and restricts foreshortening. FIG. 22 is reproduced below:

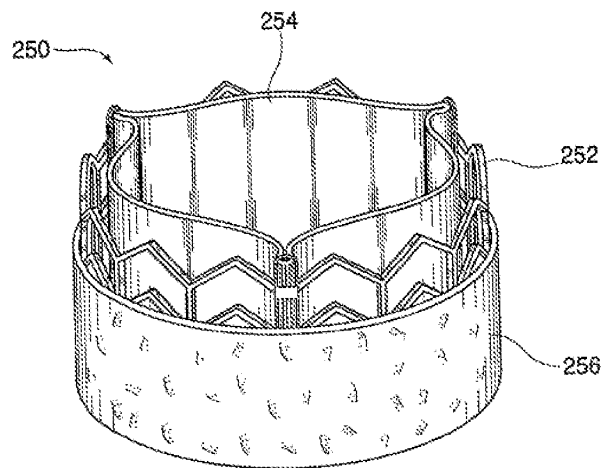
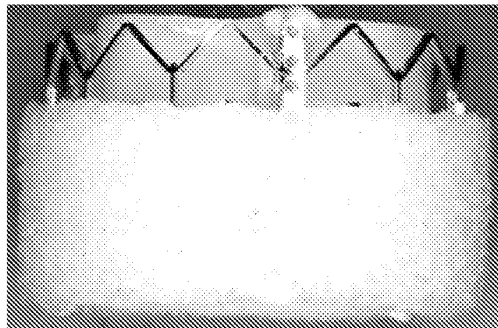


FIG. 22

And from the NPL of record that appears to be Spenser or similar to Spenser:



US Patent No. 7,381,219 (“Salaheih”) teaches a repositionable TAVR with sacs filled by hydrogel or similar on an exterior of the TAVR for sealing the TAVR:

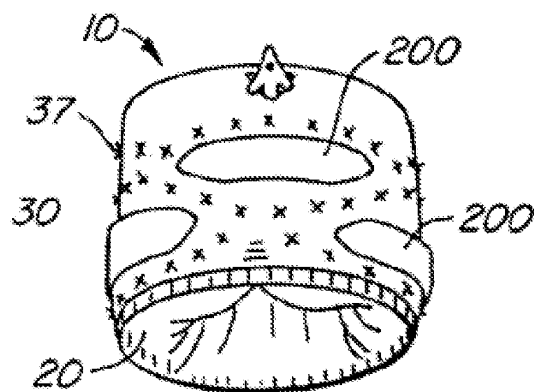


FIG. 15A

US Patent No. 9,333,075 ("Delaloye") teaches a TAVR with an outer seal at a proximal end.

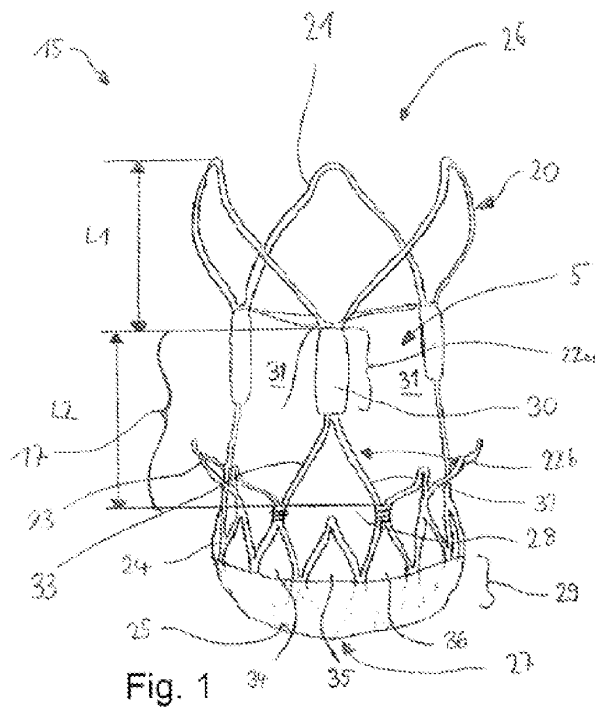
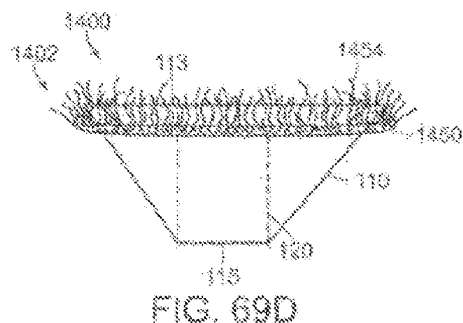


Fig. 1

US Patent No. 10,299,917 (“Morris”) teaches a ring having fibers emanating therefrom on a mitral valve design. The fiber design does not appear to teach a first array of fibers, and a second array of fibers positioned radially inwardly from the first array, among other limitations.



STENT GRAFT TECHNOLOGY

Various stent grafts have also been developed that include one or more seals. US Patent Publication No. 2004/0256759 (“Hartley”) teaches a velour band at a distal end of the stent graft.

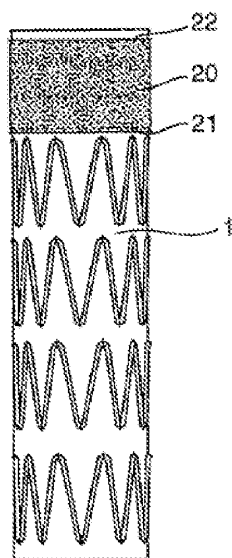
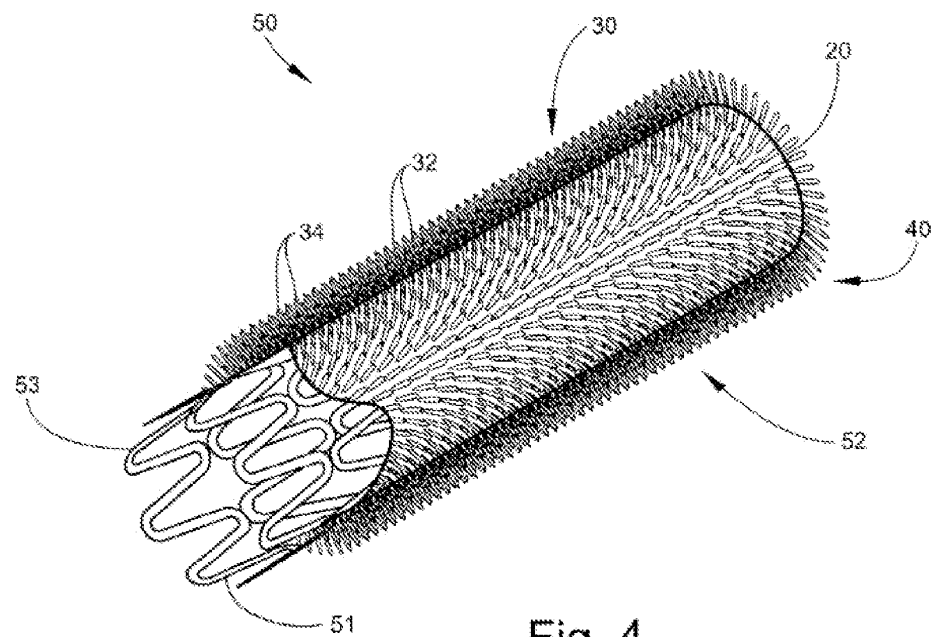
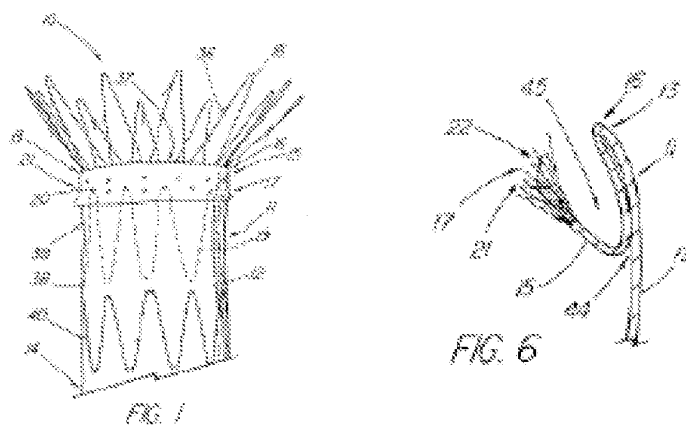


Fig 2

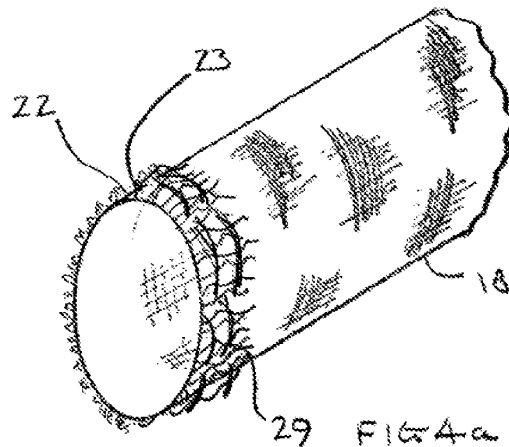
Similarly, US Patent No. 7,921,678 (“Norris”) teaches a stent graft with loops of outwardly extending material.



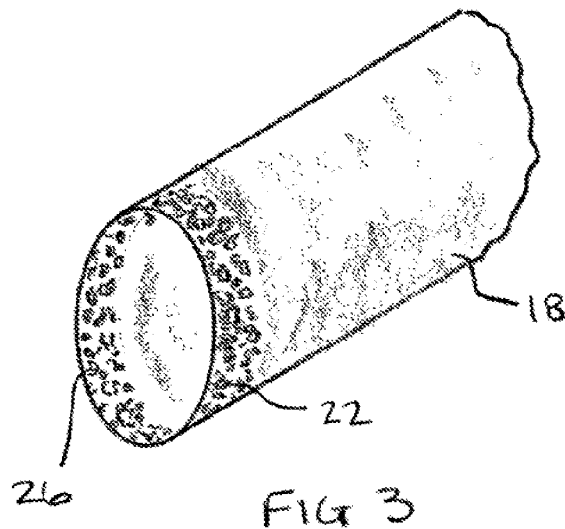
US Patent Publication No. 2004/0082989 (“Cook”) teaches a cuff portion with a frayed portion 22:



US Patent Publication No. US 2002/0052649 (“Greenhalgh”) teaches a stent graft with fibers emanating therefrom.

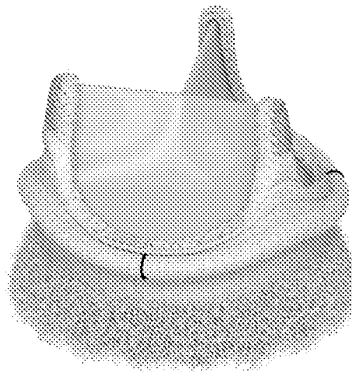


Greenhalgh also further teaches pores, as an example, in FIG. 3 that may be formed by mechanically piercing the membrane, etching with chemicals or ablating with a laser. However, as indicated in Greenhalgh, these “pores” are formed in a “membrane of expanded polytetrafluoroethylene (ePTFE) is used to form the graft substrate 18” and thus, the “pores” in Greenhalgh are not formed in an array of fibers as claimed, but instead within a graft substrate.



SURGICAL VALVES

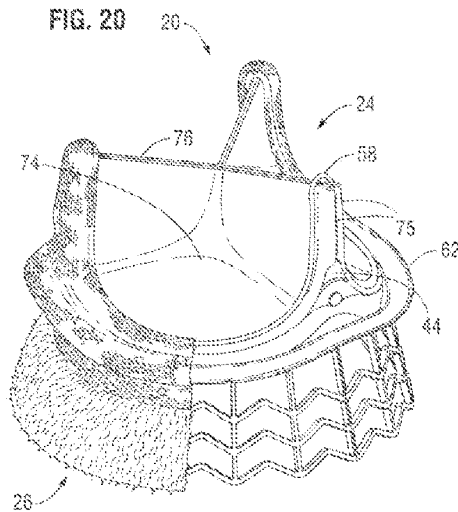
The non-patent literature of Intuity does appear to teach an external seal that includes fibers. Intuity appears to show a surgical valve from 2011 that has a plush outer seal similar to the valve shown in US Patent No. 9,370,418 (“Pintor”), which has been discussed in prosecution of Application No. 16/808,137 in front of Examiner Shipmon and that is related to this pending application.



This surgical valve would appear to teach a seal that seals below the leaflets, and not against native valve leaflets of the patient. In fact, typically the native leaflets are surgically removed during surgical heart valve replacement. Additionally, because a surgical valve does not have the access issues associated with transcatheter valves, the increased overall profile of a surgical valve such as Intuity is not as problematic. Furthermore, the Intuity valve appears to teach an outer graft covering between the outer frame and the fibers.

The portions of Pintor that generally disclose “fibers” appear to have an effective filing date after Applicant’s effective filing date. However, Applicant notes that both of Pintor and Applicant’s claimed invention are pre-AIA. Assuming, *arguendo*, that Pintor could have a conception and diligence date before Applicant’s, Pintor does not appear to teach or render obvious the claimed invention. Pintor is a surgical valve, not an endovascularly deployed valve. Pintor teaches many embodiments and Applicant will discuss a few of each.

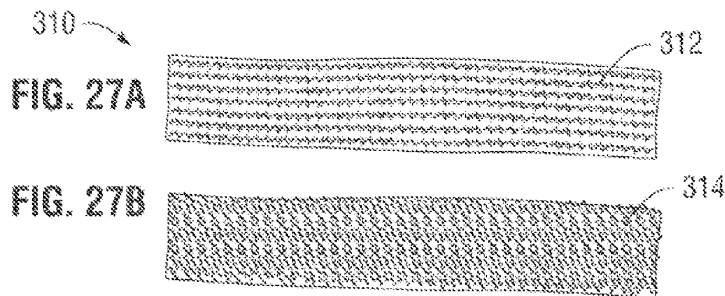
The embodiment illustrated in FIG. 20 is similar to the image shown above. As illustrated, a plurality of fibers appears to extend out of a graft covering that is stitched to the main frame. FIG. 20 is reproduced below:



Thus Applicant submits that this embodiment of Pintor does not teach a first array of fibers, and a second array of fibers, among other limitations as claimed.

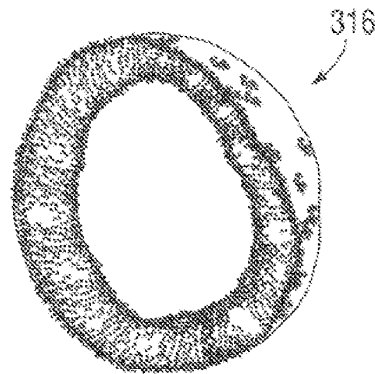
FIG. 27A and 27B of Pintor may appear to teach a seal material having a first array of fibers (312) and a second array of fibers (314). From the specification of Pintor:

FIGS. 27A-27B show opposite sides of a strip 310 of plush fabric used to create a sealing flange 84 on the expandable anchoring skirt 26. The material of the strip 310 includes a relatively smooth side 312 with rows of ribs of the fabric weave, and a plush or relatively fluffy side 314 with outwardly projecting loops and loose threads of the polymer material.



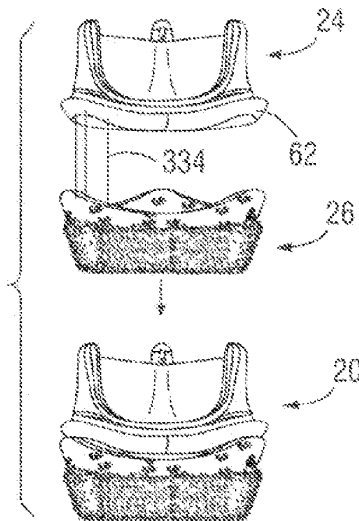
Consistent with a surgical valve where overall valve profile is not as significant of a concern as with a transcatheter valve, Pintor then teaches looping the strip 310 around to form a sewing ring of significant thickness. This is well-illustrated in FIG. 29A, reproduced below:

FIG. 29A



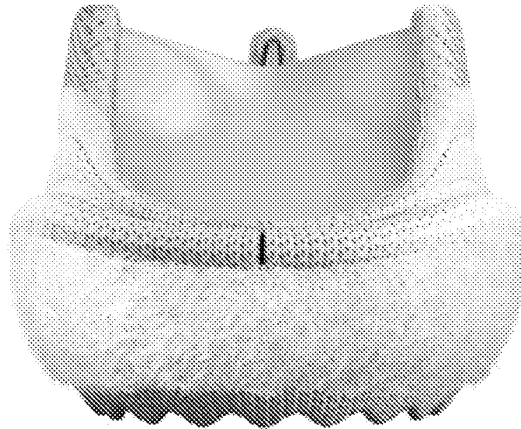
The enlarged skirt is then attached with the frame as illustrated in FIG. 32 in one embodiment:

FIG. 32



Various other embodiments are illustrated in FIGS. 36A through 41C, including various embodiments where there is no fabric cover between frame 80 and outer seal (326, 328, 330 as

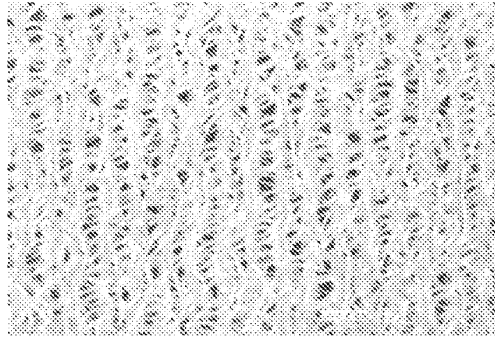
examples). To the extent that any of the embodiments are enabled, the embodiments appear to teach a thick outer seal consistent with the “folded over” disclosure with reference to FIG. 29A. Applicant submits that these embodiments may have some overlap with the Intuity embodiment shown below:



To the extent that these embodiments teach an array of fibers in contact with the frame of the stent, it is the same array of fibers that seal against the annulus of the patient, and not a different (i.e. the difference between claimed first array of fibers and second array of fibers) array of fibers as found in the claimed invention.

ADOPTION OF A SEALING SKIRT COVERED BY THE CLAIMED INVENTION HAS REDUCED PVL RATES

The Sapien 3 Ultra sealing skirt appears to be covered by the claimed invention. It is submitted that there is a first array of fibers forming a mesh, and a second array of fibers that end therefrom and into engagement with native leaflets of a patient. The fiber seal provided by the valve design is disclosed having the depicted construction where the openings within the seal provide for proper expansion of the valve with improved valve foreshortening and expansion, while maintaining overall desirable valve profile size:



Compared to the Sapien 3 product, largely embodied by Levi discussed herein, this Ultra seal assembly showed a mild PVL rate of 18.7% versus 43.0% for the Levi design in at least one study.⁵ This significant reduction in mild PVL has addressed a long felt but unresolved need after years of failure by others to address the problem. Furthermore, the valve design has enjoyed significant commercial success, and quickly displaced the Levi design valve for most procedures.

**APPLICANT'S CLAIMED INVENTION ADDRESSES THE PROBLEMS OF THE
PRIOR ART AND IS NOT TAUGHT OR RENDERED OBVIOUS BY THE PRIOR ART**

Amended claim 11 recites:

An endovascular prosthetic heart valve for use in a patient, comprising:
a frame formed of a plurality of struts that cooperate to form a plurality of cells,
wherein the frame is radially expandable from a radially compressed orientation to a
radially expanded orientation;
a leaflet assembly within the frame;
~~an inner skirt~~ a polymer covering, wherein the polymer covering is attached to the leaflet
assembly and positioned radially inwardly of the frame and radially outwardly of the leaflet
assembly;
~~an outer seal that extends radially outwardly of the frame,~~
~~wherein the outer seal comprises a first array plurality of fibers that extend away from~~
the frame,[[and]]
wherein the first array plurality of fibers [[are]] is configured for being pressed against
native leaflets of the patient when the prosthetic heart valve is endovascularly deployed to the
radially expanded orientation within a native heart valve annulus of the patient.

⁵ <https://www.crtonline.org/news-detail/early-data-suggest-edwards-fourth-generation-sapie>

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a second array of fibers that is positioned radially inwardly from the first array of fibers, wherein the second array of fibers are in direct contact with the frame.

The remaining independent claims recite somewhat generally similar limitations. Applicant submits that this claim addresses the problems in the prior art, notably restricted foreshortening, underexpansion of the valve assembly, enlarged valve profile, and paravalvular leakage. The first array of fibers and the second array of fibers provide multiple seal opportunities, including against the native leaflets of the patient in an endovascular procedure, and against the main frame of the valve assembly. However, the fibrous nature of the combined seal does not cause undesired increase in rigidity of the seal, while allowing for thrombus and tissue in-growth to promote seal against paravalvular leakage.

The prior art of record does not appear to teach these limitations. Applicant thus submits that the claimed invention is patentable over the references of record.

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: August 14, 2021

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