2019-2111

United States Court of Appeals for the Federal Circuit

SNYDERS HEART VALVE LLC,

Appellant,

– v. –

ST. JUDE MEDICAL, LLC,

Appellee.

On Appeal from the United States Patent and Trademark Office, Patent Trial and Appeal Board in No. IPR2018-00107

BRIEF FOR APPELLANT

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FORM 9. Certificate of Interest **Form 9**
Rev. 10/17

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

Snyders Heart Valve LLC **v.** St. Jude Medical, LLC

Case No. 19-2111

CERTIFICATE OF INTEREST

Counsel for the:
☐ (petitioner) ■ (appellant) ☐ (respondent) ☐ (appellee) ☐ (amicus) ☐ (name of party)

Matthew J. Antonelli

certifies the following (use "None" if applicable; use extra sheets if necessary):

1. Full Name of Party Represented by me	2. Name of Real Party in interest (Please only include any real party in interest NOT identified in Question 3) represented by me is:	3. Parent corporations and publicly held companies that own 10% or more of stock in the party
Snyders Heart Valve LLC	Snyders Heart Valve LLC	None

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this court **(and who have not or will not enter an appearance in this case)** are:

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FORM 9. Certificate of Interest **Form 9**
Rev. 10/17

5. The title and number of any case known to counsel to be pending in this or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal. *See* Fed. Cir. R. 47. 4(a)(5) and 47.5(b). (The parties should attach continuation pages as necessary).

Snyders Heart Valve LLC v. St. Jude Medical SC, Inc. et al, C.A. No. 18-cv-02030-JRT/DTS, the United States District Court for the District of Minnesota;
St. Jude Medical, LLC v. Snyders Heart Valve LLC, 19-2108 (Fed. Cir.);
St. Jude Medical, LLC v. Snyders Heart Valve LLC, 19-2109, 19-2140 (Fed. Cir.);
St. Jude Medical, LLC v. Snyders Heart Valve LLC, 19-2110 (Fed. Cir.).

7/22/2019
Date

/s/ Matthew J. Antonelli
Signature of counsel

Please Note: All questions must be answered

Matthew J. Antonelli
Printed name of counsel

cc: All counsel of record by CM/ECF

Reset Fields

Table of Contents

Table of Authorities

Cases:

Constitutional Provisions, Statutes, & Regulations:

Other Materials:

Statement of Related Cases

No other appeal was previously before this or any other appellate court. The following cases might directly affect or be affected by this Court's decision: *St. Jude Medical, LLC v. Snyders Heart Valve LLC*, Consolidated Case Nos. 2019-2108, 2019-2109, 2019-2140 (Fed. Cir.); *Snyders Heart Valve LLC v. St. Jude Medical S.C., Inc.,* Case No. 18-cv-2030 (JRT/DTS) (D. Minn.).

I. Introduction

The Administrative Patent Judges who decided to institute the IPR below, and who issued the final written decision, acted as Principal Officers of the United States. Yet they were not appointed by the President nor confirmed by the Senate as require by the Appointments Clause. For this reason, the final written decision should be vacated.

In *Arthrex*, this Court recently held that this violation of the Appointments Clause could be remedied by severing certain job protections for APJs from the America Invents Act. But that remedy does not solve the Appointments Clause problem for two reasons.

First, in enacting the AIA, Congress intended that APJs would enjoy independent decision making, without fear of political interference. There was thus no basis to sever the portion of the AIA providing APJs with job protections.

Second, *Arthrex's* severance does not solve the Appointments Clause problem. Even after severance, APJs still issue final decisions on behalf of the executive branch. And they do so with no opportunity for review by any executive branch officer who has been appointed by the President and confirmed by the Senate. Indeed, in this case, the only officer of the Patent Office who was so appointed, Director Iancu, was recused from any involvement in the IPR proceedings because he represented Petitioner as lead trial counsel in the patent

infringement suit pending between Petitioner and Patent Owner over the patent-in-suit. Because they provide the final word on behalf of the executive branch, APJs remain Principal Officers who must be appointed by the President and confirmed by the Senate.

The final written decision below was also deeply flawed on the merits. In determining that the claims of the patent-in-suit were unpatentable as obvious, the PTAB improperly shifted the burden of proof to Patent Owner. Additionally, its findings that certain claim limitations were disclosed by the Bessler prior-art reference were based on incorrect readings of the patent claims. So if this case is not dismissed, or at least not vacated and remanded for a new decision under *Arthrex*, then the final written decision below should be vacated on the merits.

II. Jurisdictional Statement

The Patent Trial and Appeal Board issued a final written decision on May 2, 2019 in inter partes review no. IPR2018-00107 filed by Appellee St. Jude Medical, LLC. Appx1. Appellant Snyders Heart Valve timely filed a Notice of Appeal to this Court on July 1, 2019. Appx207.

This Court has jurisdiction over this appeal from a final agency action of the United States Patent and Trademark Office (USPTO) under 28 U.S.C. § 1295(a) and 35 U.S.C. § 141(c).

III. Statement of the Issues

1. The Administrative Patent Judges assigned to the IPR below were not appointed by the President or confirmed by the Senate. Yet they made both the institution decision and the final written decision below with no meaningful review by anyone in the executive branch who was appointed by the President and confirmed by the Senate. Indeed, Director Iancu—the only officer at the Patent Office so appointed—was recused from any involvement in the IPR proceedings. Should the final written decision be vacated for this violation of the Appointments Clause?

2. Andrei Iancu represented Petitioner in litigation with Patent Owner over the patent-in-suit. In the middle of that litigation, and while the petition below was pending, Mr. Iancu was appointed Director of the Patent Office. Patent Owner moved to dismiss the petition in view of the conflict generated by Director Iancu's appointment. The PTAB denied Patent Owner's motion because "Patent Owner has not established sufficiently that Administrative Patent Judges are unable to carry out their pre-designated duties impartially." But in *Arthrex*, this Court relied on the fact that APJs are sufficiently answerable to superior officers (at least after severance) so as to not qualify as Principal Officers. Did the PTAB err in not dismissing the petition given the conflict generated by Mr. Iancu's appointment?

3. The PTAB found all of the challenged claims to be obvious in view of Bessler and Johnson (or Bessler and Johnson in further view of Taylor or Thompson). But the PTAB did not rely on any motivation to combine Bessler and Johnson. Instead, the PTAB only rejected one of Snyders' counter-arguments regarding motivation to combine. Moreover, the PTAB rejected that counter-argument only because "we see no reason why Johnson's strut-based frame and membrane combined with Bessler's stent would not easily collapse into the 18 mm diameter instrument 70M of the '297 patent." Did the PTAB improperly shift the burden of proof to Patent Owner on obviousness?

4. The PTAB found all challenged claims of the 297 Patent to be unpatentable in view of Bessler or in view of combinations of prior art references including Bessler. In each case, the PTAB relied on Bessler as disclosing a valve frame that, as required by the claims, is "sized and shaped" for insertion between an "upstream region" and a "downstream region" separated by "a damaged heart valve having a plurality of cusps." But Bessler discloses a valve frame that is sized and shaped for insertion in the native anatomy only after the cusps of the damaged heart valve are removed. Did the PTAB err in finding these claim limitations met by Bessler?

5. In support of its argument that Bessler did not disclose a valve that was "sized and shaped" as required by the claims, Patent Owner relied on the

teachings of another prior-art reference, Bailey. (Bailey teaches that the Bessler valve is unsuitable for use when the diseased cusps of the native valve are not removed.) The PTAB rejected this evidence as inadmissible hearsay, noting that the "Patent Owner has not adduced any evidence that Mr. Bailey had any personal knowledge of the functionality of Bessler's barbed valves." Appx53. Did the PTAB err in dismissing teachings of the prior art as "inadmissible hearsay?"

6. Claims 38, 39, and 45 each require a flexible valve element that is fixedly attached to the frame. The PTAB found these claims to be anticipated by Bessler (and to be obvious in view of the combinations of Bessler and Thompson and Bessler and Taylor), determining that it was sufficient that Bessler taught an attachment of the valve element to the valve cuff, which in turn was attached to the frame. Did the PTAB err in construing these claims to include this indirect attachment?

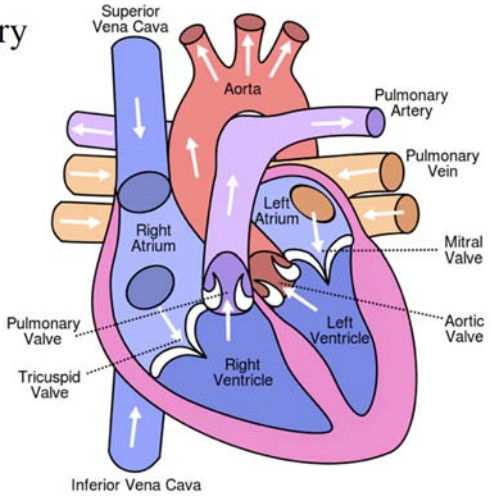
IV. Statement of the Case and the Facts

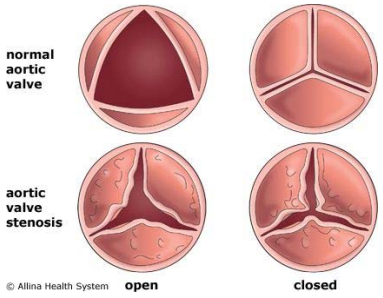
A. Dr. Snyders' Patents

Dr. Robert Snyders is a pioneer in the field of collapsible artificial heart valves suitable for transluminal delivery. He designed—and patented—collapsible prosthetic heart valves, and corresponding delivery systems, *years* before Petitioner even thought about entering the field. Dr. Snyders has been awarded numerous patents for his innovations, including the 297 Patent at issue in this case.

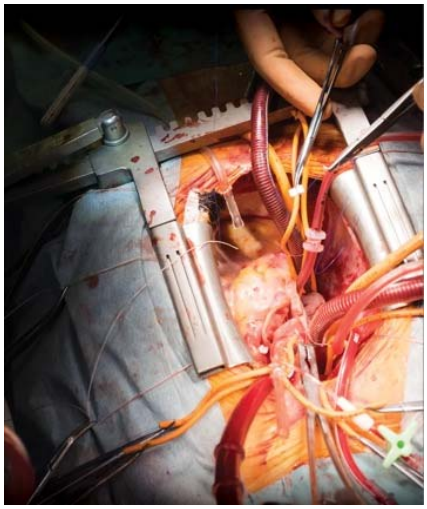
Appx81 [297 Patent].

The human heart contains valves between its atria and ventricles, and between its ventricles and the major vessels that carry blood away from the heart. *See* Appx82 at 1:17-23 [297 Patent]. For example, the aortic valve is the valve between the left ventricle and the aorta, which is the major vessel of the heart that delivers oxygenated blood throughout the body. In some people, the aortic valve hardens over time (becoming "stenotic"). This restricts the amount of blood the heart can pump through the aorta when the left ventricle contracts because the stenotic valve cannot open fully. This may also allow blood to flow back from the aorta into the left ventricle ("regurgitation") when the left ventricle relaxes, since a stenotic aortic valve may not close completely. *See id.* at 1:24-29.





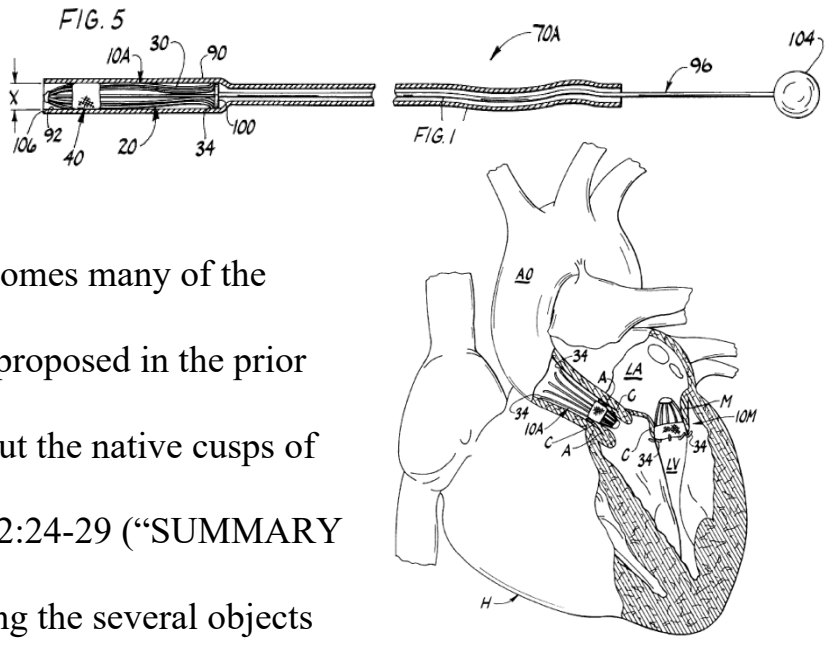
For many years, stenotic valves have been treated by surgically replacing them with artificial valves. That requires surgically opening the chest, spreading the ribs, stopping the heart, and surgically cutting the heart open to implant the



replacement valve. *See id*. at 1:30-35; 1:46-65. This surgical treatment is highly stressful and is unsuitable for older or sicker patients who are too frail to undergo the ordeal of open-heart surgery. *See id.* at 1:36-37.

At the time of Dr. Snyders' invention, several valves for percutaneous (through the skin) and transluminal (using a catheter, or lumen) implantation had been proposed. *See id*. at 1:37-42; 1:66-2:9. There were many problems with those proposals. In particular, many of them still required the diseased cusps of the native valve to be surgically removed. *See id.* at 1:42-46 ("However, many of these valves also require the damaged native heart valve be removed prior to implanting the artificial valve. Removing the native valve increases the risk that a portion of the valve will migrate through the body and block vessels downstream from the heart.").

Dr. Snyders designed a valve suitable for percutaneous, transluminal delivery to the heart that overcomes many of the problems posed by the valves proposed in the prior art, including the need to cut out the native cusps of the damaged valve. *See id.* at 2:24-29 ("SUMMARY OF THE INVENTION: Among the several objects



and features of the present invention may be noted the provision of an artificial heart valve which accommodates implantation without removing the damaged native heart valve . . . .”). Its frame is made of a flexibly resilient material so that it can be compressed for loading into a delivery instrument. *See id.* at 2:41-43. A small incision can then be made in a vessel leading to the heart (such as the femoral artery) and the end of the instrument can be advanced through the artery, up through the ascending aorta, until the loaded valve is in the correct position adjacent the cusps of the damaged heart valve. *See id*. at 3:64-4:3. The valve can then be ejected from the end of the instrument without removing the damaged valve from the heart. *See id.* at 3:61-64.

B. The Prior Art Relied On During The IPR Proceedings

The PTAB primarily relied on two references, Bessler and Johnson, both of which were before the Patent Office during the original prosecution of the patent-in-suit.

1. Bessler

Dr. Snyders’ patent discusses Bessler in its “Background of the Invention” section. It specifically criticizes Bessler because Bessler requires surgical removal of the diseased cusps of the native valve before implantation of its artificial valve. Appx94 at 2:18-23 (“U.S. Pat. No. 5,885,601 (Bessler) describes a transluminal valve implantation but does not describe the specific valve construction. The

Bessler procedure includes excision, vacuum removal of the native valve, cardio-pulmonary bypass and backflushing of the coronary arterial tree.").

2. Johnson

Johnson was also before the Patent Office during prosecution of the patent-in-suit. Appx81 (identifying Johnson as a cited reference). Johnson discloses a non-collapsible surgical valve, which is not suitable at all for transluminal delivery. *See* Appx1493. It must be surgically sutured into the native annulus of the valve after the diseased cusps are removed. *See* Appx1496 at 2:62-64.

C. Director Iancu's Recusal

Andrei Iancu served as lead trial counsel for Petitioner in litigation with Patent Owner over the 297 Patent. Appx2277 [Litigation Docket]. Mr. Iancu handled numerous discovery issues. *See, e.g., id*. at Dkt. 107; Appx2320 [Minutes from May 30 Teleconference]. Mr. Iancu also argued as lead counsel for Petitioner at the *Markman* hearing, arguing the term "central portion," which was a contested construction in the present IPR, as well as the terms "u-shaped elements," "frame," "flexible valve element," "peripheral anchors," "releasable fastener," and "concave/convex." Appx2277 at Dkt. Nos. 180, 195, 196 [Litigation Docket]. And while Mr. Iancu was lead counsel in the litigation, Petitioner made arguments nearly identical to those in the IPR petition below in its May 2017 invalidity contentions, its November 2017 expert reports, and its December 2017 summary

judgment motion (regarding the Leonhardt reference). *See* Appx2322 [St. Jude Invalidity Contentions]; Appx2373 [Table of Contents from Expert Report of Dr. Ajit Yoganathan]; Appx2277 at Dkts. 217, 218 [Litigation Docket].

In the middle of that litigation, and after Petitioner had filed its IPR petitions, Mr. Iancu was appointed as the Director of the Patent Office. In view of his representation of Petitioner, Director Iancu recused himself from any involvement in the IPR proceedings, including both in the institution decision and the final written decision. Appx492 at 1 n.1 [Institution Decision] ("Director Andrei Iancu has taken no part in this Decision due to recusal."); Appx1 at 1 n.1 [Final Written Decision] ("Director Andrei Iancu has taken no part in this Decision due to recusal.").

D. The PTAB's Decisions

Before the PTAB's institution decision, Patent Owner moved to dismiss the petition in view of the conflict generated by Director Iancu's appointment. *See* Appx463 [Patent Owner's Motion to Dismiss]. The PTAB denied that motion because "Patent Owner has not established sufficiently that Administrative Patent Judges are unable to carry out their pre-designated duties impartially." Appx490 [Decision Denying Motion To Dismiss].

The PTAB also rejected Patent Owner's argument that the IPR proceeding violated the Appointments Clause because the APJs had not been appointed by the

President nor confirmed by the Senate and because their decisions were not reviewed by anyone in the executive branch who had been so appointed. Appx54 [Final Written Decision] ("[W]e are not persuaded that Administrative Patent Judges conducting *inter partes* reviews is unconstitutional.").

In its final written decision, the PTAB found all challenged claims to be obvious in view of combinations of Bessler and Johnson (and, in some cases, in further view of additional prior art). Appx54-55 at ¶¶ 2-6 [Final Written Decision]. But it made no findings supporting the conclusion that a person of skill in the art would have been motivated to combine Bessler and Johnson. Instead, it only rejected a counter-argument made by Patent Owner, and did so only because "we see no reason" to accept Patent Owner's counter-argument. *See* Appx35-39 [Final Written Decision].

The PTAB also found that Bessler disclosed a frame that was "sized and shaped" for insertion between an "upstream region" and a "downstream region" separated by "a damaged heart valve having a plurality of cusps." Appx22-24. Each of the PTAB's determinations that a claim was unpatentable depended on this finding. Appx24 (anticipation of claim 38); Appx25-26 (anticipation of claims 39 and 45); Appx27-32 (obviousness of claim 39 in view of Bessler and Thompson and in view of Bessler and Taylor); Appx39 (obviousness of all challenged claims in view of Bessler and Johnson); Appx41-42 (obviousness of claims 3, 23, and 39

in view of Bessler, Johnson, and Thompson and in view of Bessler, Johnson, and Taylor).

The PTAB also determined that the teachings of the Bailey prior-art reference about the size and shape of the Bessler valve were "inadmissible hearsay." For that reason, and noting that "Patent Owner has not adduced any evidence that Mr. Bailey had any personal knowledge of the functionality of Bessler's barbed valves," the PTAB did not consider Bailey to be persuasive evidence. Appx53.

Finally, the PTAB also found claims 38, 39, and 45 to be anticipated by Bessler (and claim 39 to be obvious in view of the combinations of Bessler and Thompson and Bessler and Taylor), determining that Bessler's disclosure of a valve element attached to a valve cuff, which in turn was attached to the frame, satisfied claim limitations requiring the valve element to be attached to the frame. Appx21-22, Appx25-26.

V. Summary of the Argument

For the reasons set forth in this Court's recent decision in *Arthrex*, the APJs who decided to institute the IPR below, and who issued the final written decision, acted as Principal Officers under the Appointments Clause. Contrary to the Court's decision in *Arthrex*, severance does not remedy this constitutional problem for two reasons. First, in enacting the AIA, Congress intended an IPR regime in

which independent judges would make determinations free of political influence. Second, even with the *Arthrex* severance, APJs still issue final decisions on behalf of the executive branch with no meaningful review by any executive officer who has been appointed by the President and confirmed by the Senate. Accordingly, the decision below should be vacated, and the IPR should be dismissed.

This Appointments Clause problem is even worse in this case because the only officer of the Patent Office who was nominated by the President and confirmed by the Senate, Director Iancu, had to recuse himself from any involvement in the IPR given his past role as lead trial counsel for Petitioner in the patent litigation with Patent Owner.

The PTAB's denial of Patent Owner's motion to dismiss in view of Director Iancu's conflict was also erroneous. The PTAB denied Patent Owner's motion to dismiss because it found that the APJs could act impartially despite the authority of Director Iancu over them. But given this Court's ruling in *Arthrex* that, at least after severance, APJs are sufficiently answerable to their superior officers, that ruling should not stand. The PTAB should have found that the conflict generated by Director Iancu's appointment required dismissal of the IPR.

If the final written decision is not vacated in view of the above issues, it should be vacated or reversed because the PTAB made several fundamental mistakes on the merits. First, the PTAB shifted the burden of proof to Patent

Owner on the issue of obviousness. Second, its anticipation and obviousness determinations in view of the Bessler reference were based on erroneous constructions of the claims of Dr. Snyders' patent, which this Court should reverse. And, finally, on one of those issues, the PTAB disregarded highly probative evidence—the teachings of a prior-art reference relied on by Petitioner—as inadmissible hearsay. That error alone would require the final written decision to be vacated so that proper weight can be given to this non-hearsay evidence.

VI. Standard of Review

When reviewing the Board's decision, the Federal Circuit assesses the Board's compliance with governing legal standards *de novo* and its underlying factual determinations for substantial evidence." *Randall Mfg. v. Rea*, 733 F.3d 1355, 1362 (Fed. Cir. 2013).

VII. Argument

A. APJs Are Unconstitutionally Appointed Principal Officers

This Court should vacate the final written decision below because it violates the Appointments Clause, U.S. Const., art. II, § 2, cl. 2, as a final agency decision requiring members of the PTAB to act as "principal officers" without having been appointed by the President and confirmed by the Senate. *Arthrex, Inc. v. Smith & Nephew, Inc*., 941 F.3d 1320 (Fed. Cir. 2019).

Although Patent Owner agrees with *Arthrex's* finding that PTAB judges are

principal officers not properly appointed by the President and confirmed by the Senate, Patent Owner does not agree that the severance remedy in *Arthrex* resolves the Appointments Clause problem because:

(1) it does not provide for reviewability of final agency decisions; and

(2) the *Arthrex* severance was inconsistent with the intent of Congress that APJs act independently of political influence.

The *Arthrex* remedy of rendering PTAB judges terminable at-will employees is not enough to resolve the Appointments Clause problem because it does not allow for any reviewability of final decisions by PTAB judges. Supreme Court precedent requires some form of executive branch review of final decisions. *Edmond v. United States,* 520 U.S. 651, 664–65 (1997). And just because a PTAB judge can be terminated at-will ***after*** a Final Written Decision does not make ***that*** decision reviewable by a superior officer.

In addition to not resolving the Appointments Clause problem, the *Arthrex* remedy is flawed because it is inconsistent with congressional intent. In *Arthrex*, the court severed the portion of 35 U.S.C. § 3(c) that applies Title 5 to APJs. *Arthrex*, No. 18-2140 at 25. That severance rendered APJs removable at will. *Id*. But severability of a statute turns on whether "the statute will function in a *manner* consistent with the intent of Congress." *Alaska Airlines, Inc. v. Brock*, 480 U.S. 678, 685 (1987) (emphasis in original). *Arthrex's* severance of the portion of § 3(c) that applies Title 5 to APJs is inconsistent with the intent of Congress. In 35

U.S.C. § 3, Congress specified that Title 5 protections applied to some PTAB and PTO personnel, but did not apply to others. This shows that Congress made a deliberate and intentional choice that PTAB judges not be terminable at will employees. So *Arthrex's* severance of the statute to make PTAB judges terminable at will is inconsistent with Congress' intent and thus improper.

Because the decision below was not decided by a properly appointed official, "[a] new 'hearing before a properly appointed' official" is required. *Lucia v. SEC*, 138 S. Ct. 2044, 2055 (2018). But because no properly appointed PTAB panel exists, this Court should vacate and dismiss this case.

B. The PTAB Erred By Not Dismissing Based On Director Iancu's Conflict

The inter partes review statute requires the Director to determine whether to institute an inter partes review. *See* 35 U.S.C. § 314 ("The Director may not authorize an inter partes review to be instituted unless the Director determines that the information presented in the petition…;" "The Director shall determine whether to institute an inter partes review under this chapter…;" "the Director's determination;" "The determination by the Director whether to institute an inter pares review…"). Under PTO regulations, "[t]he Board institutes the trial *on behalf of* the Director." 37 § C.F.R. 42.4(a) (emphasis added).

As the PTAB correctly recognized, Director Iancu was required to recuse from the IPR proceedings below, both from the institution decision and the final

written decision. *See, e.g.,* 5 C.F.R. § 2635.502. Director Iancu's conflict was particularly strong. He was not only an attorney for Petitioner, but he was *lead counsel* for Petitioner in a patent litigation case involving the *same parties*, the *same patents*, the *same claim terms* to be construed, and the *same invalidity arguments* with the *same prior art* references. Moreover, Irell & Manella, the firm where Director Iancu was managing partner for years, continued to represent Petitioner in the litigation even after Director Iancu's recusal.

In view of Director Iancu's conflict, he and anyone acting on his behalf should have been recused from participating in the IPR proceedings below. Even if other Patent Office employees were allowed to perform the role expressly assigned to the Director by 35 U.S.C. § 314, those employees would also have a conflict of interest. Those subordinate employees were subject to a significant risk that their representation of the U.S. Patent and Trademark Office in the IPR proceeding would be limited by their loyalty to their boss, Director Iancu.

The concept that disqualification of an attorney may extend to that attorney's subordinate employees is well established. For example, the American Bar Association's Model Rules of Professional Conduct recognize a conflict where representation of a client is materially limited by an attorney's personal interest. *See* Model Rules of Prof'l Conduct R. 1.7(a)(2) (2016). Those rules also recognize that disqualification of an attorney due to a personal conflict may be imputed to

fellow employees where the employees would be materially limited due to their loyalty to the attorney. *Id*. at R. 1.10 cmt.

The APJs who decided to institute, and who issued the final written decision, were materially limited in their ability to remain impartial given their loyalty to Director Iancu, particularly given his strong positions regarding the validity of the specific patent at issue. As noted above, immediately prior to being sworn in as Director, Mr. Iancu zealously advocated against the validity of the specific patents at issue throughout the litigation. Moreover, Petitioner's arguments in its petition put Director Iancu's *Markman* arguments directly at issue in this proceeding. *See* Appx404-407 [Patent Owner Preliminary Response] (quoting Director Iancu's litigation arguments). The subordinates were thus put in a position of evaluating the import of Director Iancu's words regarding whether a "central portion" must have some "structure," which was a material issue in the IPR proceedings.

Given the extent of Director Iancu's direct involvement in the litigation and the authority that Director Iancu holds over subordinate employees—particularly given the removal of their job protections pursuant to the *Arthrex* severance—the APJs who made the institution decision and final written decision below also had a conflict of interest. Accordingly, the PTAB should have dismissed the IPR below.

C. The PTAB Erred By Shifting The Burden To Patent Owner On Obviousness

It was Petitioner's burden of proof to establish obviousness, including motivation to combine the Bessler and Johnson references. *See, e.g., Magnum Oil Tool's Int'l, Ltd.,* 829 F.3d 1364 (Fed. Cir. 2016). Shifting this burden to Patent Owner is reversible error. *See id.* at 1377-79 (reversing PTAB because it erred in shifting the burden of proof regarding motivation to combine).

The PTAB did not hold Petitioner to its burden, but instead shifted it to Patent Owner. For each finding that a claim was unpatentable based on the combined teachings of Bessler and Johnson (or Bessler and Johnson combined with yet additional prior art), the PTAB did not find any motivation to combine at all. Instead, the PTAB merely summarized the Petitioner's arguments, Appx35-36, and then immediately moved on to consideration of Patent Owner's counter-arguments, Appx36-39. The PTAB then rejected one of Patent Owner's counter-arguments and did so only on the ground that "we see no reason why" Patent Owner's counter-argument was correct. Appx37. That is all. Based solely on that analysis, the PTAB concluded that a person of skill in the art would have been motivated to combine the teachings of Bessler and Johnson as argued by Petitioner. Appx38-39.

The PTAB's shifting of the burden to Patent Owner was a significant error. The only motivation to combine argued by Petitioner (besides purely conclusory

assertions that such combinations were matters of "routine engineering") was that a person of skill would have been motivated to incorporate the valve element of Johnson into Bessler's stent and cuff structure in order to obtain a more durable valve. Appx35. The Board simply did not address this alleged motivation to combine in its final written decision. Moreover, when the same panel of APJs did address it in a co-pending IPR of the same patent, ***they expressly rejected it.*** *See* Appx75-77 [Final Written Decision—Case IPR2018-00109].

D. The PTAB Erred By Determining That Bessler Disclosed A Frame That Was Sized And Shaped As Required By The Claims

Each of the claims found to be unpatentable by the PTAB requires an "an artificial valve for repairing a damaged heart valve having a plurality of cusps separating an upstream region from a downstream region" where the artificial valve has a "flexibly resilient frame sized and shaped for insertion in a position between the upstream region and the downstream region." *See, e.g.,* Appx103 at 19:11-16 [297 Patent].

The PTAB acknowledged that Bessler discloses a valve frame for implantation only after the diseased cusps of the native valve are cut out. Appx23 ("Patent Owner correctly notes that Bessler's valve is implanted after removal of 'the diseased or defective heart valve.'"). But the PTAB concluded that Bessler still met the limitations of the challenged claims because "the preamble does not limit the claim as implied." *Id*. According to the PTAB, the preamble merely

defines the location of upstream regions and downstream regions, thus allowing the claim to "encompass any valve sized and shaped to fit in this location including valves sized and shaped to fit the location after a native heart valve is removed." *Id.*

The PTAB's construction in this regard is not true to the plain meaning of the claim language. The preambles define two regions by reference to their relationship to a damaged heart valve having a plurality of cusps. The claims go on to specify that the frame of the valve must be sized and shaped to be inserted in the position between those two regions, *i.e.,* the region that contains the damaged heart valve having a plurality of cusps. This does not encompass an artificial valve that is sized and shaped for insertion in a larger region after the native cusps have been removed.

The PTAB's construction is also inconsistent with the express teachings of the specification. The specification explains in its Background section that a key problem with the valves proposed for transluminal delivery in the prior art is that "many of these valves also require the damaged native heart valve to be removed prior to implanting the artificial valve." Appx94 at 1:42-44 [297 Patent]. That poses a significant risk of stroke. Appx94 at 1:44-46 ("Removing the native valve increases the risk that a portion of the valve will migrate through the body and block vessels downstream from the heart."). And the specification specifically

distinguishes Bessler because Bessler requires the native cusps to be removed. Appx94 at 2:18-23 ("The Bessler procedure includes excision, vacuum removal of the native valve, cardiopulmonary bypass and backflushing of the coronary arterial tree."). The specification also emphasizes that the artificial valve disclosed by it is implanted without removing the native cusps. *See, e.g.,* Appx94 at 1:25-29 ("SUMMARY OF THE INVENTION: Among the several objects and features of the present invention may be noted the provision of an artificial heart valve which accommodates implantation without removing the damaged native heart valve.").

In view of the plain language of the claims, and these teachings of the specification, the PTAB erred when it concluded that the challenged claims encompassed artificial valves having frames sized and shaped for insertion in a region in which the native cusps have been removed.

E. The PTAB Erred By Disregarding Bailey

Patent Owner relied on the teachings of a prior-art reference, Bailey, regarding the unsuitability of the Bessler valve for implantation between the diseased cusps of the native valve (*i.e.*, that the Bessler valve would not work without first surgically removing the diseased cusps). Appx716 [Patent Owner Sur-Reply]. The PTAB concluded that Bailey was not persuasive evidence because it was inadmissible hearsay, noting that Patent Owner had not "adduced any evidence that Mr. Bailey had any personal knowledge of the functionality of

Bessler's barbed valves." Appx53 [Final Written Decision]. Based on this decision, the PTAB disregarded the teachings of Bailey. *Id.*

The Board erred in determining that Bailey was inadmissible. The point of the obviousness determination is to determine what the prior art teaches to persons of skill in the art. Patent Owner's reliance on Bailey was thus not for a hearsay purpose. *See, e.g. In re Etter*, 756 F.2d 852, 859 (Fed. Cir. 1985) (rejecting argument that a teaching of a prior-art reference, for purposes of determining obviousness, was "mere hearsay"). Nor was it necessary to prove that Mr. Bailey had personal knowledge of the Bessler valve: what mattered was the teachings of Mr. Bailey's patent, which indisputably were part of the relevant prior art.

F. The PTAB Erred By Determining That Bessler Discloses A Valve Element Attached To The Frame

In finding claims 38, 39, and 45 anticipated by Bessler (and obvious in view of certain combinations of Bessler), the PTAB erred by determining that Bessler discloses an artificial valve in which the valve element is attached to the frame.

As the PTAB acknowledged, Bessler discloses a cuff that is attached to the frame, not that the valve leaflets of Bessler (which were what was found by the PTAB to meet the "valve element" limitation) are attached to the frame. Appx21-22. Bessler discloses that the cuff extends from the periphery of the valve leaflets, but it is the cuff that is sutured to the frame, not the valve leaflets. Appx1231 at Fig. 4 & 5:36-42 [Bessler] ("The leaflets 36 are the actual valve and allow for one-

way flow of blood. Extending from the periphery of the leaflet portion is a cuff portion 37. The cuff portion 37 extends adjacent the stent walls 31 in the direction of the arrow A. The cuff portion is attached to the stent by sutures 38.").

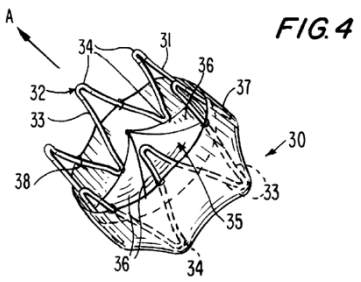


FIG. 4

The PTAB determined that this attachment satisfied the claim limitations because direct attachment was not required. Appx21. The PTAB explicitly construed the claims to not require direct attachment because it viewed the specification as teaching indirect attachment through the band. Appx12-13. But the portions of the specification relied on by the PTAB merely taught that the valve element could be attached both to the frame and to band. Appx97 at Figs. 2, 3; 7:57-66 [297 Patent]. Bessler is very different: the sutures that attach the cuff to the frame in Bessler are not connected to the valve leaflets at all.

The PTAB's construction of claims 38, 39, and 45 is also wrong because it renders the claim limitation essentially meaningless. If the valve leaflets of Bessler qualify as being attached to the frame simply because they are attached to another part of the valve, the valve cuff, which in turn is attached to the frame, then every part of an artificial valve will qualify as being attached to every other part. The requirement of the claims that a specific part of the artificial valve (the valve

element) be attached to another specific part (the frame) should not be construed in that manner.

VIII. Conclusion

For the foregoing reasons, the Court should vacate the final written decision and dismiss the IPR proceeding below.

Dated: December 2, 2019

Respectfully submitted,

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ADDENDUM

TABLE OF CONTENTS

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Paper 55
Entered: May 2, 2019

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ST. JUDE MEDICAL, LLC,
Petitioner,

v.

SNYDERS HEART VALVE LLC,
Patent Owner.

Case IPR2018-00107
Patent 6,821,297 B2

Before PATRICK R. SCANLON, MITCHELL G. WEATHERLY, and JAMES A. WORTH, *Administrative Patent Judges.*[1]

WEATHERLY, *Administrative Patent Judge*.

FINAL WRITTEN DECISION
35 U.S.C. § 318(a), 37 C.F.R. § 42.73

I. INTRODUCTION

A. BACKGROUND

St. Jude Medical, LLC ("Petitioner") filed a petition (Paper 3, "Pet.") to institute an *inter partes* review of claims 1–3, 8, 9, 22, 23, 31–35, 37–39, and 45 (the "challenged claims") of U.S. Patent No. 6,821,297 B2 (Ex. 1001,

[1] Director Andrei Iancu has taken no part in this Decision due to recusal.

"the '297 patent"). 35 U.S.C. § 311. Petitioner supported the Petition with a Declaration from Lakshmi Prasad Dasi, Ph.D. (Ex. 1003). Snyders Heart Valve LLC ("Patent Owner") timely filed a Preliminary Response. Paper 10 ("Prelim. Resp."). On May 3, 2018, based on the record before us at the time, we instituted an *inter partes* review of all challenged claims. Paper 16 ("Institution Decision" or "Dec."). The challenges to the claims are:

References	Basis	Claims challenged
U.S. Patent No. 5,855,601 (Ex. 1008, "Bessler")	§ 102	1–3, 8, 9, 22, 23, 31–35, 37–39, and 45
U.S. Patent No. 5,957,949 (Ex. 1017, "Leonhardt")	§ 102	1–3, 8, 9, 22, 23, 31–35, 37–39, and 45
Bessler	§ 103	1–3, 8, 9, 22, 23, 31–35, 37–39, and 45
Leonhardt	§ 103	1–3, 8, 9, 22, 23, 31–35, 37–39, and 45
Bessler and U.S. Patent No. 6,623,518 B2 (Ex. 1053, "Thompson")	§ 103	3, 23, and 29
Bessler and International Patent Pub. No. WO 1997/016133 A1 (Ex. 1054, "Taylor")	§ 103	3, 23, and 29
Bessler and U.S. Patent No. 4,339,831 (Ex. 1021, "Johnson")	§ 103	1–3, 8, 9, 22, 23, 31–35, 37–39, and 45
Bessler, Johnson, and Thompson	§ 103	3, 23, and 39
Bessler, Johnson, and Taylor	§ 103	3, 23, and 39

After we instituted this review, Patent Owner filed a Patent Owner Response in opposition to the Petition (Paper 30, "PO Resp.") that was supported by a Declaration from Dr. Nicholas Chronos (Ex. 2026).

Petitioner filed a Reply in response to the Patent Owner's Response (Paper 38, "Reply"). With our prior authorization, Patent Owner filed a Surreply in response to the Reply (Paper 40, "Surreply"). Patent Owner did not move to amend any claim of the '297 patent.

With our prior authorization, Petitioner filed a motion to strike portions of the Surreply (Paper 45 "Motion"), and Patent Owner filed an opposition to the Motion (Paper 47 "Opp." or "Opposition").

We heard oral argument on January 30, 2019. A transcript of the argument has been entered in the record (Paper 54, "Tr.").

We have jurisdiction under 35 U.S.C. § 6. The evidentiary standard is a preponderance of the evidence. *See* 35 U.S.C. § 316(e); 37 C.F.R. § 42.1(d). This Final Written Decision is issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73.

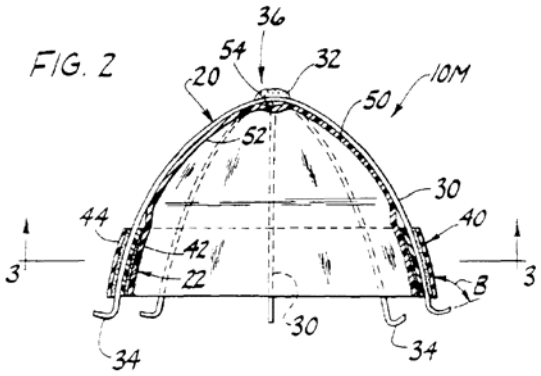
For the reasons expressed below, we conclude that Petitioner has demonstrated by a preponderance of evidence that all challenged claims are unpatentable, but not for every challenge. We provide our analysis of every challenge to claims below.

B. RELATED PROCEEDINGS

The parties identified as a related proceeding the co-pending district court proceeding of *Snyders Heart Valve LLC v. St. Jude Medical SC, Inc., et al*, Case Number 4:16-cv-00812 (E.D. Tex.). Pet. 1; Paper 5, 2. Patent Owner also identified *Snyders Heart Valve LLC v. Medtronic, Inc. et al*, 4:16-cv-00813 (E.D. Tex.). Paper 5, 2. Petitioner identified three petitions for *inter partes* review filed in IPR2018-00105, -00106, and -00109 as being related. *See* Pet. 1 (identifying these proceedings using Petitioner's docket numbers).

C. THE '297 PATENT

The '297 patent, titled "Artificial Heart Valve, Implantation Instrument and Method Therefor," issued November 23, 2004, with claims 1–46. Ex. 1001, (54), (45), 19:11–24:65. The '297 patent is directed to "artificial heart valves for repairing damaged heart valves." *Id.* at 1:15–16. Figures 2 and 3 of the '297 patent are reproduced below.



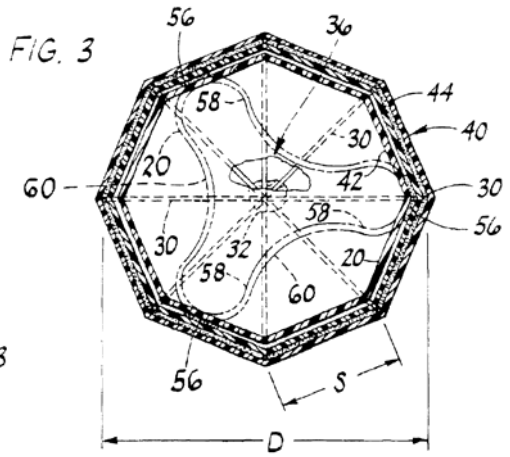


Figure 2 depicts "a vertical cross section of an artificial valve," and Figure 3 depicts "a cross section of the valve taken in the plane of line 3–3 of FIG. 2." *Id.* at 4:11–13. Artificial valve 10M shown in Figures 2 and 3 "is specifically configured for repairing a damaged mitral valve," although the '297 patent also discloses an artificial valve configured to repair a damaged pulmonary heart valve. *Id.* at 4:33–5:5.

Artificial valve 10M comprises flexibly resilient external frame 20 and flexible valve element 22. *Id.* at 5:17–19. Frame 20 includes U-shaped stenting elements 30 that are joined together generally midway between their respective ends at junction 32. *Id.* at 5:25–30. U-shaped elements 30 are sufficiently compressible to allow valve 10M to be compressed into a configuration for implantation and sufficiently resilient to hold valve 10M in position between the cusps of a native heart valve after implantation while

holding the cusps open. *Id.* at 5:30–38. Peripheral anchors 34 are formed at each end of the U-shaped elements to attach frame 20 in position between an upstream region and a downstream region. *Id.* at 5:58–62. Frame 20 further includes central portion 36 located between peripheral anchors 34. *Id.* at 6:4–7.

Artificial valve 10M also comprises band 40 that extends around frame 20 between U-shaped frame elements 30 to limit maximum spacing between the frame elements, but permit the frame elements to be pushed together so flexibly resilient frame 20 can be collapsed to a collapsed configuration. *Id.* at 6:8–17. Band 40 preferably includes internal strip 42 and external strip 44 joined in face-to-face relation. *Id.* at 6:52–56.

Flexible valve element 22 is attached to central portion 36 of frame 20 and has convex upstream side 50 facing an upstream region and concave downstream side 52 facing a downstream region. *Id.* at 7:7–18. With this arrangement, "valve element 22 moves in response to differences between fluid pressure in the upstream region and the downstream region between an open position (as shown in phantom lines in FIG. 3) and a closed position (as shown in solid lines in FIG. 3)." *Id.* at 7:17–22. Flexible valve element 22 permits flow between the upstream and downstream regions when in its open position and blocks flow between the upstream and downstream regions when in its closed position. *Id.* at 7:22–27.

More specifically, apex 54 of upstream side 50 is attached to junction 32 of frame 20. *Id.* at 7:55–57. As shown in Figure 3, flexible valve element 22 also is attached to band 40 at several attachment points 56, such that flexible valve element 22 defines flaps 58 between adjacent attachment points 56. *Id.* at 7:57–8:1. Flaps 58 and corresponding portions

of band 40 define openings 60 when valve element 22 moves to its open position. *Id.* at 8:1–5.

Figure 4 of the '297 patent is reproduced below.

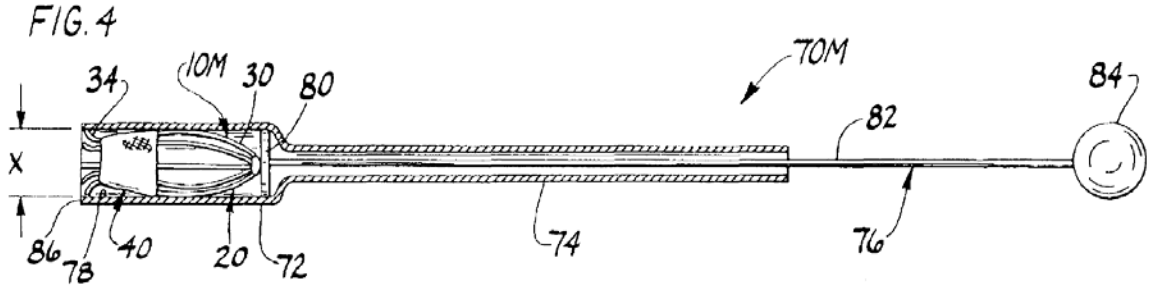


Figure 4 depicts "a vertical cross section of an instrument for implanting a valve using an endothoracoscopic procedure." *Id.* at 4:14–16. The instrument of Figure 4 includes tubular holder 72 and elongate tubular manipulator 74 attached to the holder for manipulating the holder into position. *Id.* at 8:28–31. The instrument further includes ejector 76 that is positioned in the hollow interior of holder 72 for ejecting an artificial heart valve from the holder. *Id.* at 8:31–34.

Claims 1, 22, 31, and 38 are the independent claims among the challenged claims. *Id.* at 19:11–52 (claim 1), 21:54–22:25 (claim 22), 22:57–23:33 (claim 31), 23:56–24:45 (claim 38). Claim 1, which is representative, recites:

> 1. An artificial valve for repairing a damaged heart valve having a plurality of cusps separating an upstream region from a downstream region, said artificial valve comprising:
>
> a flexibly resilient frame sized and shaped for insertion in a position between the upstream region and the downstream region, the frame having
>
> a plurality of peripheral anchors for anchoring the frame in the position between the upstream region and the downstream region and

a central portion located along a centerline extending between the plurality of peripheral anchors and between the upstream region and the downstream region when said frame is inserted in the position between the upstream region and the downstream region;

a flexible valve element attached to the central portion of the frame having

an upstream side facing said upstream region when the frame is anchored in the position between the upstream region and the downstream region and

a downstream side opposite the upstream side facing said downstream region when the frame is anchored in the position between the upstream region and the downstream region,

said flexible valve element moving in response to a difference between fluid pressure in said upstream region and fluid pressure in said downstream region between

an open position in which the flexible valve element permits downstream flow between said upstream region and said downstream region and

a closed position in which the flexible valve element blocks flow reversal from said downstream region to said upstream region,

wherein the flexible valve element moves to the open position when fluid pressure in said upstream region is greater than fluid pressure in said downstream region to permit downstream flow from said upstream region to said downstream region and

the flexible valve element moves to the closed position when fluid pressure in said downstream region is greater than fluid pressure in said upstream region to prevent flow reversal from said downstream region to said upstream region; and

an opening extending through at least one of said frame and said flexible valve element for receiving an implement.

Id. at 19:11–52 (with line breaks added for clarity).

II. ANALYSIS

A. LEGAL STANDARDS

Petitioner challenges the patentability of claims 1–3, 8, 9, 22, 23, 31–35, 37–39, and 45 on the grounds that the claims are either anticipated or obvious in light of various references including: Bessler, Leonhardt, Thompson, Taylor, and Johnson. To prevail in its challenges to the patentability of the claims, Petitioner must establish facts supporting its challenges by a preponderance of the evidence. 35 U.S.C. § 316(e); 37 C.F.R. § 42.1(d). "In an [*inter partes* review], the petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable." *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016) (citing 35 U.S.C. § 312(a)(3) (requiring *inter partes* review petitions to identify "with particularity . . . the evidence that supports the grounds for the challenge to each claim")). This burden remains with Petitioner during the trial. *See Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015) (citing *Tech. Licensing Corp. v. Videotek, Inc.*, 545 F.3d 1316, 1326–27 (Fed. Cir. 2008)) (discussing the burden of proof in *inter partes* review).

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros., Inc. v. Union Oil Co. of Cal.*, 814 F.2d 628, 631 (Fed. Cir. 1987). The Supreme Court in *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398 (2007), reaffirmed the framework for determining obviousness as set forth in *Graham v. John Deere Co.*, 383

U.S. 1 (1966). The *KSR* Court summarized the four factual inquiries set forth in *Graham* that we apply in determining whether a claim is unpatentable as obvious under 35 U.S.C. § 103(a) as follows:
(1) determining the scope and content of the prior art, (2) ascertaining the differences between the prior art and the claims at issue, (3) resolving the level of ordinary skill in the pertinent art, and (4) considering objective evidence indicating obviousness or nonobviousness. *KSR*, 550 U.S. at 406 (citing *Graham*, 383 U.S. at 17–18). In an *inter partes* review, Petitioner cannot satisfy its burden of proving obviousness by employing "mere conclusory statements." *In re Magnum Oil Tools Int'l, Ltd.*, 829 F. 3d 1364, 1380 (Fed. Cir. 2016). Thus, to prevail Petitioner must explain how the proposed combinations of prior art would have rendered the challenged claims unpatentable. With these standards in mind, we address each challenge below.

B. LEVEL OF ORDINARY SKILL

Petitioner contends that a person having ordinary skill in the art to which the '297 patent pertains "is a medical doctor or has an advanced degree (at least a master's degree) in a relevant engineering discipline with several years of experience or someone who holds a lesser degree with more experience in the field of artificial heart valves." Pet. 15 (citing Ex. 1001; Ex. 1006; Ex. 1008; Ex. 1009; Ex. 1010; Ex. 1020; Ex. 1003, ¶¶ 15–17). Patent Owner neither disputes this contention in its Response, or Surreply, nor proffer its own definition of the level of ordinary skill in the art.

Factual indicators of the level of ordinary skill in the art include "the various prior art approaches employed, the types of problems encountered in the art, the rapidity with which innovations are made, the sophistication of

the technology involved, and the educational background of those actively working in the field." *Jacobson Bros., Inc. v. U.S.*, 512 F.2d 1065, 1071 (Ct. Cl. 1975); *see also Orthopedic Equip. Co. v. U.S.*, 702 F.2d 1005, 1011 (Fed. Cir. 1983) (quoting with approval *Jacobson Bros.*). We find, based on our review of the record before us, that Petitioner's stated level of ordinary skill in the art is reasonable because it is consistent with the record, including the asserted prior art and, for the purposes of this Final Written Decision, we adopt Petitioner's definition.

C. THE PARTIES' POST-INSTITUTION ARGUMENTS

In our Institution Decision, we concluded that the argument and evidence adduced by Petitioner demonstrated a reasonable likelihood that at least one claim was unpatentable as anticipated by Leonhardt, and we instituted trial on all challenges identified in the table in Part I.A above. Dec. 15. We must now determine whether Petitioner has established by a preponderance of the evidence that the specified claims are unpatentable over the cited prior art. 35 U.S.C. § 316(e). We previously instructed Patent Owner that "any arguments for patentability not raised in the [Patent Owner Response] will be deemed waived." Paper 17, 7; *see also In re Nuvasive, Inc.*, 842 F.3d 1376, 1381 (Fed. Cir. 2016) (holding that patent owner's failure to proffer argument at trial as instructed in scheduling order constitutes waiver). Additionally, the Board's Trial Practice Guide states that the Patent Owner Response "should identify all the involved claims that are believed to be patentable and state the basis for that belief." Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,766 (Aug. 14, 2012).

D. CLAIM INTERPRETATION

"A claim in an unexpired patent that will not expire before a final written decision is issued shall be given its broadest reasonable construction in light of the specification of the patent in which it appears." 37 C.F.R. § 42.100(b) (2018); *see also Cuozzo Speed Techs., LLC v. Lee*, 136 S.Ct. 2131, 2144–46 (2016) (affirming that USPTO has statutory authority to construe claims according to Rule 42.100(b)). When applying that standard, we interpret the claim language as it would be understood by one of ordinary skill in the art in light of the specification, and absent any special definition, we give claim terms their ordinary and customary meaning. *See In re Suitco Surface, Inc.*, 603 F.3d 1255, 1260 (Fed. Cir. 2010); *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007) ("The ordinary and customary meaning is the meaning that the term would have to a person of ordinary skill in the art in question." (internal quotation marks omitted)). Only terms that are in controversy need to be construed, and then only to the extent necessary to resolve the controversy. *See Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999).

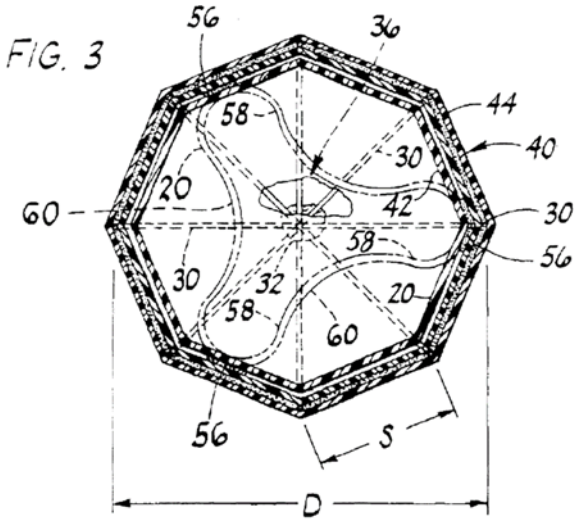
We consider it necessary to construe the terms below to resolve issues presented by the parties during the trial.

1. Claims 1, 22, 31, and 38: "attached to"

Independent claims 1, 22, 31, and 38 require that the "flexible valve element" is "attached to" a frame in various ways. Ex. 1001, 19:25 (claim 1), 21:64 (claim 22), 23:3–4 (claim 31), 24:3 (claim 38). Patent Owner argues that "attached to" as recited in each claim means "directly attached to" and excludes securing the valve element to a frame indirectly through an intervening structure. PO Resp. 7. We disagree.

Patent Owner correctly notes that the Specification "contemplates direct attachment" of the flexible valve element to the frame. *Id*. at 8. However, the portion of the Specification on which Patent Owner relies also describes indirectly attaching the flexible valve element to a frame by securing it to a band that is directly attached to the frame. Ex. 1001, 7:55–66. This type of indirect attachment is illustrated in Figure 3, reproduced below right. The Specification describes Figure 3 as follows:

> As illustrated in FIG. 3, the flexible valve element 22 is attached to the central portion 36 of the frame 20 at a position substantially centered between the anchors 34. Although the valve element 22 may be attached to the frame 20 by other means without departing from the scope of the present invention, the valve element of the preferred embodiment is attached to the frame by adhesive bonding. *Further, the flexible valve element 22 is attached to the frame 20, and more particularly to the band 40, at several attachment points 56 around the frame*.



Id. at 7:57–66 (emphasis added). This passage indicates that the flexible valve element is attached to the frame in two ways: (1) directly by being bonded to the central portion 36 of frame 20 and (2) indirectly by being attached to band 40 at attachment points 56. The Specification later expresses a preference for bonding valve element 22 to band 40 with adhesive. *Id*. at 8:11–14. Interpreting "attached to" to mean "directly attached to" as suggested by Patent Owner would be inconsistent with the Specification's broader description of how valve element 22 is attached to frame 20.

We interpret claim language "in light of the specification of the patent in which it appears." 37 C.F.R. § 42.100(b) (2018). Doing so requires us to interpret claim language in a manner that "corresponds with what and how the inventor describes his invention in the specification." *In re Smith Int'l, Inc*., 871 F.3d 1375, 1383 (Fed. Cir. 2017). The inventor describes both direct and indirect methods of attaching the flexible valve element to the frame. Accordingly, we interpret "attached to" as encompassing both direct and indirect ways of attaching the flexible valve element to the frame.

2. Claims 1, 31, and 38: "central portion of the frame"

Each of claims 1, 31, and 38 recites a relationship between the flexible valve element and the "central portion of the frame." Patent Owner argues that "central portion of the frame" means "central structural frame portion," which cannot refer solely to an "empty space." PO Resp. 3–7. Patent Owner explains that, during the related litigation, Petitioner agreed that the central portion of the frame must "actually be part of the structure of the frame." *Id*. at 6 (quoting Ex. 2001, 119–20). Accordingly, we discern no dispute on the issue of whether "central portion of the frame" refers to a structural portion of the frame; it does.

3. Claim 22: "flexible valve element . . . having a convex upstream side . . . and a concave downstream side"

Claim 22 recites a "flexible valve element . . . having a convex upstream side . . . and a concave downstream side." Ex. 1001, 21:64–22:3. The District Court declined to adopt an express construction for these terms and construed them to have their plain meaning. Ex. 2002, 63–64.

Petitioner argues that "convex upstream side" means "an upstream side that bulges out in the upstream direction," and "concave downstream side" means "a downstream side that bulges away from the downstream

side." Pet. 19. Petitioner neither analyzes nor cites evidence from the Specification or prosecution history of the '297 patent in support of its position. *Id*. (citing Ex. 1040, 4; Ex. 1041, 36–37).

Patent Owner argues that Leonhardt fails to describe the convex and concave sides of the flexible valve element without providing its own interpretation of these phrases. PO Resp. 26–28. To resolve that dispute and compare the claims to other prior art including Bessler and Johnson, we address the meaning of the phrases below.

The phrase "convex upstream side" plainly limits the "side" of the flexible valve element to a side that both faces "upstream" and exhibits a "convex" shape. Similarly, "concave downstream side" refers to a "side" that faces "downstream" and exhibits a "concave" shape. A plain reading of the phrases also indicates that the entire sides, not just a portion, are "convex" or "concave." Claim 22 recites "a flexible valve element fixedly attached to the frame so that *at least a portion of the element* is substantially immobile with respect to *at least a portion of the frame*." Ex. 1001, 21:64–66 (emphasis added). Thus, when only a portion of the flexible valve element must exhibit a characteristic, the claim expressly refers to a "portion" of the valve element.

The Specification supports a plain reading of "convex upstream side" and "concave downstream side" as referring to characteristics of the sides as a whole rather than only a portion of each side. Claims should be interpreted in a manner that "corresponds with what and how the inventor describes his invention in the specification." *In re Smith*, 871 F.3d at 1383. The Specification only describes flexible valve elements in which the entire side of the valve element is either convex or concave as follows.

> The valve element 22 has a *convex upstream side 50 facing an upstream region (e.g., the left atrium LA)* when the frame 20 is anchored between the cusps C of the damaged heart valve (e.g., mitral valve M) in a position between the upstream region and a downstream region; and *a concave downstream side 52 opposite the upstream side facing the downstream region (e.g., the left ventricle LV)* when the frame 20 is anchored between the cusps of the damaged heart valve in a position between the upstream region and the downstream region.

Ex. 1001, 7:8–18 (emphasis added). Figure 2 and the pertinent portion of Figure 1, which are reproduced below left and right respectively, illustrate convex upstream side 50 and concave downstream side 52.

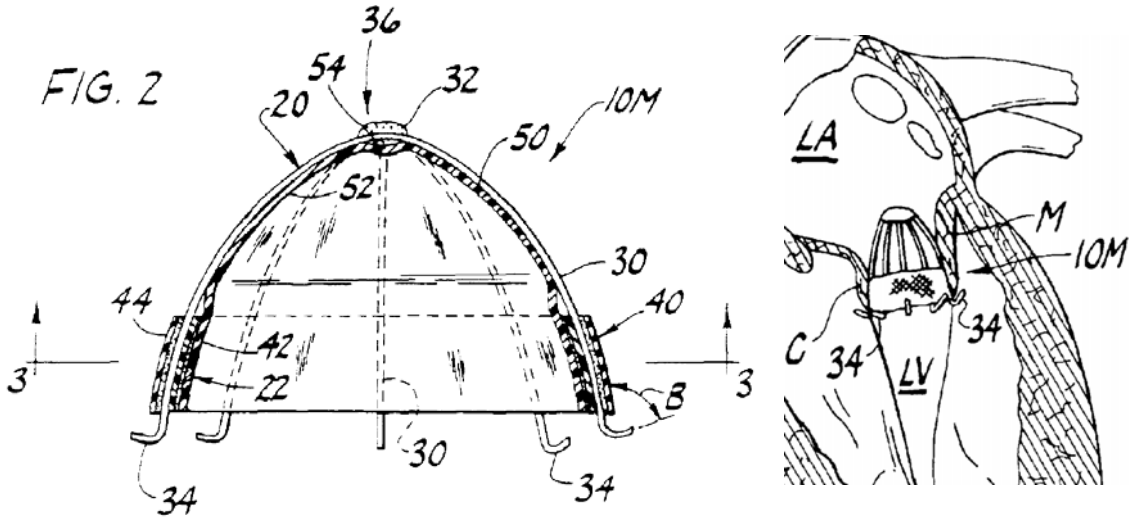
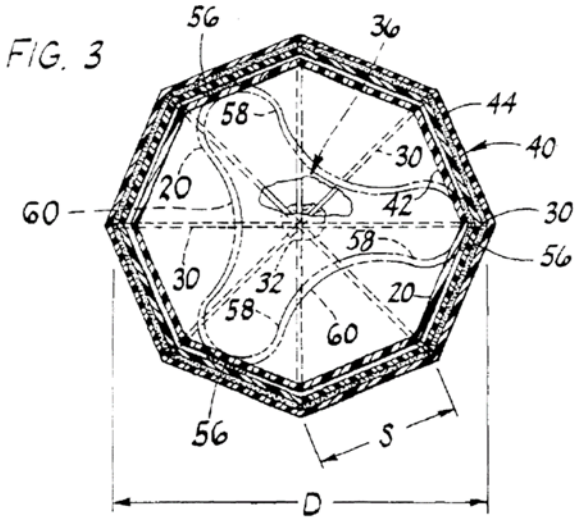


Figure 2, reproduced above left, is a cross-sectional view of valve 10M illustrating convex upstream side 50 and concave downstream side 52 of flexible valve element 22. *Id*. at 4:11. The portion of Figure 1 that is reproduced above right illustrates valve 10M placed with its concave side facing the left ventricle LV (i.e., the downstream region) and the convex side facing the left atrium LA (i.e., the upstream region). *Id*. at 4:9–10, 7:8–18.



The entirety of upstream side 50 is convex and the entirety of downstream side 52 is concave when valve element 22 is "extended outward" in the "closed position" as shown in the solid-line depiction of valve element 22 in Figures 2 (above) and 3 (reproduced at right). *Id*. at 7:18–36. Figure 3 illustrates an open valve element 22 in phantom lines such that valve element 22 is "collapsed inward" with openings 60 to permit blood flow that are defined by flaps 58 between adjacent attachment points 56. *Id*. at 7:64–8:5.[2] The Specification, therefore, describes only a valve having a "convex upstream side" and a "concave downstream side" in which the "convex" or "concave" shape of the "side" refers to the overall shape of the entire respective side when the valve is closed.

During the hearing, Patent Owner was asked to identify any evidence of record from the Specification or prosecution history that weighed against interpreting "convex" and "concave" as referring to the overall shapes of the opposing sides of the claimed flexible valve element in their entirety, and Patent Owner identified none. Tr. 72:16–79:11.

Based on the plain meaning of "convex upstream side" and "concave downstream side" and the description of the invention in the Specification,

[2] The Specification describes another embodiment of the flexible valve element 222 having convex upstream side 250 and concave downstream side 252 that is configured materially the same way as flexible valve element 22. *Id*. at 10:13–29, Figures 8, 9.

we conclude that the overall shape of the entire "upstream side" of the flexible valve element is convex, and the overall shape of the entire "downstream side" of the flexible valve element is concave.

E. CLAIMS 1–3, 8, 9, 22, 23, 31–35, 37–39, AND 45: ANTICIPATION BY BESSLER

Petitioner contends that Bessler anticipates claims 1–3, 8, 9, 22, 23, 31–35, 37–39, and 45. Pet. 19–36. For the reasons expressed below, we conclude that Petitioner has proven by a preponderance of evidence that Bessler anticipates claims 38, 39, and 45, but has failed to do so for claims 1–3, 8, 9, 22, 23, 31–35, and 37.

1. Overview of Bessler

Bessler "relates to novel heart valves that are especially adapted for placement using minimally invasive surgical techniques and to the method and device useful for such placement." Ex. 1008, 1:8–11. Bessler's Figure 4, reproduced at right, depicts artificial heart valve 30 having a generally cylindrical shape defined by stent member 32. *Id.* at 5:28–31. Stent member 32 is a wire formed into a closed zig-zag configuration having straight sections 33 joined by bends 34. *Id.* at 5:31–34. Flexible valve member 35 extends across the cylindrical stent and includes a plurality of leaflets 36. *Id.* at 5:34–37. Leaflets 36 "are the actual valve and allow for one-way flow of blood." *Id.* at 5:37–38. Cuff portion 37 extends from the periphery of the leaflet portion and along walls 31 of stent member 32 and is attached to the stent member by sutures 38. *Id.*

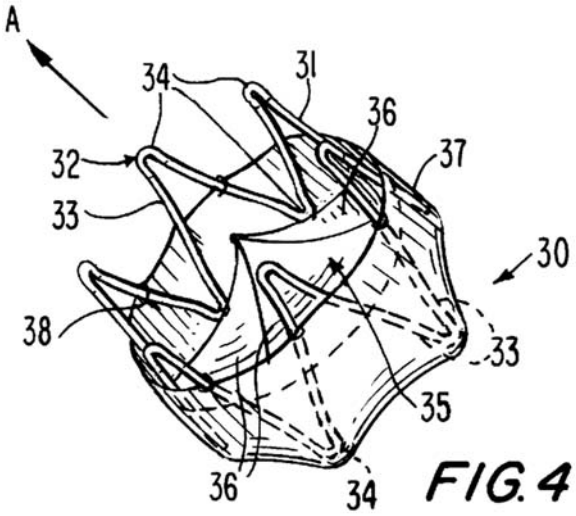


FIG. 4

at 5:38–42. In another embodiment, the stent member includes a plurality of barbs 64 for holding the valve in place. *Id.* at 5:67–6:2, Fig. 7.

The configuration and flexible, resilient material of construction of stent member 32 allows the valve to collapse into relatively small cylinder 40. *Id.* at 5:43–45, Fig. 5. Bessler also discloses device 90 including flexible catheter 91 for percutaneous and transluminal delivery of a heart valve to the desired site. *Id.* at 7:26–30, Figs. 12, 13. Device 90 includes hollow pusher member 93 disposed within catheter 91 and guidewire 94 disposed within pusher member 93 to guide the distal end of the catheter to the desired site. *Id.* at 7:33–38. Means 96 disposed with pusher member 93 holds a collapsed valve in the distal end of catheter 91 and allows the valve to be released when desired. *Id.* at 7:38–40.

2. Petitioner's Argument and Evidence

Petitioner contends that Bessler anticipates each of claims 1–3, 8, 9, 22, 23, 31–35, 37–39, and 45 and identifies specific portions of Bessler that describe each element of the artificial valve of those claims. Pet. 30–37 (citing Ex. 1008, 2:57–63, 3:46–4:21, 4:60–5:14, 5:19–6:31, 7:26–67, 9:59–61, FIGS. 1–7, 12–15). Petitioner also relies on Dr. Dasi's testimony to support its contentions. *Id*. (citing Ex. 1003 ¶¶ 59–88).

3. Analysis of Patent Owner's Counterarguments

Each of independent claims 1, 22, 31, and 38 recite materially differing versions of an artificial valve. Patent Owner argues that Bessler fails to anticipate each independent claim and proffers distinct arguments for patentability of dependent claims 3, 9, 23, and 39. For the reasons expressed below, we find that Patent Owner's arguments are persuasive for claims 1, 22, and 31, and thus also for their respective dependent claims 2, 3, 8, 9, 22,

23, 31–35, 37. However, we also determine that Petitioner has demonstrated by a preponderance of evidence that Bessler anticipates claims 38, 39, and 45.

a) Claims 1–3, 8, 9, 31–35, and 37

Patent Owner argues that Bessler does not anticipate independent claims 1 and 31 because Bessler's flexible valve member is not directly attached to a central portion of its frame. PO Resp. 14; Surreply 1–2. For claims 1 and 31, the central portion of the frame is "located *along a centerline* extending between the plurality of peripheral anchors." Ex. 1001, 19:19–20 (claim 1), 22:67–23:2 (claim 31) (emphasis added).

Petitioner contends that Bessler describes various embodiments in which the valve is attached to a central portion of the frame. Pet. 29–30 (citing Ex. 1008, 3:54–4:3, 5:20–28, 5:35–43, 5:60–6:2, 6:19–31, FIGS. 1–4, 7) For example, Bessler's valve 35 includes cuff portion 37 that wraps around periphery of walls 31, extends in direction A, and is attached to stent 32 via sutures 38. Ex. 1008, 5:28–43. This arrangement is illustrated in Figure 4, which we reproduce at right. Leaflets 36, when closed as shown in Figure 4, form a valve that prevents flow opposing direction A. *Id*. at 5:37–38. Petitioner identifies the "central portion" of stent 32 as the "straight sections 33." Pet. 21.

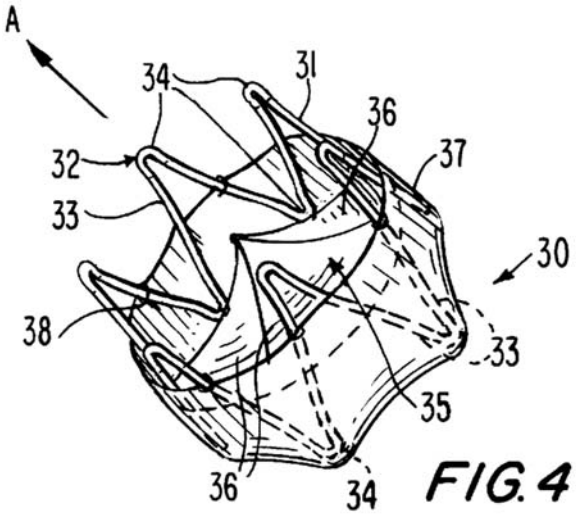


FIG. 4

Petitioner's argument that Bessler's valve is attached to the central part of the frame of claims 1 and 31 fails. Bessler's valve is undeniably

attached to its frame because the cuff portion of the valve is sutured to its stent. Claims 1 and 31 require the valve element to be attached to a portion of the frame located along the radial centerline. Ex. 1001, 19:19–20 (claim 1), 22:67–23:2 (claim 31). Bessler's valves fail to meet this requirement. Bessler's stent 32 is a hollow cylinder devoid of structure located along its centerline,[3] and the "central portion of the frame" identified by Petitioner, straight sections 33, is part of walls 31 located on the radial periphery of stent 32. *Id*. at 5:28–43, Figure 4. Regardless of how Bessler's valve is attached to the wall of its stent, the valve is not attached to structure "located along a centerline" as recited in claims 1 and 31. Therefore, we determine that Petitioner fails to establish by a preponderance of evidence that Bessler anticipates claims 1 and 31 or their respective dependent claims 2, 3, 8, 9, 32–35, and 37.

b) Claims 22 and 23

Independent claim 22 requires the flexible valve to include a "convex upstream side" and a "concave downstream side." Ex. 1001, 21:64–22:3. As explained in Part II.D.3 above, we conclude that the overall shape of the entire "upstream side" of the flexible valve element is convex, and the overall shape of the entire "downstream side" of the flexible valve element is concave.

Petitioner contends that Bessler's valve 35 includes a "convex upstream side" and a "concave downstream side" formed by the plurality of leaflets 36. Pet. 23–24, 42 (citing Ex. 1008, 3:54–64, 5:20–27, 5:36–42, 6:19–24; Ex. 1003 ¶ 72). Dr. Dasi testifies that Bessler's valve exhibits a

[3] Bessler's stents 21, 50, 60 are the same as stent 32 in this respect. Ex. 1008, Figures 1, 6, 7.

complex shape in which individual portions bulge in the upstream direction. *Id*. ¶ 72.

Bessler fails to describe a valve element having opposing convex and concave sides because Bessler's valve does include any side in which the entire side exhibits a convex or concave shape. Accordingly, we determine that Petitioner has failed to prove by a preponderance of evidence that Bessler anticipates claim 22 or its dependent claim 23.

c) Claims 38, 39, and 45

(1) Independent Claim 38

(a) Flexible Valve Element Attached to Central Portion of the Frame

Patent Owner groups claim 38 with claims 1 and 31 when arguing that Bessler fails to describe a valve element directly attached to the frame. PO Resp. 14. Patent Owner argues that, although Bessler's cuff is directly attached to its stent, Bessler's valve leaflets are not directly attached to the frame. *Id*. This argument is unpersuasive because, as explained in Part II.D.1 above, we do not interpret claim 38 to require "direct attachment" of the valve to the frame.

Independent claim 38 recites a frame having "a central portion located between the plurality of peripheral anchors" without further requiring the central portion being "located along a centerline" as recited in claims 1 and 31. Ex. 1001, 24:1–2. Accordingly, the "central portion" of the frame of claim 38 may refer to any portion of the frame that is "between the plurality of peripheral anchors," including a portion that is longitudinally centered.

Cuff portion 37 of Bessler's valve element 35 is attached to stent 32 by sutures 38. Ex. 1008, 5:28–43, Figure 4. Sutures 38 are located close to

the longitudinal center of straight portions 33. *Id*. at Figure 4. The cuff portion 25 of Bessler's valve 22 is similarly attached via sutures 26. *Id*. at Figure 1. A similar arrangement is illustrated in Bessler's valve 63 which is shown with its cuff attached to the walls of the stent near the tops of sections 61 near the longitudinal center of sections 62. *Id*. at Figure 7. Accordingly, Bessler describes attaching its valve to a "central portion" of the frame.

Bessler's longitudinally "central portion" is also located "between the plurality of peripheral anchors." Bessler's Figure 4 illustrates bends 34 in one embodiment and barbs 64 in another that anchor the stent in place once it has been appropriately positioned. *Id*. at 5:28–6:2, Figures 4, 7; Ex. 1003 ¶¶ 63–64. In this way, Bessler "anchors" its stent using a "plurality of peripheral anchors" as recited in claim 38. Bessler's longitudinally centered portion of its stents is located between these "peripheral anchors." For all these reasons, we determine that Bessler's valves are "attached to the central portion of the frame," which is "located between the plurality of peripheral anchors."

(b) Sized and Shaped for Insertion

Claim 38 recites that its "artificial valve" includes a "frame sized and shaped for insertion between the upstream region and the downstream region." Ex. 1001, 23:63–66. The preamble recites that the artificial valve of the claimed combination is "for repairing a damaged heart valve having a plurality of cusps separating an upstream region from a downstream region." *Id*. at 23:57–61.

Patent Owner argues that Bessler fails to describe a valve that is "sized and shaped for insertion between the upstream region and the

downstream region" because Bessler requires removal of the native heart valve prior to insertion of its replacement valve. PO Resp. 14–16. Patent Owner correctly notes that Bessler's valve is implanted after removal of "the diseased or defective heart valve." Ex. 1008, 2:63–65. Patent Owner further explains that when the native heart valve is removed, it is no longer a "damaged heart valve having a plurality of cusps" as recited in the preamble of claim 38. *Id*. at 16.

Patent Owner's argument is unpersuasive because the preamble does not limit the claim as implied. First, the preamble of claim 38 recites the "damaged heart valve" as a mechanism for defining the locations of the upstream and downstream regions. However, those regions remain in the same locations regardless of whether a surgeon has removed the cusps of the damaged heart valve. By reciting that the valve includes a "frame sized and shaped for insertion between the upstream region and the downstream region," the claim merely recites a frame that fits in a location between those two regions. That location remains the same regardless of whether the cusps of the native valve are present. Second, claim 38 is directed to a combination of an artificial valve and an instrument, not a method of implanting an artificial valve without removing the native valve. The claim refers to the cusps of the native valve only to identify the location separating the upstream and downstream regions without commenting upon whether the cusps remain in place when the claimed valve is implanted. Accordingly, the claim may encompass any valve sized and shaped to fit in this location including valves sized and shaped to fit the location after a native heart valve is removed.

Patent Owner also argues that Bessler's barbed embodiment would malfunction if implanted on top of damaged cusps of a native heart valve. Surreply 3 (citing Ex. 1024, 3:48–4:4). Patent Owner cites a patent of another inventor, Bailey, to support its argument. *Id*. Patent Owner's argument is unpersuasive. First, the cited portion of Bailey says nothing about whether Bessler's non-barbed embodiments, which Petitioner also contends to anticipate claim 38, would "malfunction" if implanted without removing an existing native heart valve. Ex. 1024, 3:48–4:4. Second, we have no evidence in the record on whether Bailey is an authoritative source of information for whether any embodiment of Bessler would "malfunction" under any circumstances. Third, the claim encompasses valves sized and shaped for insertion in a location where the native valve has been removed.

For all these reasons, we determine that Petitioner has proven by a preponderance of evidence that Bessler describes a valve with a frame that is "sized and shaped for insertion between the upstream region and the downstream region."

(c) Remaining Elements of Claim 38

We determine that Petitioner has proven by a preponderance of evidence that Bessler describes all remaining elements of claim 38. Our determination is based on Petitioner's argument and evidence, which we adopt as our own. Pet. 23–24, 42 (citing Ex. 1008, 3:54–64, 5:20–27, 5:36–42, 6:19–24; Ex. 1003 ¶ 72).

(d) Conclusion

For the foregoing reasons, we determine that Petitioner has proven by a preponderance of evidence that Bessler anticipates independent claim 38.

(2) Dependent Claim 39

Claim 39 depends from claim 38 and further recites that the: "frame includes a mount for selectively connecting the valve to the instrument." Ex. 1001, 24:46–48. Petitioner identifies the claimed "mount" as the peaks of Bessler's stent around which sutures loop to hold the stent in the instrument until the stent is deployed. Pet. 34–35 (citing Ex. 1008, 7:43–51, 7:53–61, Figures 14, 15; Ex. 1003 ¶¶ 82–83). Patent Owner argues that Bessler's sutures are not a releasable "fastener mounted on the frame" and that just "because you can wrap threads around the Bessler frame does not mean that the frame itself has a 'fastener' or 'mount.'" PO Resp. 16–17; *see also* Surreply 3–4 (reiterating same argument). We disagree.

Claim 39 does not recite a "fastener mounted on the frame" or a "fastener" of any type as implied by Patent Owner. Rather, claim 39 merely recites a "mount for selectively connecting the valve to the instrument." The peaks of Bessler's stent are such a "mount" as reflected by Bessler's use of this structure for "selectively connecting the valve to the instrument" with sutures 105. Accordingly, we determine that Petitioner has proven by a preponderance of evidence that Bessler anticipates claim 39.

(3) Dependent Claim 45

Patent Owner does not argue that Bessler fails to describe any limitation introduced in dependent claim 45, which depends from claim 38. Petitioner identifies the manner in which Bessler describes the limitations introduced in claim 45. Pet. 36–37 (citing Ex. 1008, 7:26–42, Figures 12–13; Ex. 1003 ¶ 87). We adopt as our own Petitioner's argument and evidence, and, on that basis and for the reasons expressed above

regarding base claim 38, we determine that Petitioner has proven that Bessler anticipates claim 45.

(4) Conclusion

For the reasons expressed above, we determine that Petitioner has proven by a preponderance of evidence that Bessler anticipates claims 38, 39, and 45.

4. Summary

For the reasons expressed above, we determine that Petitioner has proven by a preponderance of evidence that Bessler anticipates claims 38, 39, and 45, but has failed to do so for claims 1–3, 8, 9, 22, 23, 31–35, and 37.

F. CLAIMS 1–3, 8, 9, 22, 23, 31–35, 37–39, AND 45: OBVIOUSNESS BY BESSLER

Petitioner argues that even if Bessler fails to describe elements as claimed, an ordinarily skilled artisan would consider "variations" of Bessler to meet the claimed limitations would have been obvious "in view of the general knowledge in the art and the limited number of ways of using known elements to achieve expected results." Pet. 48–50. Petitioner addresses specific "variations" relating to meeting limitations introduced in claims 3 and 23 requiring "releasable fasteners" and limitations introduced in dependent claim 9 requiring a "band." *Id*. However, none of Petitioner's arguments persuasively addresses Bessler's failure to describe elements recited in independent claims 1, 22, and 31 as discussed in Part II.E above. Accordingly, we conclude that Petitioner has failed to prove by a preponderance of evidence that Bessler alone renders claims 1–3, 8, 9, 22, 23, 31–35, and 37 unpatentable as obvious.

Because we determine that Bessler anticipates claims 38, 39, and 45, we consider Petitioner's challenge that Bessler renders these claims unpatentable as obvious to be moot, and we offer no opinion on that aspect of Petitioner's challenge.

G. CLAIM 3, 23, AND 39:
OBVIOUSNESS IN VIEW OF BESSLER AND THOMPSON

1. Claims 3 and 23

Claims 3 and 23 depend ultimately from claims 1 and 22 respectively and recite that the artificial valve further comprises: "a releasable fastener mounted on the frame for selectively connecting the valve to an instrument." Ex. 1001, 19:56–58 (claim 3), 23:26–28 (claim 23). Petitioner relies upon Thompson as describing the "releasable fastener" and Bessler as describing the elements recited in base claims 1 and 22. Pet. 51–53.

We have already determined that Bessler fails to describe at least one element of each of base claims 1 and 22. *See* Part II.E.3.a) (claim 1), Part II.E.3.b) (claim 22). Petitioner's reliance upon Thompson does not cure the deficiencies in its showing of anticipation for base claims 1 and 22. Therefore, we determine that Petitioner has failed to demonstrate by a preponderance of evidence that the combination of Bessler and Thompson renders claims 3 and 23 unpatentable as obvious.

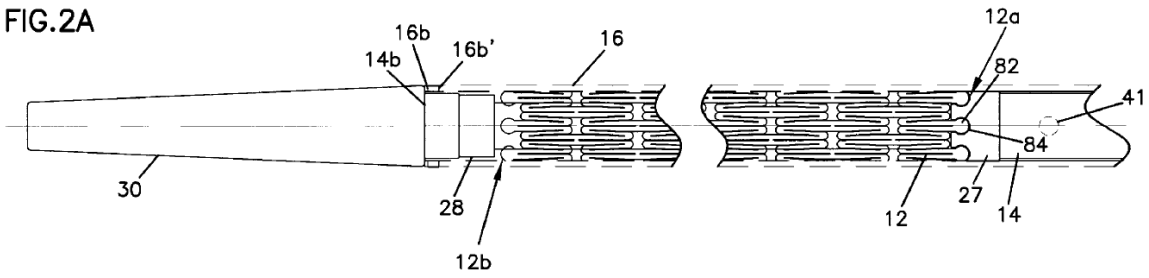
2. Claim 39

Claim 39 depends from claim 38 and further recites that the: "frame includes a mount for selectively connecting the valve to the instrument." Ex. 1001, 24:46–48.

Petitioner relies upon Thompson as describing the "mount for selectively connecting the valve to the instrument" in the form of its male

interlock structures 82 on the end of its stent 12. Pet. 51 (citing Ex. 1053, 6:37–43, Figure 2A). Thompson's male structures 82 mate with complementary female structures 84 on Thompson's collar 27 within its delivery catheter. Ex. 1053, 6:42–56, Figure 2A. The interlocking of male structures 82 and female structures 84 are shown on the right portion of Thompson's Figure 2A, which we reproduce below.

FIG.2A



Thompson's Figure 2A illustrates its stent 12 in a collapsed form. *Id*. at 3:50–51.

Petitioner argues that an ordinarily skilled artisan would have found it obvious to replace Bessler's sutures 105 with the interlocking arrangement of structures 82, 83 because both Thompson and Bessler recognized the need to mitigate premature deployment of a stent from a delivery catheter. Pet. 51 (citing Ex. 1053, 1:65–2:2). Petitioner also contends that the combined teachings of Bessler and Thompson would result in a simpler device with fewer moving parts and a more compact design. *Id*. at 52 (citing Ex. 1003 ¶ 154). Thompson expressly indicates that its stent delivery system is useful for delivering a percutaneous valve, which is the type of implant described by Bessler. Ex. 1053, 11:30–38; Ex. 1003 ¶ 149.

Relying solely upon testimony by Dr. Chronos, Patent Owner argues that Petitioner fails to explain how Thompson's interlocking structures 82, 84 are compatible with the frames for Bessler's valves. PO Resp. 28–29 (citing Ex. 2026 ¶ 4.3.3.1). Patent Owner argues that the alleged lack of

compatibility precludes a finding of obviousness in view of the combined teachings of Bessler and Thompson. *Id*. Patent Owner reiterates its argument in its Surreply without citing any additional supporting evidence. Surreply 11–12. We find Petitioner's argument and evidence to be more persuasive than Patent Owner's evidence.

"[I]t is not necessary that the inventions of the references be physically combinable to render obvious the invention under review." *In re Sneed*, 710 F.2d 1544, 1550 (Fed. Cir. 1983). The relevant inquiry is whether the claimed subject matter would have been obvious to an ordinarily skilled artisan in light of the combined teachings of those references. *See In re Keller*, 642 F.2d 413, 425 (CCPA 1981). "Combining the teachings of references does not involve an ability to combine their specific structures." *In re Nievelt*, 482 F.2d 965, 968 (CCPA 1973). Petitioner persuades us that Thompson suggests using its interlocking features with percutaneous stent structures like those described by Bessler. Ex. 1053, 11:30–38; Ex. 1003 ¶ 149. Although we have determined that Bessler describes the mount introduced in claim 39, we also determine that the combined teachings of Bessler and Thompson render claim 39 unpatentable as obvious.

H. CLAIM 3, 23, AND 39:
OBVIOUSNESS IN VIEW OF BESSLER AND TAYLOR

1. Claims 3 and 23

Claims 3 and 23 depend ultimately from claims 1 and 22 respectively and recite that the artificial valve further comprises: "a releasable fastener mounted on the frame for selectively connecting the valve to an instrument." Ex. 1001, 19:56–58 (claim 3), 23:26–28 (claim 23). Petitioner relies upon Taylor as describing the "releasable fastener" and Bessler as describing the elements recited in base claims 1 and 22. Pet. 53–54.

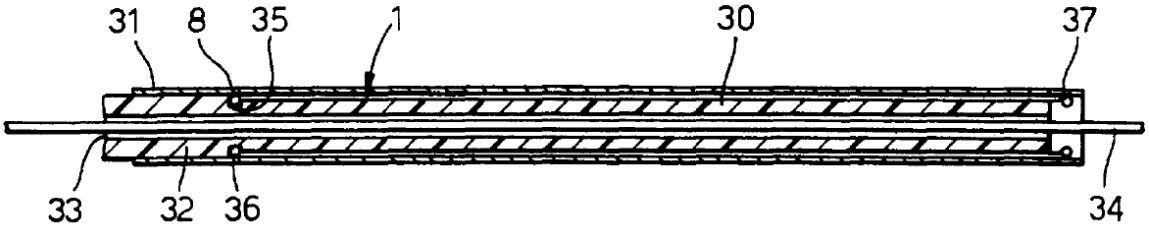
We have already determined that Bessler fails to describe at least one element of each of base claims 1 and 22. *See* Part II.E.3.a) (claim 1), Part II.E.3.b) (claim 22). Petitioner's reliance upon Taylor does not cure the deficiencies in its showing of anticipation for base claims 1 and 22. Therefore, we determine that Petitioner has failed to demonstrate by a preponderance of evidence that the combination of Bessler and Taylor renders claims 3 and 23 unpatentable as obvious.

2. Claim 39

Claim 39 depends from claim 38 and further recites that the: "frame includes a mount for selectively connecting the valve to the instrument." Ex. 1001, 24:46–48.

Petitioner relies upon Taylor as describing the "mount for selectively connecting the valve to the instrument" in the form of beads 8 of the stent at its proximal end 36. Pet. 53 (citing Ex. 1054, 25:16–20, Figure 8). Taylor's male structures 82 mate with complementary female structures 84 on Taylor's collar 27 within its delivery catheter. Ex. 1054, 25:16–20, Figure 8. Beads 8 on proximal end 36 of Taylor's stent mate with circumferential groove 35 in Taylor's pusher tube 32 as shown in Taylor's Figure 8, which we reproduce below.

Fig.8.



Taylor's Figure 8 illustrates its stent 1 in a collapsed form with beads 8 mated to groove 35 in pusher 32. *Id*. at 3:50–51.

Taylor incorporates beads 8 to ensure that the stent does not inadvertently fully release from the device.

Petitioner argues that an ordinarily skilled artisan would have found it obvious to replace Bessler's sutures 105 with the interlocking arrangement of beads 8 and circumferential groove 35 in a valve pusher because both Taylor and Bessler recognized the need to mitigate premature deployment of a stent from a delivery catheter. Pet. 53–54 (citing Ex. 1054, 25:13–20, 25:28–26:9, Figures 8–9; Ex. 1003 ¶¶ 150, 152). Petitioner also contends that the combined teachings of Bessler and Taylor would result in a simpler device with fewer moving parts and a more compact design. *Id*. at 54 (cross referencing motivations to combine teachings describing in connection with Bessler and Thompson). Taylor expressly indicates that its stent delivery system is useful for delivering stents in "peripheral and coronary blood vessels." Ex. 1054, 1:3–5.

Relying solely upon testimony by Dr. Chronos, Patent Owner argues that Petitioner fails to explain how Taylor's beads 8 are compatible with the frames for Bessler's valves. PO Resp. 28–29 (citing Ex. 2026 ¶ 4.3.4.1). Patent Owner argues that the alleged lack of compatibility precludes a finding of obviousness in view of the combined teachings of Bessler and Taylor. *Id*. Patent Owner reiterates its argument in its Surreply without citing any additional evidence. Surreply 11–12. We find Petitioner's argument and evidence to be more persuasive than Patent Owner's evidence.

"[I]t is not necessary that the inventions of the references be physically combinable to render obvious the invention under review." *In re Sneed*, 710 F.2d 1544, 1550 (Fed. Cir. 1983). The relevant inquiry is whether the claimed subject matter would have been obvious to an ordinarily

skilled artisan in light of the combined teachings of those references. *See In re Keller*, 642 F.2d 413, 425 (CCPA 1981). "Combining the teachings of references does not involve an ability to combine their specific structures." *In re Nievelt*, 482 F.2d 965, 968 (CCPA 1973). Petitioner persuades us that Taylor suggests using its interlocking bead structures with transluminally implanted stents like those described by Bessler. Ex. 1054, 25:13–20, 25:28–26:9, Figures 8–9; Ex. 1003 ¶¶ 150, 152. Although we have determined that Bessler describes the mount introduced in claim 39, we also determine that the combined teachings of Bessler and Taylor render claim 39 unpatentable as obvious.

I. CLAIMS 1–3, 8, 9, 22, 23, 31–35, 37–39, AND 45: OBVIOUSNESS IN VIEW OF BESSLER AND JOHNSON

Petitioner contends that the combination of Bessler and Johnson renders claims 1–3, 8, 9, 22, 23, 31–35, 37–39, and 45 unpatentable as obvious. Pet. 54–67. For the reasons expressed below, we conclude that Petitioner proves that all the challenged claims are unpatentable as obvious.

1. Overview of Johnson

Johnson is directed to a synthetic aortic or mitral heart valve prosthesis. Ex. 1021, 1:8–9. One embodiment of Johnson's valve is illustrated in Figure 2, reproduced at right. *Id*. at 3:57–58. Struts 10, 12, and 14 form an arcuate shape extending about 90° from point of joinder 16 to suture pads 18, 20, 22 are positioned at the free ends of the struts. *Id*. at 4:35–42. Flexible membrane 30 covers the frame formed the struts

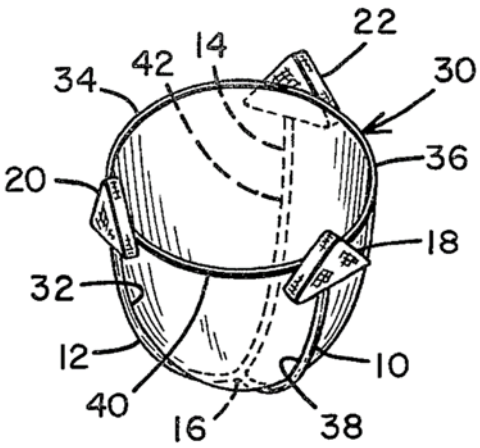


Fig. 2

to form a valve element having a hemispherical or paraboloid overall shape. *Id*. at 4:57–61.

Figures 4 and 5, reproduced below left and right, illustrate Johnson's valve in closed and open positions respectively. *Id*. at 5:37–50.

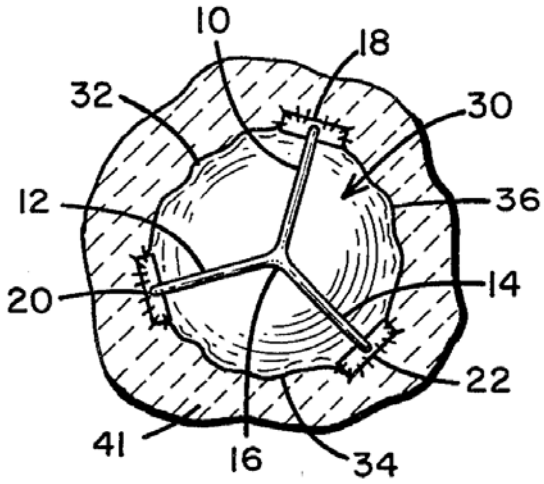


Fig. 4

Figure 4 is an axial view of Johnson's closed valve in the direction of blood flow.

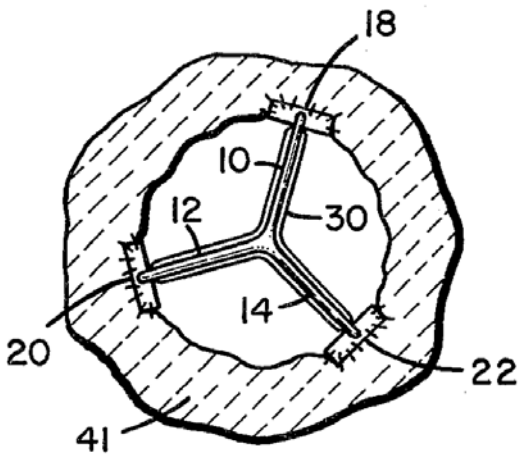


Fig. 5

Figure 5 is an axial view of Johnson's open valve in the direction of blood flow.

Membrane 30 includes free edges 32, 34, 36 that balloon out to contact tissue annulus 41 to which pads 18, 20, 22 are sutured when the valve is closed as shown in Figure 4. *Id*. at 5:37–45. Free edges 32, 34, 36 of membrane 30 collapse against one another in the open position shown in Figure 5 so that blood flows between annulus 41 and the collapsed membrane 30. *Id*. at 5:45–53. Although a three-strut frame is illustrated above, Johnson also describes an embodiment in which four struts are joined at joinder point 16 and radially distributed to form 90° angles between adjacent struts. *Id*. at 5:25–27.

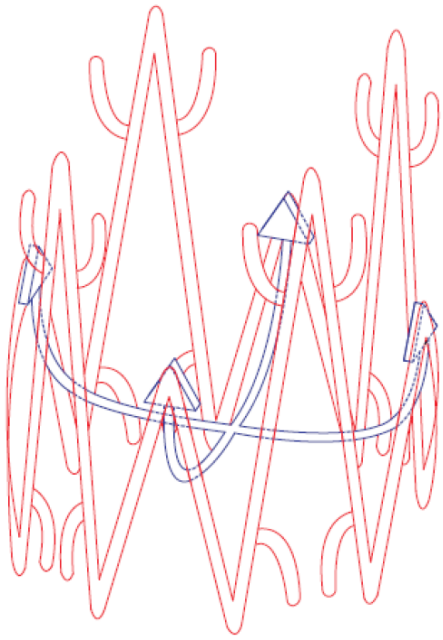
2. Petitioner's Argument and Evidence

Petitioner supports its contentions that the proposed combination of Bessler and Johnson describes every element of all the challenged claims with citations to precise portions of Bessler and Johnson and testimony by Dr. Dasi. *Id*. at 57–66 (citing Ex. 1008, 2:25–28, 2:55–62, 3:46–64, 4:12–21, 4:53–58, 4:60–5:1, 5:3–27, 5:31–36, 5:40–6:18, 7:26–67, 8:46–49, Figures 1, 6, 7, 12–15; Ex. 1021, 2:39–61, 3:26–47, 4:10–68, 5:12–53, 6:2–7, 6:14–19, Figures 1, 2, 4, 5, 7, 8; Ex. 1003 ¶¶ 122–144).

Petitioner's proposed combination of Bessler and Johnson addresses the ways in which Bessler alone fails to describe each missing element of the independent claims 1, 22, and 31 that we noted in Parts II.E.3.a)–b) above. In connection with claims 1 and 31, Johnson's struts form a frame that includes structure, near joinder point 16, that is located along the centerline of the valve. Ex. 1021, 4:35–42. Johnson's membrane 30 is attached along the entire length of its struts 10, 12, 14, including the common joinder point 16 of those struts. *Id*. at 4:61–63. These aspects of Johnson meet the requirement of claims 1 and 31 that the flexible valve element be attached to a central portion of the structure of the frame that is located along a centerline of the artificial valve. In connection with claim 22, Johnson describes the required "convex upstream side" and "concave downstream side" because Johnson's membrane 30 drapes over its struts 10, 12, 14 to form a hemispheric shape. *Id*. at 4:57–66, Figures 2, 7, 8.

3. Motive to Combine Bessler and Johnson

FIG.E



Petitioner contends that an ordinarily skilled artisan would have been motivated to incorporate Johnson's "dynamic annulus heart valve" into Bessler's stent and cuff structure to obtain a more durable valve. *Id*. at 56 (citing Ex. 1003 ¶¶ 118–119). Petitioner provides the Figure at right to illustrate its proposed combination without the flexible valve element to ease vizualization. *Id*.

Petitioner contends that Bessler recognized the benefits of delivering prosthetic heart valves through a catheter to avoid the invasive nature of open heart surgery. *Id*. at 54 (citing Ex. 1008, 1:14–34). Petitioner further contends that Bessler and Johnson both recognized, however, that prosthetic heart valves delivered through a catheter may suffer from a lack of durability. *Id*. at 54–55 (citing Ex. 1008, 2:11–12; Ex. 1021, 3:37–47). Johnson suggested that its valve would exhibit "extreme durability" by attaching its membrane to the center of its frame and leaving the peripheral edges free to open and close against a tissue annulus. Ex. 1021, 3:36–47. Petitioner argues that Bessler's recognition of potential durability issues associated with prosthetic valves implanted via catheter would have motivated an ordinarily skilled artisan to look to incorporate Johnson's durable valve design into Bessler's stent, which was adapted for the safer, less invasive transcatheter delivery. Pet. 55–56 (citing Ex. 1003 ¶¶ 115–116, 118–119). Because Johnson's device drapes a flexible membrane over a framework of curved flexible struts joined at one end to a

common central point, Petitioner contends that an ordinarily skilled artisan would consider Johnson's valve for use in a collapsible device. *Id*. at 57 (citing Ex. 1021, 2:43–50; Ex. 1003 ¶ 121). Dr. Dasi testifies that an ordinarily skilled artisan would have reasonably expected to be able to succeed in making the proposed combination of Bessler and Johnson because Johnson's valve with enhanced durability in Bessler's frame would work in the same way as described in Johnson, and Bessler's stent and delivery instrument would have permitted Johnson's valve to be delivered percutaneously. *Id*. at 66–67 (citing Ex. 1003 ¶¶ 41, 145–147).

4. Analysis of Patent Owner's Counterarguments

Patent Owner argues that the combination of Bessler and Johnson fails to render any claims obvious for two reasons. PO Resp. 30–33. First, Patent Owner argues that an ordinarily skilled artisan would not have been motivated to combine teachings of Bessler and Johnson for any challenged claim and that the proposed combination is based upon impermissible hindsight. *Id*. at 30–33. Second, Patent Owner argues that Johnson does not cure deficiencies in Petitioner's showing that Bessler fails to disclose a frame that is sized and shaped for insertion between the upstream and downstream regions as recited in all claims. *Id*. at 33. Patent Owner also argues that the proposed combination of Bessler and Johnson fails to describe a frame with a "collapsible configuration" as recited in dependent claim 32. *Id*. at 33–34. We address each argument below and determine that none is persuasive.

a) Alleged Lack of Motivation to Combine

Patent Owner argues that Petitioner's proposed combination of Bessler and Johnson is improper because it contends that placing Johnson's

strut-based frame into Bessler's stent "would increase the collapsible diameter of the TAVR[4] valve, rendering it too large for transluminal delivery." PO Resp. 32 (citing Ex. 1009, 21:27–29; Ex. 2026 ¶ 4.1.5.1). Patent Owner's argument is unpersuasive for at least three reasons.

First, the claims are not limited to TAVR procedures. The '297 patent describes and its claims encompass valves suitable for more than TAVR procedures. The Specification describes valve 10A, which is a TAVR valve, Ex. 1001, 4:64–66, but it also describes valve 10M, which is a replacement for a mitral valve, *id*. at 4:66–67. Because of the surgical method of delivering a TAVR valve 10A and the typical diameter of the aorta, the Specification indicates that valve 10A must collapse within the delivery catheter to a diameter of 4–8 mm, preferably 6 mm. *Id*. at 6:24–29, *see also* Figure 5 (illustrating instrument 70A). By contrast, delivering a mitral valve replacement 10M uses an instrument that collapses valve 10M to a larger diameter of 12–18 mm. Therefore, the claimed artificial valve may be delivered in an instrument of up to 18 mm in diameter, larger than the smaller 8 mm maximum diameter indicated for a TAVR valve.

Second, Johnson's strut-based frame and membrane are both flexible and very thin. Johnson's flexible struts are 0.030 inches (0.76 mm) in diameter and its membrane 30 is no more than 0.003 inches (0.08 mm) thick. Ex. 1021, 4:37–53. Struts 10, 12, 14 are formed of "a resilient or a springy material which is nonthrombogenic such as titanium or polytetrafluoroethylene or Teflon® polymer." *Id*. at 4:22–25. Bessler's stent is made of wire of only about 0.012–0.035 inches (0.30–0.89 mm) in

[4] TAVR appears to refer to "transcatheter aortic valve replacement." Ex. 3001 ¶ 1; Ex. 2002, p. 56, n.7.

diameter. Ex. 1008, 6:11–12. Bessler's stent collapses into a very small cylinder such that little space remains within its wire frame. *Id*. at 5:44–46, Figure 5. Given the stated, sub-millimeter sizes of all the relevant components of Johnson and Bessler, we see no reason why Johnson's strut-based frame and membrane combined with Bessler's stent would not easily collapse into the 18 mm diameter instrument 70M of the '297 patent.

Third, the only objective evidence cited by Patent Owner, Ex. 1009, 21:27–29, fails to support the proposition that the Johnson's valve within Bessler's stent would be "too large for transluminal delivery." The cited passage reads: "The presence of the internal cover makes an additional layer of plastic material that occupies the inside of the frame and increases the final size of the IV [implantable valve][5]." Ex. 1009, 21:27–29. At most, this passage demonstrates that adding more material to an implantable valve increases its collapsed diameter. The multilayer implantable valve being discussed in the Exhibit replaces an aortic valve, includes a stent structure made from bars 0.1–0.6 mm in diameter, and compresses to a diameter of 4–5 mm. Ex. 1009, 14:23–16.

For all these reasons, Dr. Chronos's assertion that incorporating Johnson's strut-based frame and membrane into Bessler's stent would render the combined structure too large is not supported by the objective evidence of record. Patent Owner's argument rests upon Dr. Chronos's testimony. Accordingly, we find Patent Owner's argument unpersuasive. Instead, we determine that Petitioner has proven that an ordinarily skilled artisan would

[5] Ex. 1009, 1:12–13.

have been motivated to combine the teachings of Bessler and Johnson as alleged.

b) Sized and Shaped for Insertion as Recited in Independent Claims 1, 22, 31, and 38

Patent Owner argues that Bessler fails to describe a frame that is sized and shaped for insertion between the upstream and downstream regions recited in the claims and that combining Johnson with Bessler does not cure the deficiency in Bessler's disclosure. PO Resp. 33. We disagree.

As explained in Part II.E.3.c)(1)(b) above, we find that Bessler meets these limitations of independent claim 38. Independent claims 1, 22, and 31 recite the same limitations as claim 38. *Compare* Ex. 1001, 23:57–66 (claim 38), *with id*. at 19:12–17 (claim 1), *and id*. at 21:55–60 (claim 22), *and id*. at 22:57–65 (claim 31). For the same reasons that we expressed above in connection with our analysis of this limitation in claim 38, we also determine that Bessler alone describes the limitation as recited in claims 1, 22, and 31.

c) Collapsible Valve as Recited in Dependent Claim 32

Claim 32 depends from claim 31 and further recites: "a holder having a hollow interior sized for holding the artificial valve when the frame is in the collapsed configuration." Ex. 1001, 23:34–37. Patent Owner argues that because Johnson's valve is "not a collapsible valve," placing it within Bessler's stent would also render the combination non-collapsible. PO Resp. 33–34 (citing Ex. 2026 ¶ 3.2.1.1 (addressing alleged non-collapsibility of Johnson valve)); Surreply 14. Dr. Chronos cites no objective evidence for his conclusion that Johnson cannot collapse to a width of less than 18 mm. Ex. 2026 ¶ 3.2.1.1. Based on our review of Johnson as described above, we find Dr. Chronos's testimony to be inconsistent with Johnson, which

describes a frame made of very thin (less than 1 mm) struts that are flexible and covered by a very thin (less than 0.1 mm) membrane. Ex. 1021, 4:22–57. Accordingly, Petitioner persuades us that the combination of Bessler and Johnson describes the collapsible valve of claim 32.

d) Remaining Elements of Claims 1–3, 8, 9, 22, 23, 31–35, 37–39, and 45

Patent Owner identifies no other deficiency in Petitioner's showing that the combination of Bessler and Johnson describes every other element of claims 1–3, 8, 9, 22, 23, 31–35, 37–39, and 45. *See* PO Resp. 30–34. We adopt as our own Petitioner's argument and evidence and find that Petitioner proves by a preponderance of evidence that the combination of Bessler and Johnson describes all elements of claims 1–3, 8, 9, 22, 23, 31–35, 37–39, and 45. Pet. 57–66 (citing Ex. 1008, 2:25–28, 2:55–62, 3:46–64, 4:12–21, 4:53–58, 4:60–5:1, 5:3–27, 5:31–36, 5:40–6:18, 7:26–67, 8:46–49, Figures 1, 6, 7, 12–15; Ex. 1021, 2:39–61, 3:26–47, 4:10–68, 5:12–53, 6:2–7, 6:14–19, Figures 1, 2, 4, 5, 7, 8; Ex. 1003 ¶¶ 122–144).

e) Conclusion

We also conclude that Petitioner has proven by a preponderance of evidence that an ordinarily skilled artisan would have been motivated to combine teachings of Bessler and Johnson to arrive at the artificial valves and instruments recited in claims 1–3, 8, 9, 22, 23, 31–35, 37–39, and 45. Petitioner also persuades us that the combination of Bessler and Johnson describes every element of these claims. Accordingly, we conclude that Petitioner has proven by a preponderance of evidence that the combination of Bessler and Johnson renders claims 1–3, 8, 9, 22, 23, 31–35, 37–39, and 45 unpatentable as obvious.

J. CLAIMS 3, 23, AND 39:
OBVIOUSNESS IN VIEW OF BESSLER, JOHNSON, AND THOMPSON

Claims 3 and 23 depend ultimately from claims 1 and 22 respectively and recite that the artificial valve further comprises: "a releasable fastener mounted on the frame for selectively connecting the valve to an instrument." Ex. 1001, 19:56–58 (claim 3), 23:26–28 (claim 23). Claim 39 depends from claim 38 and further recites that the: "frame includes a mount for selectively connecting the valve to the instrument." Ex. 1001, 24:46–48. Petitioner relies upon Thompson as describing the "releasable fastener" and the combination of Bessler and Johnson as describing the elements recited in base claims 1, 22, and 38. Pet. 67–68 (citing Ex. 1003 ¶¶ 149, 151, 153, 155).

When addressing this challenge, Patent Owner relies upon its argument that the combination of Bessler and Thompson fails to render claims 3, 23, and 39 unpatentable. PO Resp. 34–35. We have already determined that the combination of Bessler and Johnson renders claims 3, 23, and 39 obvious. *See* Part II.I above. We have also concluded that the combined teachings of Bessler and Thompson render claim 39 unpatentable as obvious. *See* Part II.G.2 above. For all the reasons expressed in those portions of this Decision, we also conclude that the combined teachings of Bessler, Johnson, and Thompson render claims 3, 23, and 39 unpatentable as obvious.

K. CLAIMS 3, 23, AND 39:
OBVIOUSNESS IN VIEW OF BESSLER, JOHNSON, AND TAYLOR

Claims 3 and 23 depend ultimately from claims 1 and 22 respectively and recite that the artificial valve further comprises: "a releasable fastener mounted on the frame for selectively connecting the valve to an instrument."

Ex. 1001, 19:56–58 (claim 3), 23:26–28 (claim 23). Claim 39 depends from claim 38 and further recites that the: "frame includes a mount for selectively connecting the valve to the instrument." Ex. 1001, 24:46–48. Petitioner relies upon Taylor as describing the "releasable fastener" and the combination of Bessler and Johnson as describing the elements recited in base claims 1 and 22. Pet. 68.

When addressing this challenge, Patent Owner relies upon its argument that the combination of Bessler and Taylor fails to render claims 3, 23, and 39 unpatentable. PO Resp. 34–35. We have already determined that the combination of Bessler and Johnson renders claims 3, 23, and 39 obvious. *See* Part II.I above. We have also concluded that the combined teachings of Bessler and Taylor render claim 39 unpatentable as obvious. *See* Part II.H.2 above. For all the reasons expressed in those portions of this Decision, we also conclude that the combined teachings of Bessler, Johnson, and Taylor render claims 3, 23, and 39 unpatentable as obvious.

L. CLAIMS 1–3, 8, 9, 22, 23, 31–35, 37–39, AND 45: ANTICIPATION BY LEONHARDT

Petitioner contends that Leonhardt anticipates claims 1–3, 8, 9, 22, 23, 31–35, 37–39, and 45 under 35 U.S.C. § 102(a), (e). Pet. 3, 27–34, 37–48. Petitioner supports its contentions with the testimony of Lakshmi Prasad Dasi, Ph.D. *Id.* Patent Owner argues that Leonhardt fails to describe various elements recited in independent claims 1, 22, 31, and 38, and other elements introduced in dependent claims 3, 9, 23, and 39. PO Resp. 18–28. For the reasons expressed below, we determine that Petitioner has failed to prove by a preponderance of evidence that Leonhardt anticipates any claim.

1. Overview of Leonhardt

Leonhardt "relates to artificial valves, specifically those placed percutaneously by a catheter" to replace existing valves, such as valves in the heart. Ex. 1017, 1:4–7. We reproduce Figure 4 of Leonhardt at right, which is a side view of Leonhardt's valve stent 20. Valve stent 20 comprises stent 26, biological valve 22, and graft material 24. *Id.* at 4:14–16. Stent 26, which is shown in more detail in Figures 1a–1c, is a single piece of super elastic wire formed into top and bottom portions that are substantially symmetrical to each other have a wavy form or zig-zags 40. *Id.* at 4:27–38, Fig. 1a. Each end 58 of stent 26 is connected to another portion of the stent by crimping tubes 50 to define imaginary cylinder 48. *Id.* at 4:41–56, Figs. 1b, 1c. In other words, once crimped, stent 26 comprises a pair of cylinders at opposing ends of the stent. *Id.* at 5:27–30. Connecting bar 29, which is a central part of the continuous wire from which the stent is formed, holds these cylinders at a predetermined distance apart. *Id.* at 5:31–33; Figs. 1a, 1b.

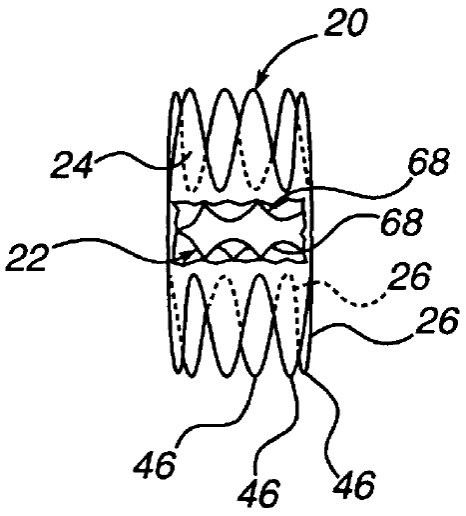


FIG. 4

Graft material 24 "is a thin-walled biocompatible, flexible and expandable, low-porosity woven fabric" that encloses, and is sutured to, stent 26. *Id.* at 5:46–48, 53–63. Graft material 24 "is heat pressed to conform to the distal and proximal cylindrical ends of stent." *Id.* at 5:63–65. In addition, when valve stent 20 must flare at one or both ends, "graft material 24 may be cut out between the plurality of distensible fingers 46 formed by zig-zags 40 of stent 26." *Id.* at 6:9–13.

Biological valve 22 fits within the internal diameter of the imaginary cylinder defined by stent 26 and is attached to stent 26, graft material 24, or both. *Id.* at 6:25–30. Although "preferably a porcine valve treated and prepared for use in a human," biological valve 22 could also be "a mechanical valve or a synthetic leaflet valve." *Id.* at 6:23–24, 31–33.

Leonhardt also discloses deployment catheter 100 for the percutaneous delivery of valve stent 20 to the placement site. *Id.* at 6:34–37, Figs. 5, 6. Deployment catheter 100 includes outer sheath 106 having axially extending sheath passage 108, which receives push rod 112. *Id.* at 6:42–45. In use, valve stent 20 is loaded into outer sheath 106, and push rod 112 causes valve stent 20 to be deployed. *Id.* at 7:17–18, 10:53–58.

2. Petitioner's Argument and Evidence

Petitioner contends that Leonhardt anticipates each of independent claims 1, 22, 31, and 38 and identifies specific portions of Leonhardt that describe each element of the artificial valve of those claims. Pet. 27–34, 37–48 (citing Ex. 1017, 1:5–21, 2:43–50, 3:15–49, 4:53–5:52, 6:9–34, 7:10–17, 8:42–9:5, 9:50–11:36, 11:59–12:5, FIGS. 1B, 1C, 2–4, 9A–9D). Petitioner also relies on Dr. Dasi's testimony to support its contentions. *Id.* (citing Ex. 1003 ¶¶ 90–105).

3. Analysis of Patent Owner's Counterarguments

Each of independent claims 1, 22, 31, and 38 recite materially differing versions of an artificial valve. Patent Owner argues that Leonhardt fails to anticipate each independent claim and proffers distinct arguments for patentability of dependent claims 3, 9, 23, and 39. For the reasons expressed below, we find that Patent Owner's arguments are persuasive for

independent claims 1, 22, 31, and 38 and thus also for their respective dependent claims 2, 3, 8, 9, 22, 23, 31–35, 37, 39, and 45.

a) Claims 1–3, 8, 9, 31–35, and 37

Patent Owner argues that Leonhardt does not anticipate independent claims 1 and 31 because Leonhardt's flexible valve member is not attached to a central portion of its frame. PO Resp. 18–19. For claims 1 and 31, the central portion of the frame is "located *along a centerline* extending between the plurality of peripheral anchors." Ex. 1001, 19:19–20 (claim 1), 22:67–23:2 (claim 31) (emphasis added).

Petitioner contends that Leonhardt describes a porcine valve element that is sutured or glued to stent 26, graft material 24, or both. Pet. 41 (citing Ex. 1017, 6:23–32, FIG. 4). Leonhardt's stent 26 includes two cylindrical sections that are joined by connecting bar 29, which is the "central part of the continuous wire from which stent 26 is formed." Ex. 1017, 5:31–33. The combination of stent 26 and connecting bar 29 constitutes Leonhardt's frame. Connecting bar 29 is also sutured, and thus attached, to graft material 24. *Id*. at 5:36–37.

Petitioner's argument that Leonhardt's valve is attached to the central part of the frame of claims 1 and 31 fails. Leonhardt's valve is undeniably attached to its frame because the valve is sutured or glued to stent 26. However, claims 1 and 31 require the valve element to be attached to a portion of the frame located along the radial centerline. Ex. 1001, 19:19–20 (claim 1), 22:67–23:2 (claim 31). Leonhardt's frame (stent 26 coupled via connecting bar 29) is a hollow cylinder devoid of structure located along its centerline. *Id*., Figure 1C. Thus, regardless of how Leonhardt's valve is attached to stent 26 and connecting bar 29, it is not attached to a structure

"located along a centerline" as recited in claims 1 and 31. Therefore, we determine that Petitioner fails to establish by a preponderance of evidence that Leonhardt anticipates claims 1 and 31 or their respective dependent claims 2, 3, 8, 9, 32–35, and 37.

b) Claims 22 and 23

Independent claim 22 requires the flexible valve to include a "convex upstream side" and a "concave downstream side." Ex. 1001, 21:64–22:3. As explained in Part II.D.3 above, we conclude that the overall shape of the entire "upstream side" of the flexible valve element is convex, and the overall shape of the entire "downstream side" of the flexible valve element is concave.

Petitioner contends that Leonhardt's "biologic porcine" valve 22 includes a "convex upstream side" and a "concave downstream side." Pet. 31, 42 (citing Ex. 1017, 6:23–34; Ex. 1003 ¶ 97). However, the portion of Dr. Dasi's testimony relied on (e.g., Ex. 1003 ¶ 97) does not contain such an opinion. Dr. Dasi testifies that a porcine valve comprises portions that individually bulge in the upstream direction. *Id.* ¶ 97. Dr. Dasi testifies that a porcine valve has the same "architecture" as a human valve. Ex. 1003 ¶ 27 (citing Ex. 1001, 1:66–24). He also provides detailed illustrations of human valves and explains that porcine valves are shaped the same way as human valves. *Id.* ¶ 28, Figure B. However, Petitioner does not provide adequate support for its contention that Leonhardt's valve 22 contains a convex side or a concave side.

Patent Owner argues that Leonhardt fails to describe the convex and concave opposing sides of a flexible valve element because Leonhardt's depiction of valve 22 in its Figure 4 does not reflect opposing sides, one

convex and the other concave. PO Resp. 26–28. Patent Owner does not address Dr. Dasi's detailed testimony of what an ordinarily skilled artisan would understand the shape of a porcine valve to be. *Id*. We accept Dr. Dasi's uncontroverted testimony about the shape of the porcine valve to which Leonhardt refers.

Nevertheless, Leonhardt fails to describe a valve element having opposing convex and concave sides because Leonhardt's porcine valve does include any side in which the entire side exhibits a convex or concave shape. As above, we have construed "convex" side as referring to an entire side that is convex and "concave" side as referring to an entire side that is concave. Leonhardt does not meet these claim limitations. Accordingly, we determine that Petitioner has failed to prove by a preponderance of evidence that Leonhardt anticipates claim 22 or its dependent claim 23.

c) Claims 38, 39, and 45

(1) Flexible Valve Element Attached to Central Portion of the Frame

Initially, Patent Owner groups claim 38 with claims 1 and 31 when arguing that Leonhardt fails to describe a valve element directly attached to the central portion of the frame. PO Resp. 18–19. This argument is unpersuasive for two reasons. First, claim 38 recites "central portion" more broadly than claims 1 and 31, and Leonhardt includes a "central portion" as recited in claim 38. Second, as explained in Part II.D.1 above, we do not interpret claim 38 to require "direct attachment" of the valve to the frame.

Independent claim 38 recites a frame having "a central portion located between the plurality of peripheral anchors" without further requiring the central portion being "located along a centerline" as recited in claims 1 and 31. Ex. 1001, 24:1–2. Accordingly, the "central portion" of the frame

of claim 38 may refer to any portion of the frame that is "between the plurality of peripheral anchors," including a portion that is longitudinally centered.

Patent Owner argues that Petitioner fails to identify a "central structural frame portion" to which Leonhardt's valve is "directly attached." PO Resp. 20.

Petitioner correctly notes that Leonhardt's valve element 22 is sutured or glued to stent 26, graft material 24, or both. Pet. 41 (citing Ex. 1017, 6:23–32, FIG. 4). Leonhardt's stent 26 includes two cylindrical sections that are joined by connecting bar 29, which is the "central part of the continuous wire from which stent 26 is formed." Ex. 1017, 5:31–33. The combination of stent 26 and connecting bar 29 constitutes Leonhardt's frame. Thus, Leonhardt describes securing valve 22 to stent 26 both directly and indirectly via attachment to graft material 24.

Additionally, Leonhardt's Figure 4 illustrates valve 22 as being positioned in the longitudinal central portion of the frame. *Id*., Figure 4. Accordingly, Leonhardt attaches its valve to a "central portion" of the frame as required in claim 38.

Leonhardt's longitudinally "central portion" is also located "between the plurality of peripheral anchors." Leonhardt's Figure 2 illustrates that both ends of valve stent 20 flare radially outward "to conform and seal to the tissue," *id*. at 6:21–22, Figure 2, by using "light activated bioadhesive material 56 on the outside of graft material 24," *id*. at 8:44–45. In this way, Leonhardt "anchors" valve stent 20, which includes graft 24, stent 26, and valve 22, around its periphery using a "plurality of peripheral anchors" as recited in claim 38. Leonhardt's longitudinally centered portion of stent 26

is located between these "peripheral anchors." For all these reasons, we determine that Leonhardt's valve 22 is "attached to the central portion of the frame," which is "located between the plurality of peripheral anchors."

(2) Substantially Immobile

Patent Owner also argues that Leonhardt fails to describe a valve element that is "substantially immobile" with respect to the "central portion of the frame" because Leonhardt fails to include a "central portion of the frame." PO Resp. 23. For the reasons expressed immediately above, we find that Leonhardt describes the claimed "central portion" of the frame and a valve that is "substantially immobile" with respect to that frame.

(3) Installer That Is Releasably Attachable to the Frame

Patent Owner also argues that Leonhardt fails to describe an "installer" that is "releasably attachable to the frame." *Id*. at 23–24. The limitation at issue from claim 38 reads in its entirety as follows:

> an instrument including
>
> a holder . . .
>
> * * *
>
> *an installer* received within the hollow interior of the holder and *releasably attachable to the frame* of the artificial heart valve for maneuvering the artificial heart valve from the hollow interior of the holder into position between the upstream region and the downstream region.

Ex. 1001, 24:32–45 (emphasis added). Although the "installer" is largely defined by its function of "maneuvering the artificial heart valve . . . into position," the installer must also be "releasably attachable to the frame."

Petitioner contends that Leonhardt's pushrod 112 is an installer that is releasable attachable to the frame. Pet. 44–45. Patent Owner contends that

pushrod 112 is not "releasably attachable to the frame" but simply contacts and pushes stent 26 during deployment. PO Resp. 23–24. Petitioner responds that Leonhardt's suture loops 174, which pass through pushrod 112 and loop around stent 26, are used to "releasably couple" pushrod 112 to stent 26. Reply 8–9. Patent Owner persuasively notes that, although suture loops 174 pass through pushrod 112, they do not "attach" pushrod 112 to stent 26. Surreply 7. We agree with Patent Owner.

The combination of Leonhardt's pushrod 112 and suture loops 174 does maneuver valve 20 into position. Ex. 1017, 8:23–27, 9:8–15. However, pushrod 112 alone cannot pull valve 20 back toward Leonhardt's deployment catheter 100; instead, suture loops 174 in "[s]pool apparatus 170 allows valve stent 20 to be retrieved into outer sheath 106 if repositioning or removal is necessary." *Id*. at 9:8–10. Suture loops 174 "extend through a central axial passage of push rod 112," which indicates that suture loops 174 are not attached to pushrod 112. *Id*. at 9:12–15. We determine that Leonhardt thus fails to attach its valve stent 20 to pushrod 112. Instead, pushrod 112 merely contacts valve stent 20 during deployment.

(4) Conclusion

Because Leonhardt fails to describe the installer that is "releasably attachable to the frame" as required in claim 38, we conclude that Petitioner has failed to demonstrate by a preponderance of evidence that Leonhardt anticipates claim 38 or its dependent claims 39 and 45.

4. Summary

For the reasons expressed above, we determine that Petitioner has failed to prove by a preponderance of evidence that Leonhardt anticipates claims 1–3, 8, 9, 22, 23, 31–35, 37–39, and 45.

M. CLAIMS 1–3, 8, 9, 22, 23, 31–35, 37–39, AND 45: OBVIOUSNESS BY LEONHARDT

Petitioner argues that even if Leonhardt fails to describe elements as claimed, an ordinarily skilled artisan would consider "variations" of Leonhardt to meet the claimed limitations would have been obvious "in view of the general knowledge in the art and the limited number of ways of using known elements to achieve expected results." Pet. 50. Petitioner addresses specific "variations" relating to meeting limitations introduced in claims 3 and 23 requiring "releasable fasteners." *Id*. However, none of Petitioner's arguments persuasively addresses Leonhardt's failure to describe elements recited in independent claims 1, 22, 31, and 38 as discussed in Part II.I above. Accordingly, we conclude that Petitioner has failed to prove by a preponderance of evidence that Leonhardt alone renders claims 1–3, 8, 9, 22, 23, 31–35, 37–39, and 45 unpatentable as obvious.

N. OBJECTIVE INDICIA OF NON-OBVIOUSNESS

Patent Owner argues that numerous objective indications "weigh heavily against deeming the invention of the '297 patent obvious" exist, including: peer recognition, long-felt but unresolved need, commercial success, and acceptance and adoption by industry. PO Resp. 35–40. Patent Owner's evidence relating to various heart valves is:

1. letters addressed to Dr. Snyders from industry executives discussing a "funnel valve" (Exs. 2007, 2008);
2. a draft article co-authored by Dr. Snyder entitled "Evaluation of a Transluminal Prosthetic Valve Implant in the Mitral Position" that discusses results of "funnel valve" implant procedures (Ex. 2009);

3. a press release describing the acquisition of "CoreValve, Inc., developer of a transcatheter, transfemoral aortic heart valve replacement" by Medtronic, Inc. (Ex. 2010);
4. a report in the Orange County Register of the settlement of a patent dispute between Medtronic Inc. and Edwards Lifesciences involving "minimally invasive heart valves" such as Medtronic's "CoreValve" product (Ex. 2011);
5. documents describing invitations to Dr. Snyder to present a paper at the 4th annual NewEra Cardiac Care: Innovation and Technology meeting, January 4–7, 2001 (Exs. 2012, 2013, 2014).

PO Resp. 35–40 (citing Exs. 2007, 2008, 2009, 2010, 2011, 2012, 2013, 2014).

Petitioner responds to this evidence by correctly noting that none of the evidence establishes a nexus between any praise, recognition, commercial success, or acceptance and adoption by industry with a product that is covered by any claim of the '297 patent. Reply 19–21.

When weighing allegations that objective indicia favor a conclusion of non-obviouseness, we must consider "whether 'the marketed product embodies the claimed features.'" *ClassCo, Inc. v. Apple, Inc.*, 838 F.3d 1214, 1222 (Fed. Cir. 2016) (quoting *Brown & Williamson Tobacco Corp. v. Philip Morris Inc.*, 229 F.3d 1120, 1130 (Fed. Cir. 2000)). Patent Owner submits no evidence to establish that Dr. Snyder's "funnel valve" (Exs. 2007, 2008, 2009) or acquisitions, licenses, and litigation settlements involving products made by Medtronic, Edwards Lifesciences, or CoreValve relate to any product covered by any claim. PO Resp. 35–40. In its Surreply, Patent Owner baldly asserts without citing any persuasive

evidence or analysis that the Medtronic CoreValve "is covered by Dr. Snyder's patents." Surreply 15. When questioned during the hearing on this very insufficiency of its evidence, Patent Owner failed to identify where it had established the required nexus to the claimed invention. Tr. 133:16–134:16. Based on our consideration of the record as whole, we determine that Patent Owner has failed to establish any nexus between its alleged objective indicia of non-obviousness and the claimed features. On that basis, we do not consider objective indicia to weigh against a conclusion of obviousness.

III. PETITIONER'S MOTION TO STRIKE

Petitioner's Motion to Strike seeks to exclude from Patent Owner's Surreply the sentence and citation at lines 2–4 on page 3. Mot. 1. That sentence and citation reads: "In fact, Bailey recognized the native annulus is more rigid than the native leaflets and that Bessler's barbs would malfunction if they were secured to native leaflets. (Ex. 1024 at 3:48-4:4)." *Id*. Petitioner argues that the offending sentence is "entirely new argument" regarding Bessler that should have been presented in the Patent Owner Response. *Id*. at 3.

We have considered the allegedly offending sentence in rendering our decision but do not consider Bailey to be persuasive evidence of whether Bessler's barbs would malfunction if they were secured to native leaflets. Bailey's statements are inadmissible hearsay when offered to prove the truth of the matter for which Patent Owner cites them. We also note that Patent Owner has not adduced any evidence that Mr. Bailey had any personal knowledge of the functionality of Bessler's barbed valves. Therefore, we *dismiss* Petitioner's Motion to Strike as moot.

IV. CONSTITUTIONAL ISSUE

Patent Owner objects to *inter partes* review "because it is carried out by a final order issued by Administrative Patent Judges who have not been nominated by the President and confirmed by the Senate." PO Resp. 40–41. According to Patent Owner, Administrative Patent Judges are "principal Officers" under the Constitution's Appointments Clause (U.S. Const. Art. II, § 2, Cl. 2), meaning they must be nominated by the President and confirmed by the Senate in order to exercise their authority constitutionally with respect to *inter partes* reviews. *Id.*

Patent Owner, however, does not direct us to any authority holding that Administrative Patent Judges are principal Officers under the Appointments Clause. Furthermore, in 2008, Congress changed the law to provide that Administrative Patent Judges be appointed by the Secretary of Commerce in consultation with the Director. Pub. L. 110–313, 122 Stat 3014 (Aug.12, 2008). Accordingly, we are not persuaded that Administrative Patent Judges conducting *inter partes* reviews is unconstitutional.

V. CONCLUSION

Based on the record before us, we conclude that Petitioner has demonstrated by a preponderance of the evidence that:

1. claims 38, 39, and 45 are unpatentable as anticipated by Bessler;
2. claim 39 is unpatentable as obvious in view of the combined teachings of Bessler and Thompson;
3. claim 39 is unpatentable as obvious in view of the combined teachings of Bessler and Taylor;

4. claims 1–3, 8, 9, 22, 23, 31–35, 37–39, and 45 are unpatentable as obvious in view of the combined teachings of Bessler and Johnson;
5. claims 3, 23, and 39 are unpatentable as obvious in view of the combined teachings of Bessler, Johnson, and Thompson; and
6. claims 3, 23, and 39 are unpatentable as obvious in view of the combined teachings of Bessler, Johnson, and Taylor.

We also conclude that Petitioner has not demonstrated by a preponderance of the evidence that:

1. claims 1–3, 8, 9, 22, 23, 31–35, 37 are unpatentable as anticipated by Bessler;
2. claims 1–3, 8, 9, 22, 23, 31–35, 37–39, and 45 are unpatentable as anticipated by Leonhardt;
3. claims 1–3, 8, 9, 22, 23, 31–35, 37 are unpatentable as obvious in view of Bessler;
4. claims 1–3, 8, 9, 22, 23, 31–35, 37–39, and 45 are unpatentable as obvious in view of Leonhardt;
5. claims 3 and 23 are unpatentable as obvious in view of the combined teachings of Bessler and Thompson; and
6. claims 3 and 23 are unpatentable as obvious in view of the combined teachings of Bessler and Taylor.

VI. ORDER

For the reasons given, it is:

ORDERED, based on a preponderance of evidence, that claims 1–3, 8, 9, 22, 23, 31–35, 37–39, and 45 of U.S. Patent 6,821,297 B2 are *unpatentable*; and

FURTHER ORDERED because this is a final written decision, the parties to this proceeding seeking judicial review of our Decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

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US006821297B2

(12) **United States Patent**
Snyders

(10) **Patent No.: US 6,821,297 B2**
(45) **Date of Patent: Nov. 23, 2004**

(54) **ARTIFICIAL HEART VALVE, IMPLANTATION INSTRUMENT AND METHOD THEREFOR**

(76) Inventor: **Robert V. Snyders**, 1638 Wolf Trail Rd., Ballwin, MO (US) 63021

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 72 days.

(21) Appl. No.: **10/135,746**

(22) Filed: **Apr. 30, 2002**

(65) **Prior Publication Data**

US 2002/0123802 A1 Sep. 5, 2002

Related U.S. Application Data

(63) Continuation-in-part of application No. 09/775,360, filed on Feb. 1, 2001, now Pat. No. 6,540,782.
(60) Provisional application No. 60/179,853, filed on Feb. 2, 2000.

(51) **Int. Cl.**[7] **A61F 2/06**
(52) **U.S. Cl.** **623/2.18**
(58) **Field of Search** 623/2.1, 2.11, 623/2.13, 2.14, 2.15, 2.16, 2.18, 2.19, 2.12

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Steven R. Bailey, *Percutaneous Expandable Prosthetic Valves*, Textbook of Interventional Cardiology 1268–76 (1995).

Dwight E. Harken, et al., *Partial and Complete Prostheses in Aortic Insufficiency*, 40 J. Thoracic and Cardiovas. Surg. 744–62 (1960).

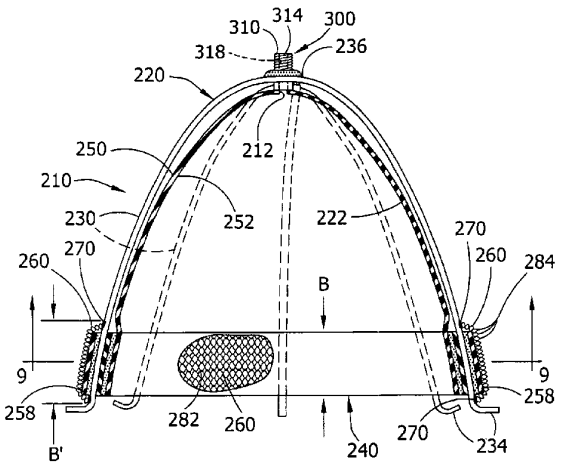
(List continued on next page.)

Primary Examiner—Corrine McDermott
Assistant Examiner—William Matthews
(74) *Attorney, Agent, or Firm*—Sonnenschein Nath & Rosenthal LLP

(57) **ABSTRACT**

An artificial valve for repairing a damaged heart valve having a plurality of cusps separating upstream and downstream regions. The artificial valve includes a flexibly resilient frame with a plurality of peripheral anchors for anchoring the frame in position between the regions. The frame includes a central portion located between the anchors. The valve includes a flexible valve element attached to the central portion of the frame having an upstream side and a downstream side opposite the upstream side. The valve element moves to an open position when fluid pressure in the upstream region is greater than fluid pressure in the downstream region to permit downstream flow. The valve element moves to a closed position when fluid pressure in the downstream region is greater than fluid pressure in the upstream region to prevent flow reversal. The valve may be used in beating heart procedures, avoiding cardiopulmonary bypass and cardioplegia.

46 Claims, 11 Drawing Sheets



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Charles A. Hufnagel, *Basic Concepts in the Development of Cardiovascular Prostheses*, 137 Great Ideas in Surgery 285–300 (Mar. 1979).

L.L. Knudsen, et al., *Catheter–implanted Prosthetic Heart Valves* 18 The International Journal of Artificial Organs 253–262 (1993).

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FIG. 1

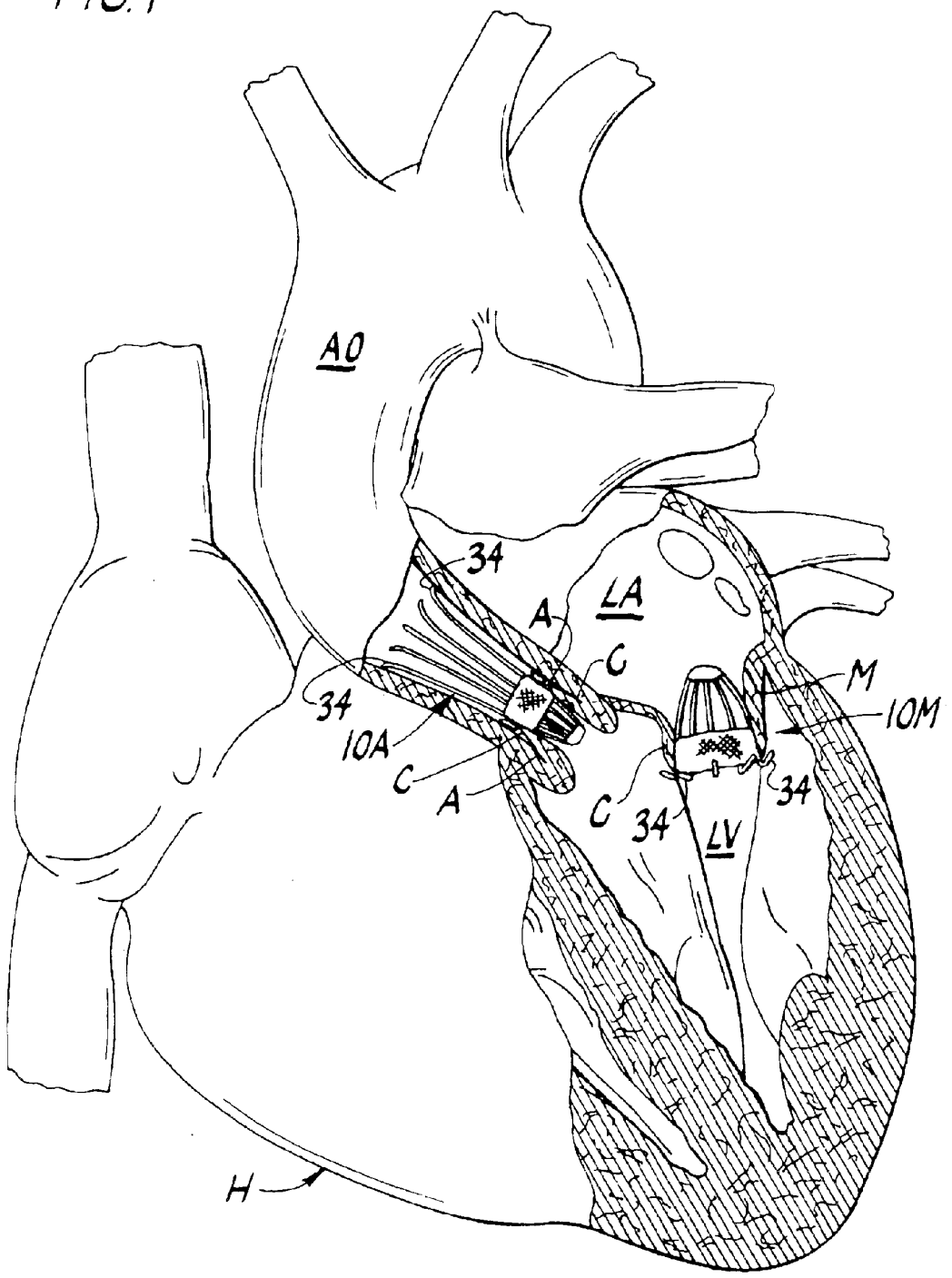


FIG. 2

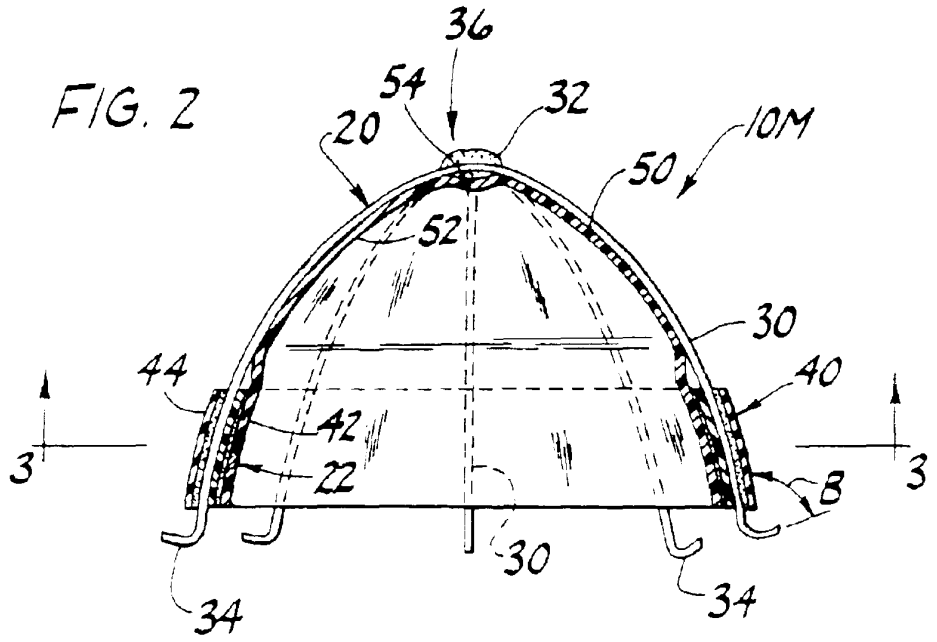
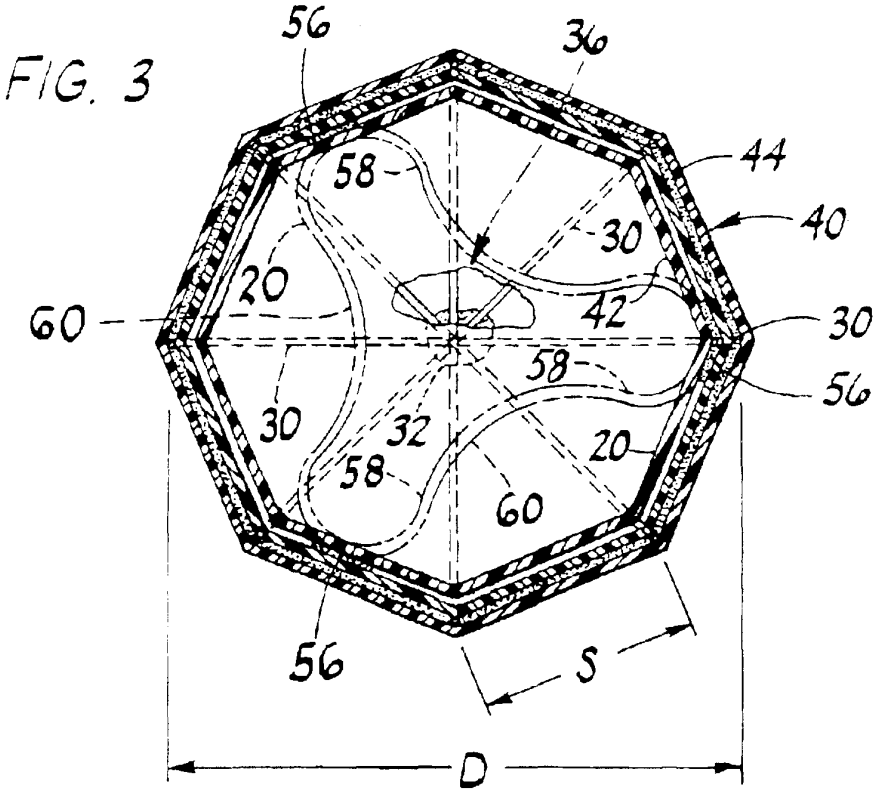


FIG. 3



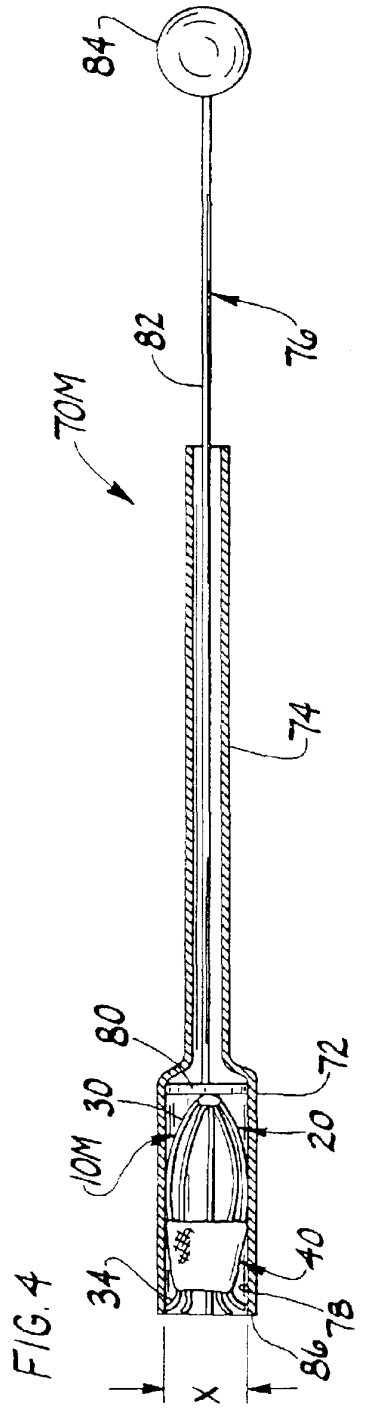


FIG. 4

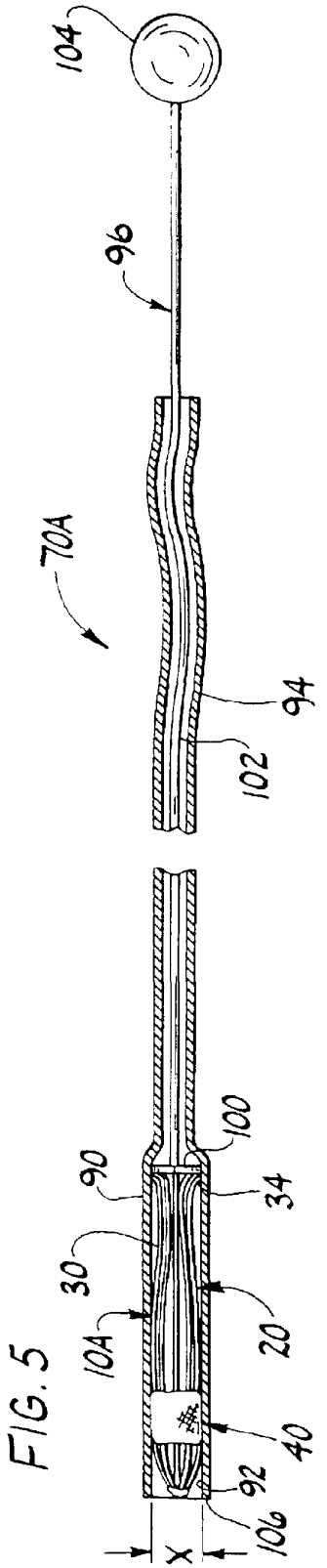


FIG. 5

FIG. 6

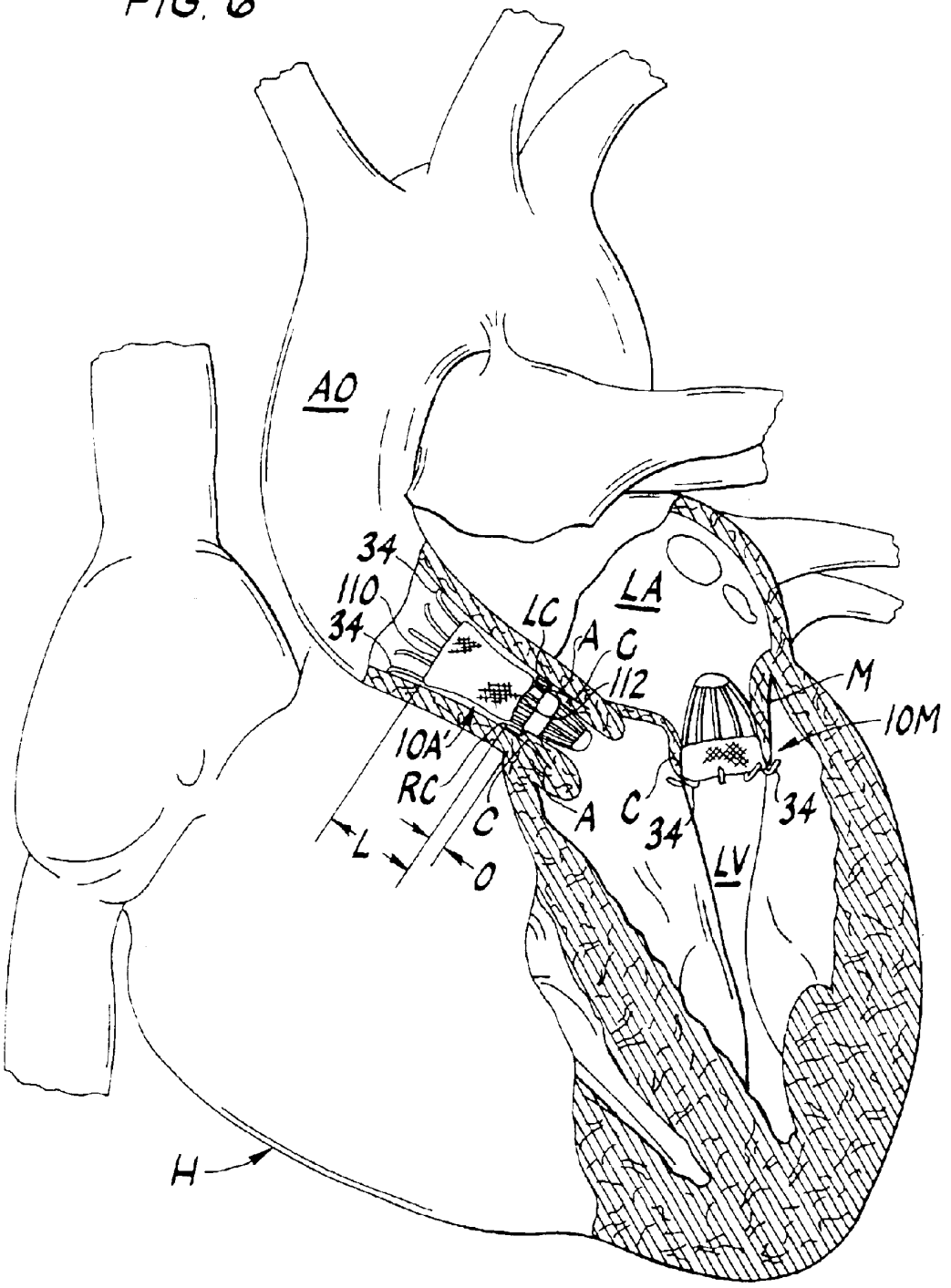


FIG. 7

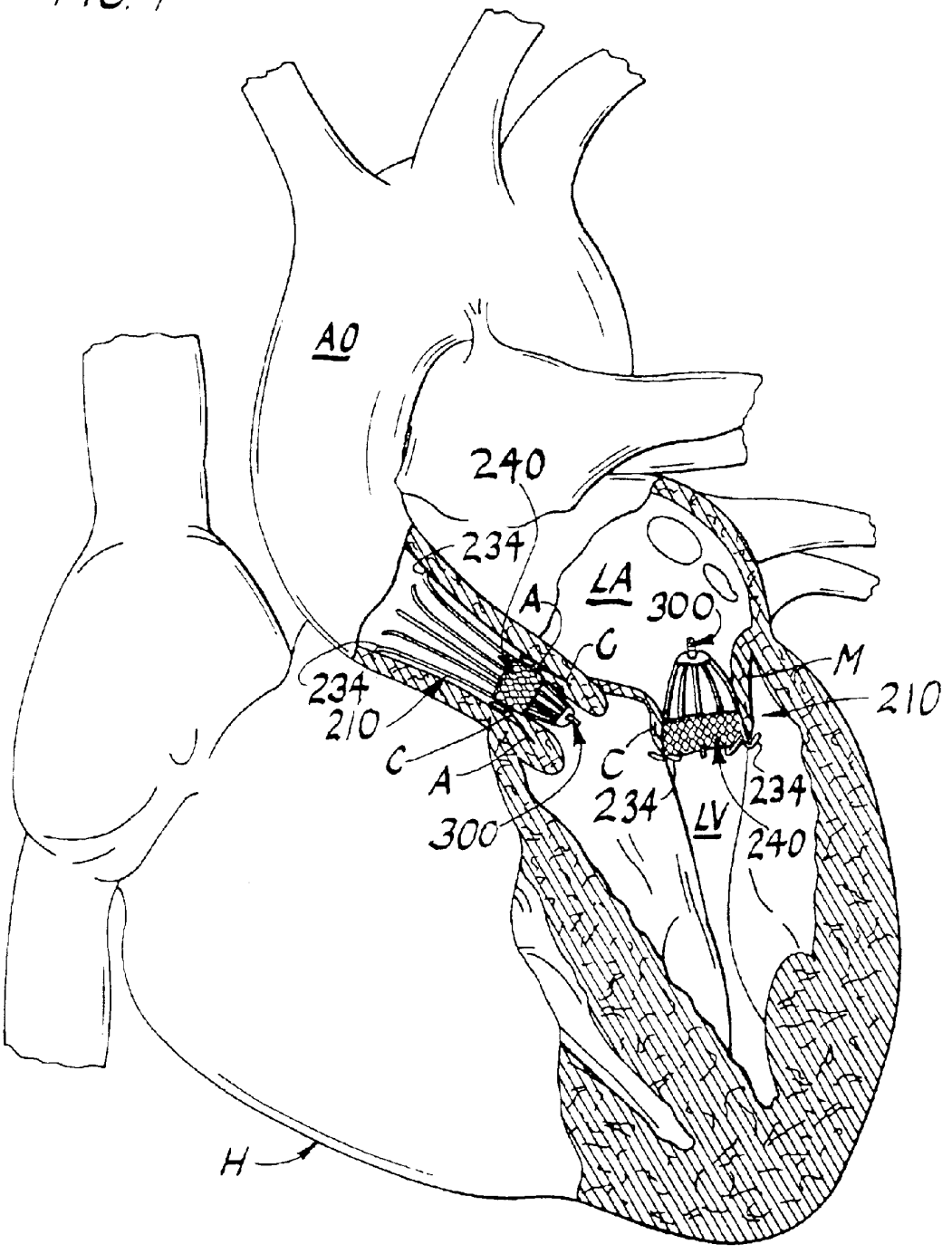


FIG.8

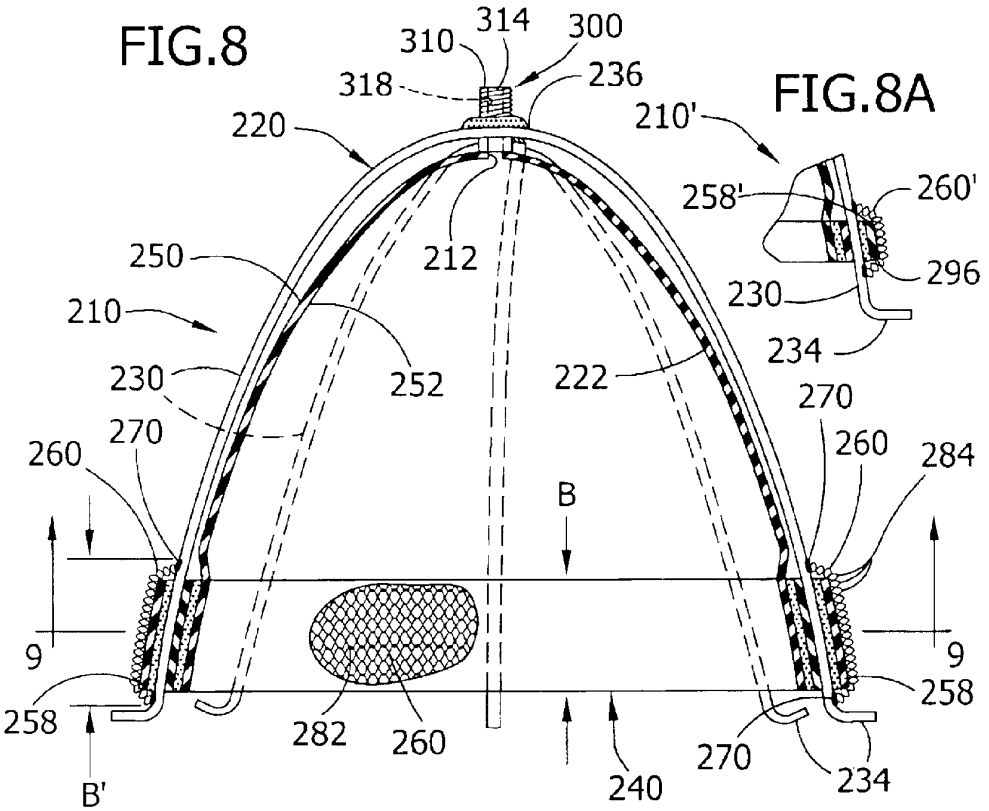


FIG.8A

FIG.9

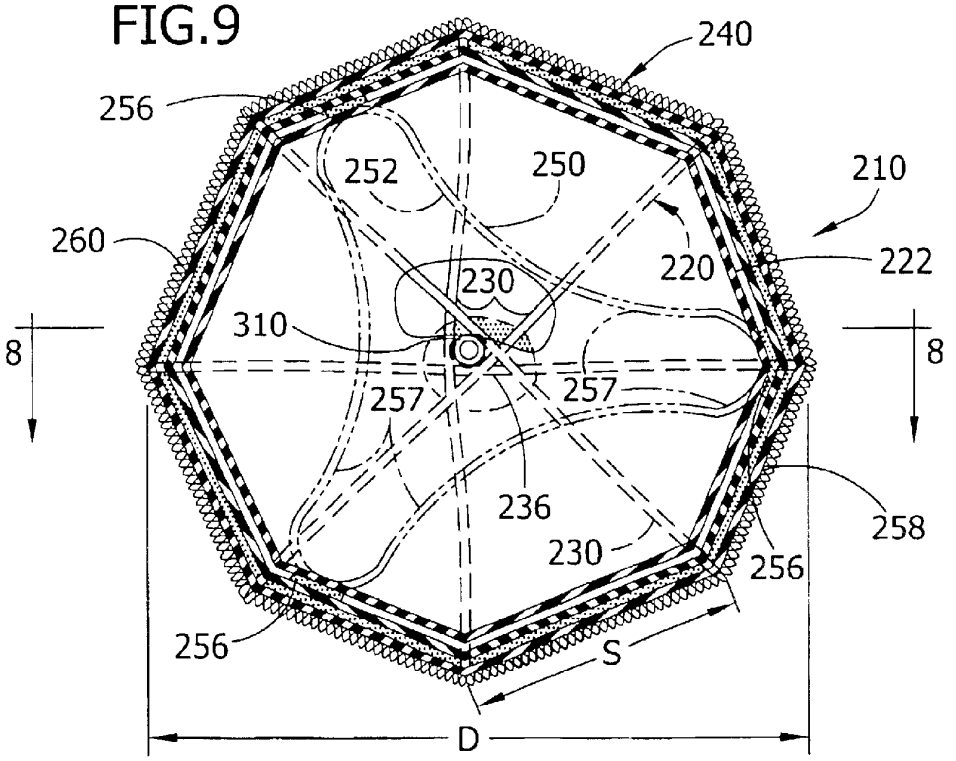


FIG. 10

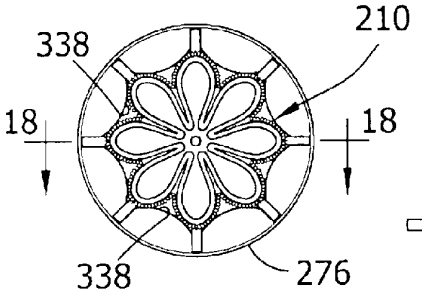


FIG. 11

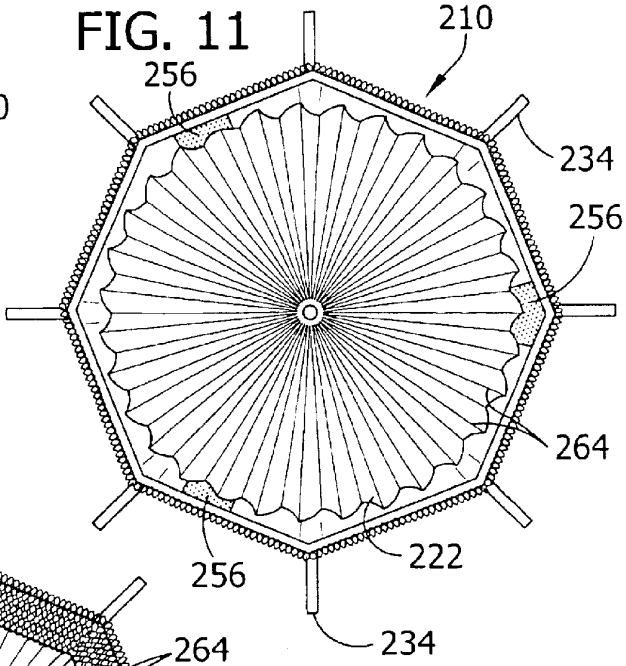


FIG. 12

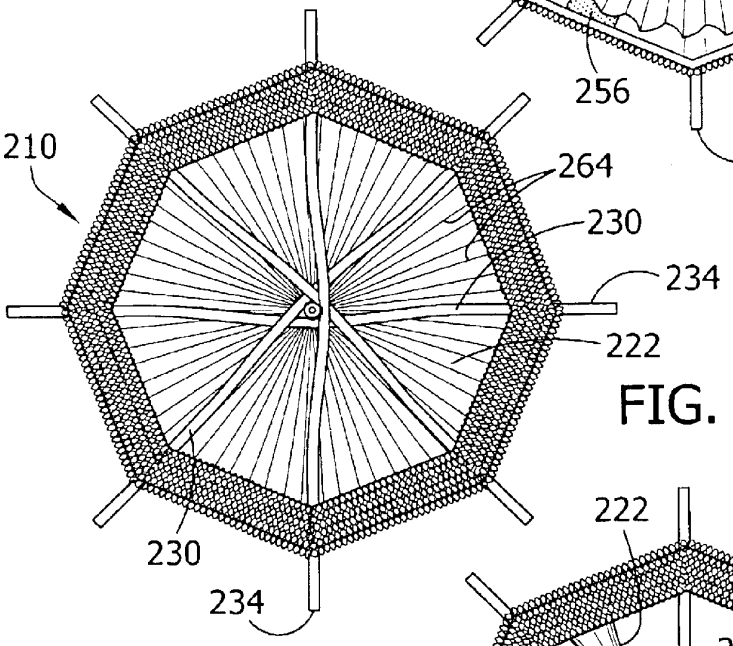


FIG. 13

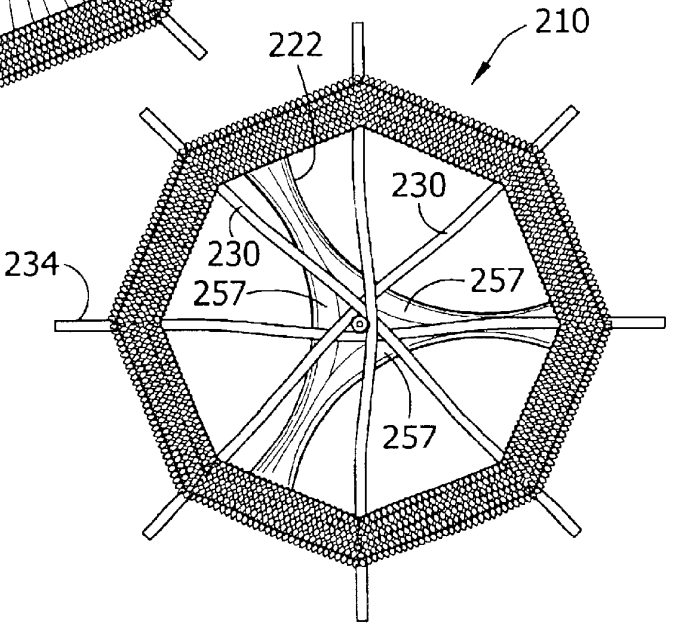


FIG. 14

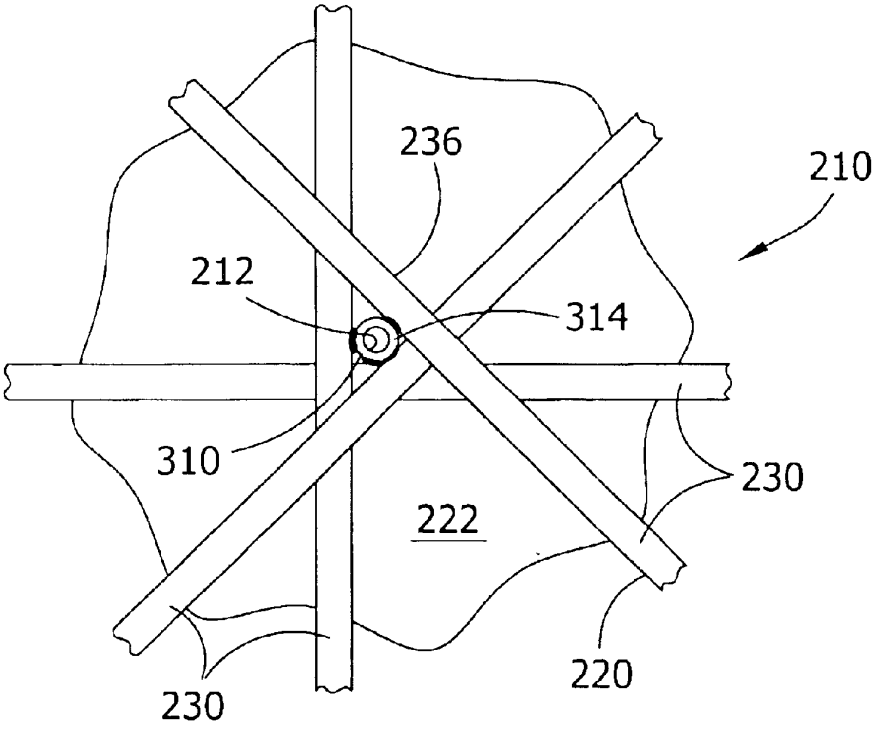


FIG. 15

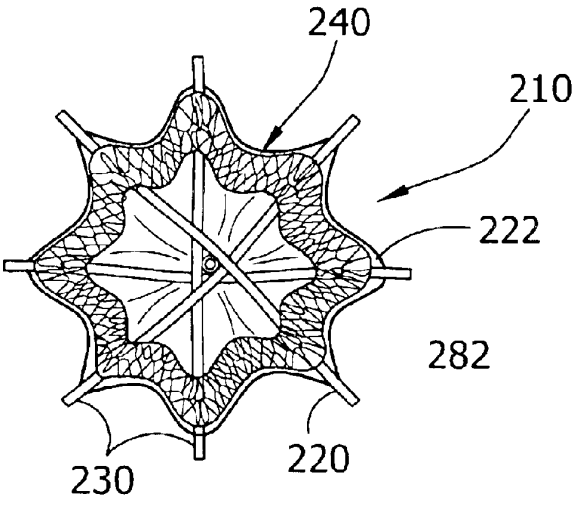


FIG. 16

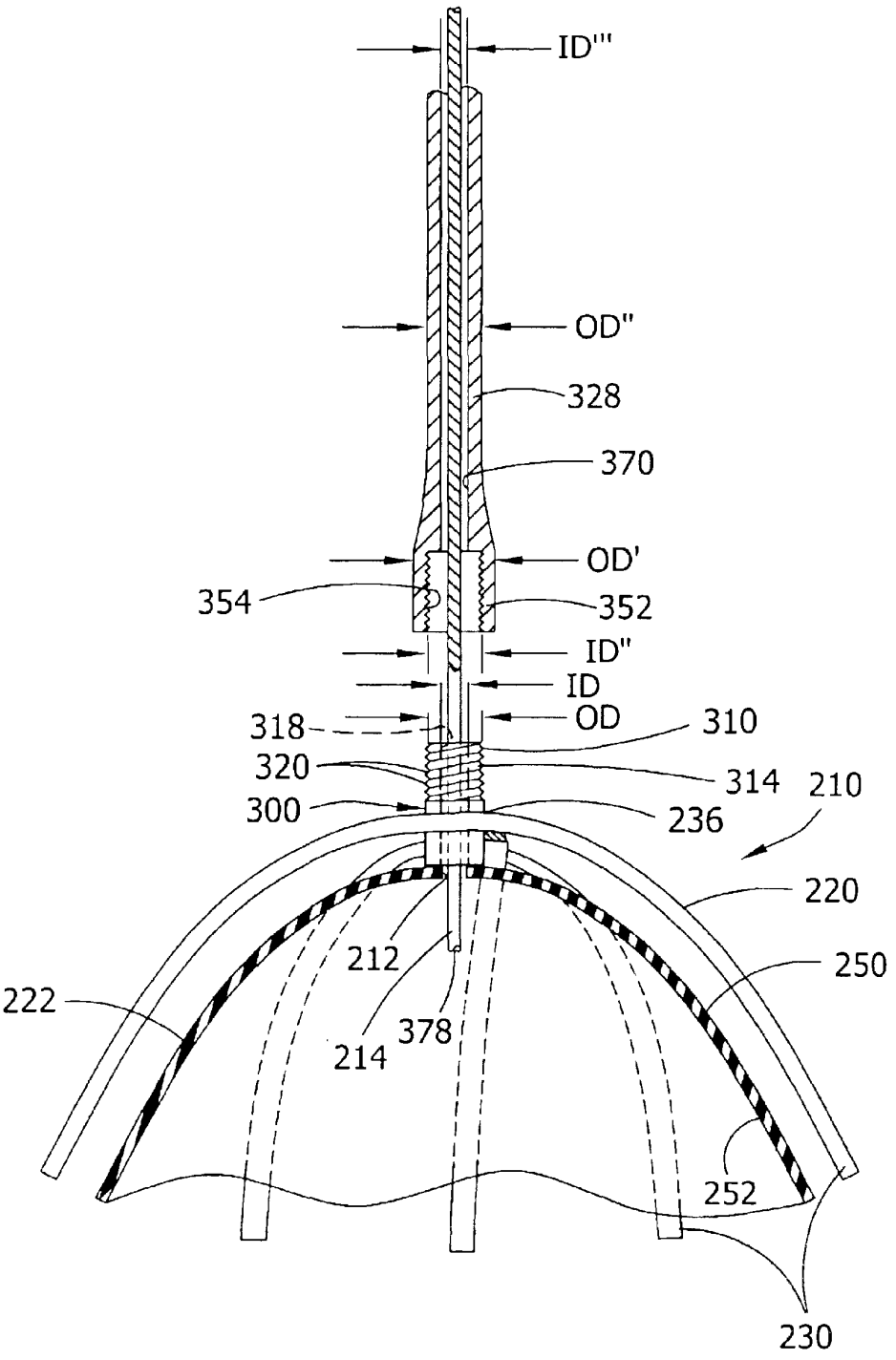
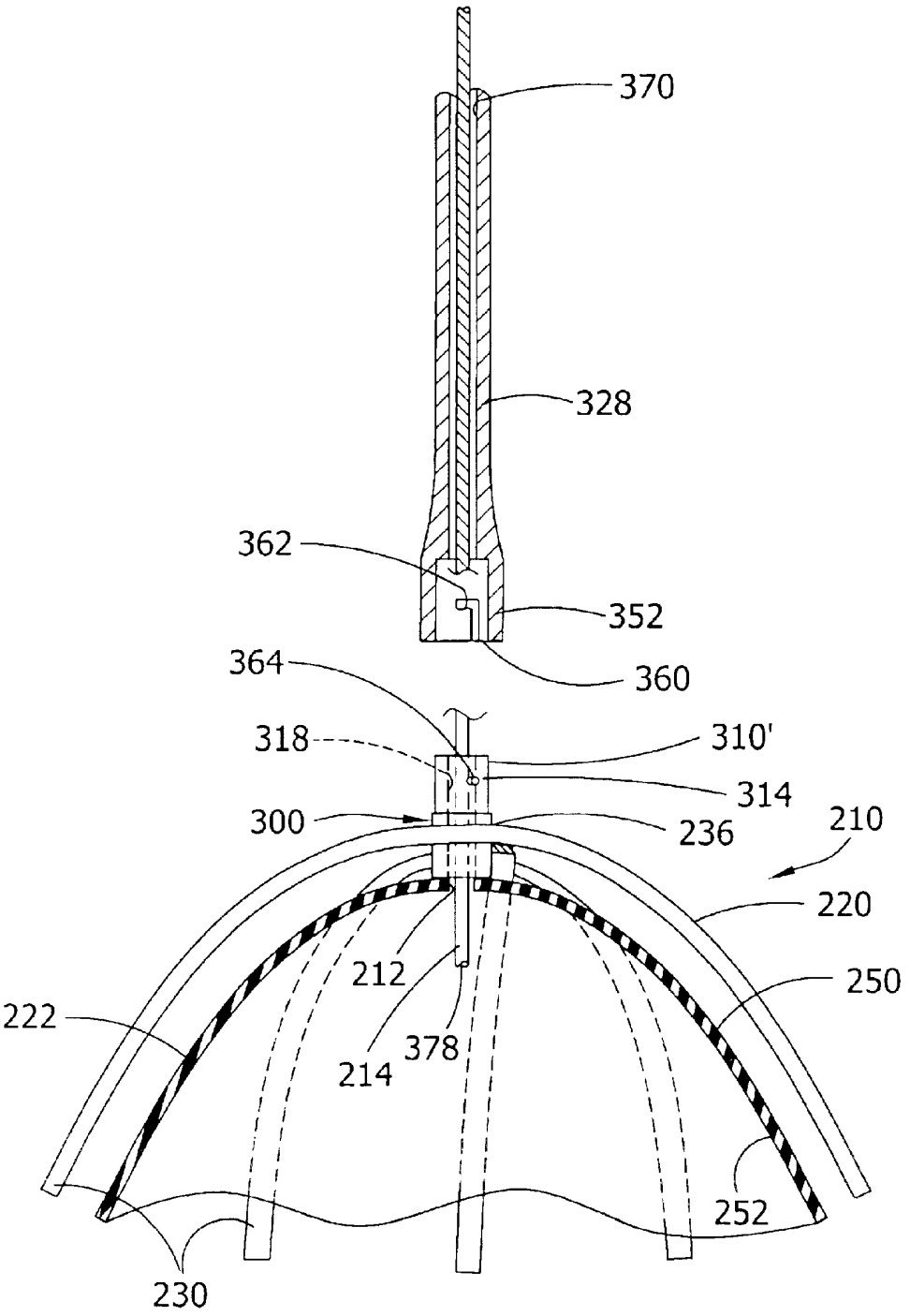


FIG. 17



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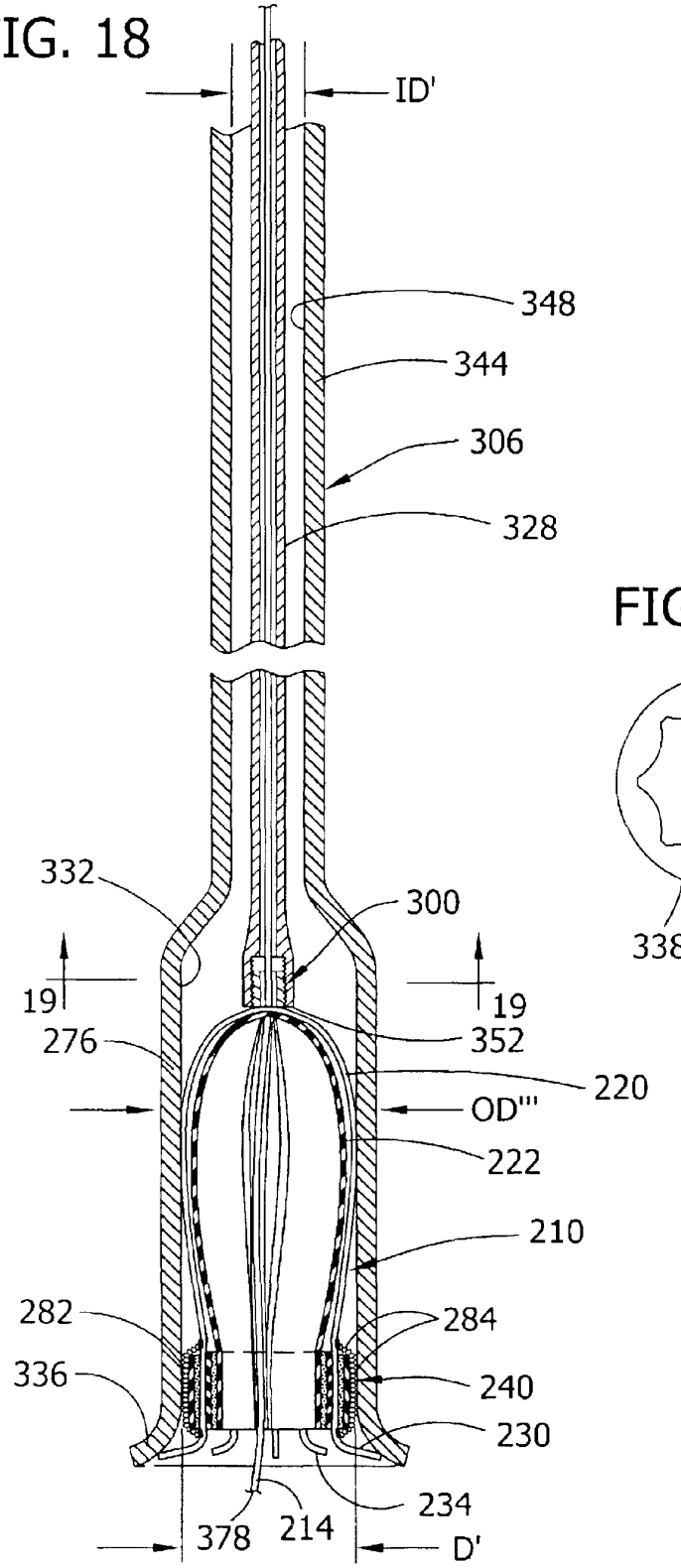
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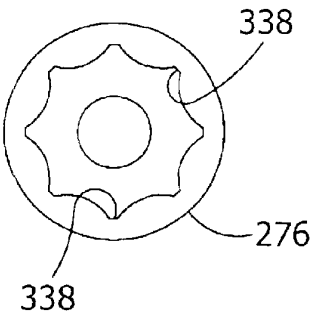
FIG. 19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ARTIFICIAL HEART VALVE, IMPLANTATION INSTRUMENT AND METHOD THEREFOR

CROSS-REFERENCE TO RELATED APPLICATION

This application is a continuation-in-part of Utility Patent application Ser. No. 09/775,360 filed Feb. 1, 2001, now U.S. Pat. No. 6,540,782, which claims benefit of Provisional Patent Application No. 60/179,853 filed Feb. 2, 2000, both of which are hereby incorporated by reference.

BACKGROUND OF THE INVENTION

The present invention relates generally to valve implants, and more particularly to artificial heart valves for repairing damaged heart valves.

A human heart has four chambers which alternately expand and contract to pump blood through the vessels of the body. The heart also includes a check valve at the upstream end of each chamber to ensure that blood flows in the correct direction through the body as the heart chambers expand and contract. These valves sometimes become damaged resulting in their inability to close when the downstream chamber contracts. When the valves do not close, blood flows backward through the valve resulting in diminished blood flow and lower blood pressure. The valves can also become damaged so they do not open sufficiently thereby resulting in diminished downstream blood flow.

Although replacement valves and surgical procedures have been developed to alleviate these conditions, they have significant drawbacks. Many earlier valves require invasive implantation techniques in which the chest is opened, the ribs are spread, the heart is paralyzed, and following cardiopulmonary bypass, the heart is cut open to implant the valve. These invasive techniques are stressful on the patient, increase the opportunity for infection and slow recovery. As a result, valves which may be implanted with non-invasive techniques have been developed. These valves are implanted by transluminal or endothoracoscopic techniques which reduce many of the drawbacks associated with invasive surgery. However, many of these valves also require the damaged native heart valve be removed prior to implanting the artificial valve. Removing the native valve increases the risk that a portion of the valve will migrate through the body and block vessels downstream from the heart.

Many mechanical and bioprosthetic valves have been developed to replace native heart valves. See C. A. Hufnagel, *Basic Concepts in the Development of Cardiovascular Prostheses,* 137 Am. J. of Surg. at 285–300 (1972). See also D. E. Harken et al., *Partial and Complete Prosthesis in Aortic Insufficiency*, 40 J. Thorac & Cdvsc Surg., no. 6., at 744–62 (1960). These valves include ball-valve prostheses, flap-valve prostheses, polymeric trileaflet synthetic valves, and bioprosthetic valves made from animal allograft tissues such as pig valves and preserved heterologous bovine and porcine pericardial tissue valves. See H. B. Lo et al., *A Tricuspid Polyurethane Heart Valve as an Alternative to Mechanical Prostheses or Bioprostheses,* 34 Trans. Am. Soc. of Art. Int. Organs at 839–44 (1988); and S. L. Hilbert et al., *Evaluation of Explanted Polyurethane Trileaflet Cardiac Valve Prostheses*, 94 J. Thorac & Cdvsc Surg. at 419–29 (1987). Most of the aforementioned valves require open chest surgery and cardiopulmonary bypass for implantation.

More recently percutaneous and transluminal implantation have been suggested. See Steven R. Bailey, *Percutaneous Expandable Prosthetic Valves* Textbook of Interventional Cardiology, chap. 75 (1995)(referencing work of Andersen et al.) See also Knudsen et al., *Catheter-implanted Prosthetic Heart Valves*, 6 Int'l J. of Art. Organs, no. 5, at 253–62 (1993); Knudsen et al. *Transluminal Implantation of Artificial Heart Valves. Description of New Expandable Aortic Valve and Initial Results With Implantation by Catheter Technique in Closed Chest Pigs*, 13 European Heart J. at 704–08 (1992); and U.S. Pat. No. 5,411,552 (Andersen). The Andersen device includes a heterologous pig valve mounted in an annular ring. Due to the size of this device, it must be implanted by direct abdominal aortic incision and entry. Further, the Andersen device requires a separate inflating balloon for its deployment. U.S. Pat. No. 5,397,351 (Pavcnik) describes an expandable caged poppet for percutaneous implantation in an aortic valve site. However, the size of the Pavcnik device makes percutaneous implantation difficult. U.S. Pat. No. 5,885,601 (Bessler) describes a transluminal valve implantation but does not describe the specific valve construction. The Bessler procedure includes excision, vacuum removal of the native valve, cardiopulmonary bypass and backflushing of the coronary arterial tree.

SUMMARY OF THE INVENTION

Among the several objects and features of the present invention may be noted the provision of an artificial heart valve which accommodates implantation without removing the damaged native heart valve; the provision of a valve which may be implanted using non-invasive surgery; the provision of a valve which permits implantation without the need for cardio-pulmonary bypass; the provision of a valve which permits implantation by conventional open chest surgery and cardio-pulmonary bypass; provision of a valve which allows for repositioning the valve during implantation; and the provision of a valve which allows for guiding the valve to the point of implantation along a guide.

Generally, an artificial valve of the present invention repairs a damaged heart valve having a plurality of cusps separating an upstream region from a downstream region. The artificial valve comprises a flexibly resilient frame sized and shaped for insertion in a position between the upstream region and the downstream region. The frame has a plurality of peripheral anchors for anchoring the frame in the position between the upstream region and the downstream region and a central portion located between the plurality of peripheral anchors. A flexible valve element attaches to the central portion of the frame having an upstream side facing the upstream region when the frame is anchored in the position between the upstream region and the downstream region and a downstream side opposite the upstream side facing the downstream region when the frame is anchored in the position between the upstream region and the downstream region. The valve element moves in response to a difference between fluid pressure in the upstream region and fluid pressure in the downstream region between an open position, in which the element permits downstream flow between the upstream region and the downstream region, and a closed position, in which the element blocks flow reversal from the downstream region to the upstream region. The valve element moves to the open position when fluid pressure in the upstream region is greater than fluid pressure in the downstream region, permitting downstream flow from the upstream region to the downstream region. The valve element moves to the closed position when fluid pressure in the downstream region is greater than fluid pressure in the upstream region, preventing flow reversal from the down-

stream region to the upstream region. An opening extends through at least one of the frame and the valve element for receiving an implement.

In a second embodiment of the present invention, an artificial valve includes a flexibly resilient frame having a plurality of peripheral anchors for anchoring the frame in the position between the upstream and the downstream region. A flexible valve element attaches to the frame having a convex upstream side and a concave downstream side. An opening extends through at least one of the frame and the valve element.

The present invention is also directed to a combination of an artificial valve, including a frame, a valve element, an opening and a flexible, elongate guide sized for receipt within the opening to guide the valve into position.

Another aspect of the present invention is directed to a combination of an artificial valve, including a frame and valve element, and an instrument including a holder, an elongate manipulator and an installer. The holder has a hollow interior sized for holding the artificial valve when the frame is in a collapsed configuration. The elongate manipulator attaches to the holder for manipulating the holder into position between the upstream region and the downstream region. The installer is received within the hollow interior of the holder and is releasably attachable to the frame of the artificial heart valve for maneuvering the artificial heart valve from the hollow interior of the holder into position between the upstream region and the downstream region.

The present invention is also directed to an endothoracoscopic method of inserting an artificial valve between a plurality of cusps of a damaged heart valve. The method comprises the steps of making an opening in a chest wall of a patient and making an incision in a heart of the patient. An end of an elongate instrument is inserted through the opening made in the chest wall and the incision made in the heart. The inserted end of the instrument is positioned adjacent the plurality of cusps of the damaged heart valve. An artificial valve is ejected from the end of the instrument positioned adjacent the plurality of cusps of the damaged heart valve into a position between the plurality of cusps of the damaged heart valve without removing the damaged heart valve from the heart. The artificial valve is then retrieved into the end of the instrument and the inserted end of the instrument is repositioned adjacent the plurality of cusps of the damaged heart valve. The repositioned artificial valve is ejected from the end of the instrument positioned adjacent the plurality of cusps of the damaged heart valve into position between the plurality of cusps of the damaged heart valve without removing the damaged heart valve from the heart.

Another aspect of the present invention is directed to a transluminal method of inserting an artificial valve between a plurality of cusps of a damaged heart valve, including the steps of ejecting, retrieving, repositioning and a second ejecting step. The method further comprises making an incision in a vessel leading to the heart and inserting an end of an elongate flexible instrument through the incision made in the vessel. The method further comprises pushing the end of the instrument through the vessel and positioning the end adjacent the plurality of cusps of the damaged heart valve.

The present invention is also directed to a transluminal method of inserting an artificial valve between a plurality of cusps of a damaged heart valve, including the steps of making, inserting and ejecting. The method further comprises inserting an end of a guide through the incision made in the vessel, pushing the guide through the vessel, threading an elongate flexible instrument having a hollow interior onto the guide and pushing the end of the instrument through the vessel along the guide until the end is adjacent the plurality of cusps of the damaged heart valve.

Other objects and features of the present invention will be in part apparent and in part pointed out hereinafter.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a front elevation of a heart in partial section showing two artificial valves of the present invention;

FIG. **2** is a vertical cross section of an artificial valve;

FIG. **3** is a cross section of the valve taken in the plane of line **3-3** of FIG. **2**;

FIG. **4** is a vertical cross section of an instrument for implanting a valve using an endothoracoscopic procedure of the present invention;

FIG. **5** is a vertical cross section of an instrument for implanting a valve using a transluminal procedure of the present invention;

FIG. **6** is a front elevation of a heart in partial section showing artificial valves of the present invention;

FIG. **7** is a front elevation of a heart in partial section showing two artificial valves of further embodiments of the present invention;

FIG. **8** is a front elevation of the artificial valve of FIG. **7** in partial section;

FIG. **8A** is an enlarged partial section of an alternative embodiment of the artificial valve illustrated in FIG. **8**;

FIG. **9** is a cross section of the valve of FIG. **8** taken in the plane of line **9—9** of FIG. **8**;

FIG. **10** is an enlarged end view of an instrument with an artificial valve;

FIG. **11** is a bottom plan of an artificial valve having a pleated valve member in its expanded configuration;

FIG. **12** is a top plan of the valve of FIG. **11**;

FIG. **13** is a top plan of the valve of FIG. **12** with the valve member collapsed inward to allow flow through the valve;

FIG. **14** is an enlarged partial top plan of the artificial valve of FIG. **8**;

FIG. **15** is a top plan of the artificial valve of FIG. **8** partially collapsed;

FIG. **16** is an enlarged partial section of an artificial valve and installer,

FIG. **17** is an enlarged partial section of an artificial valve and an installer of an alternative embodiment to that shown in FIG. **16**;

FIG. **18** is an enlarged section of an instrument with the artificial valve and installer taken in the plane of line **18-18** of FIG. **10**; and

FIG. **19** is a cross section of the instrument of FIG. **18** with the artificial valve and installer removed.

Corresponding reference characters indicate corresponding parts throughout the several views of the drawings.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring now to the drawings and in particular to FIG. **1**, artificial heart valves of the present invention are designated in their entireties by the reference numbers **10**A and **10**M. The artificial valve **10**A is specifically configured for repairing a damaged aortic valve A of a heart, generally designated by H. The artificial valve **10**M is specifically configured for repairing a damaged mitral valve M. In addition, an artificial

valve having a configuration similar to valve **10**A may be used to repair a damaged pulmonary heart valve (not shown), and a valve having a configuration similar to valve **10**M may be used to repair a damaged tricuspid heart valve (not shown). Each native heart valve (e.g., mitral valve M) normally has two cusps C (or three cusps in the case of the tricuspid valve) separating an upstream region (e.g., the left atrium LA) of the heart H from a downstream region (e.g., the left ventricle LV) of the heart positioned downstream from the upstream region. In use, the artificial heart valves (e.g., the artificial heart valve **10**M) are positioned between the upstream region and the downstream region, preferably between the cusps C of the respective native valve (e.g., the mitral valve M), to ensure blood flows through the heart H in the appropriate direction as will be explained in greater detail below.

As illustrated in FIG. **2**, the artificial valve **10**M comprises a flexibly resilient external frame, generally designated by **20**, and a flexible valve element, generally designated by **22**. The frame **20** includes a plurality of U-shaped stenting elements **30**. Each of the U-shaped elements **30** has a length extending between opposite ends. Although the elements **30** may have other lengths without departing from the scope of the present invention, the elements of the preferred embodiment have approximately equal lengths. Further, the elements **30** are joined generally midway between their respective ends at a junction **32** of the elements. Although four frame elements **30** are shown in FIGS. **2** and **3**, the valve **10**M may have fewer or more elements without departing from the scope of the present invention. Preferably, the stenting elements **30** are sufficiently compressible to permit the valve **10**M to be compressed to a configuration such as shown in FIG. **4** during implantation in the respective heart valve as will be explained below. Still further, the stenting elements **30** preferably are sufficiently resilient to hold the artificial valve **10**M in position between the cusps C of the native valve M after implantation and to hold the cusps of the native valve open. As used herein, the term "stenting" is intended to convey that the element **30** holds the cusps C of the native valve at least partially open.

Although the elements **30** of the preferred embodiment are made of nickel alloy wire, such as Nitinol superelastic alloy wire, available from Unitek Corp. of Monrovia, Calif., other materials may be used without departing from the scope of the present invention. The Nitinol may additionally include a PTFE (polytetrafluoroethylene) coating. Further, although the wire of the preferred embodiment has a rectangular cross section with dimensions of about 0.50 mm by about 0.762 mm, wires having other shapes and sizes may be used without departing from the scope of the present invention. In addition, the frame **20** may be of unitary construction. For instance, a small diameter tube of Nitinol or other appropriate material may have longitudinal slits extending from one end of the tube nearly to the opposite end, thereby forming multiple portions cantilevered from one end. Such cantilevered portions may be bent outward to form the frame of the artificial valve.

A peripheral anchor **34** is formed at each end of the frame elements **30**. As illustrated in FIG. **1**, these anchors **34** are used to attach the frame **20** between the plurality of cusps C of the damaged valve (e.g., the mitral valve M) in a position between an upstream region and a downstream region. Although other conventional anchor formations may be used without departing from the scope of the present invention, the anchors **34** of the preferred embodiment are hooks. It is envisioned the anchors **34** may also include conventional barbs (not shown) for preventing the hooks from being dislodged from the heart H after implantation. Further, as illustrated in FIG. **2**, in the most preferred embodiment the hooks form an angle B of between about 55 degrees and about 80 degrees with the ends of the frame elements **30**. In addition, the frame **20** includes a central portion, generally designated by **36**, located between the plurality of peripheral anchors **34**.

As further shown in FIG. **2**, a band, generally designated by **40**, extends around the frame **20** between each of the frame elements **30**. The band **40** extends between each frame element **30** and an adjacent frame element to limit maximum spacing S between the frame elements and to shape and cooperate with the elements to create a structurally sound frame construction. The band **40** permits the frame elements **30** to be pushed together so the flexibly resilient frame **20** can be collapsed to a collapsed configuration as shown in FIGS. **4** and **5**. Depending upon the procedure which is intended to be used when implanting the valve, the frame **20** collapses to configurations having different maximum widths X. For instance, if the artificial valve (e.g., **10**M) is implanted using endothoracoscopic methods, the maximum width X is less than about 18 mm and more preferably between about 12 mm and about 18 mm. However, if the valve (e.g., the artificial valve **10**A) is implanted through a smaller blood vessel, such as transvenously or transluminally, the maximum width X must be smaller. For instance, the maximum width X must be between about 4 mm and about 8 mm, more preferably between about 6 mm and about 8 mm and still more preferably about 6 mm. Thus, the frame **20** is sized and shaped for insertion between the plurality of cusps C of the damaged heart valve in a position between an upstream region and a downstream region. Further, because the frame **20** is flexible, it expands to an expanded configuration as shown In FIG. **2** when not collapsed. When in the expanded configuration, the frame **20** has different sizes depending upon which native valve it is intended to replace. For instance, if the artificial valve is intended to repair a damaged mitral valve M or a tricuspid valve, the opposite ends of the frame elements **30** are spaced by a distance D of between about 2 cm and about 5 cm. If the artificial valve is intended to repair a damaged aortic valve A or a pulmonary valve, preferably the opposite ends of the frame elements **30** are spaced by a distance D of between about 2 cm and about 3 cm.

Although the band **40** may be made of other materials, such as heterologous animal pericardium (e.g., bovine or porcine pericardium) or autologous tissue engineered substrates, without departing from the scope of the present invention, the band of the preferred embodiment is made of a biocompatible, radiopaque, elastic material such as silicone rubber or polyurethane or polytetrafluoroethylene. Further, although the band **40** may have other constructions without departing from the scope of the present invention, the band of the preferred embodiment comprises an internal strip **42** and an external strip **44** joined in face-to-face relation. Although the band **40** may be attached to the frame elements **30** by other means, in the most preferred embodiment, the internal and external strips **42**, **44**, respectively, are adhesively bonded to the frame elements and to each other. Further, although the band **40** illustrated in FIG. **2** is substantially cylindrical, it is envisioned the band may have other shapes without departing from the scope of the present invention. For example, it is envisioned the band **40** may include a rim or flange (not shown) surrounding the valve adjacent the hooks for engaging the cusps C. It is also envisioned that an exterior surface of the band **40** may include a continuous or interrupted sheath of

Dacron® velour material, porous PTFE (polytetrafluoroethylene) felt or the like to provide sites for vascular connective tissue ingrowth to enhance stability of the device after its implantation. (Dacron is a U.S. federally registered trademark of E.I. duPont de Nemours and Company of Wilmington, Del.)

The flexible valve element **22** is disposed within the frame **20** and attached to the central portion **36** of the frame. The valve element **22** has a convex upstream side **50** facing an upstream region (e.g., the left atrium LA) when the frame **20** is anchored between the cusps C of the damaged heart valve (e.g., mitral valve M) in a position between the upstream region and a downstream region; and a concave downstream side **52** opposite the upstream side facing the downstream region (e.g., the left ventricle LV) when the frame **20** is anchored between the cusps of the damaged heart valve in a position between the upstream region and the downstream region. The valve element **22** moves in response to differences between fluid pressure in the upstream region and the downstream region between an open position (as shown in phantom lines in FIG. **3**) and a closed position (as shown in solid lines in FIG. **3**). When the valve element **22** is in the open position, with the valve element **22** collapsed inward, it permits flow between the upstream region and the downstream region. When in the closed position, with the valve element **22** extended outward, the element **22** blocks flow between the upstream and downstream regions. The valve element **22** moves to the open position, with the element collapsed inward, when fluid pressure in the upstream region is greater than fluid pressure in the downstream region to permit downstream flow from the upstream region to the downstream region. The valve element **22** moves to the closed position, with the element extended outward, when fluid pressure in the downstream region is greater than fluid pressure in the upstream region to prevent flow reversal from the downstream region to the upstream region. Although the valve element **22** may be made of other materials without departing from the scope of the present invention, the valve element of the preferred embodiment is made of a biocompatible elastic material such as silicone rubber, polyurethane, PTFE, heterologous animal pericardium (e.g., bovine or porcine pericardium), or autologous tissue engineered substrates. Further, although the valve element **22** may have other thicknesses without departing from the scope of the present invention, the valve element of the preferred embodiment has a thickness of between about 0.127 mm and about 0.381 mm. In addition, it is envisioned the valve element **22** may be longitudinally pleated, as discussed in more detail below, without departing from the scope of the present invention (FIGS. **11–13**). Without wishing to be bound by any particular theory, it is envisioned that longitudinal pleats may encourage laminar flow through the valve when in the open position, with the valve element collapsed inward.

The upstream side **50** of the flexible valve element **22** has an apex **54** which is attached to the frame **20** at the junction **32** of the elements **30**. As illustrated in FIG. **3**, the flexible valve element **22** is attached to the central portion **36** of the frame **20** at a position substantially centered between the anchors **34**. Although the valve element **22** may be attached to the frame **20** by other means without departing from the scope of the present invention, the valve element of the preferred embodiment is attached to the frame by adhesive bonding. Further, the flexible valve element **22** is attached to the frame **20**, and more particularly to the band **40**, at several attachment points **56** around the frame. Thus, the valve element **22** forms flaps **58** extending between adjacent attachment points **56**. Each of the flaps **58** and a corresponding portion of the band **40** extending between adjacent attachment points **56** defines an opening **60** through the valve when the valve element **22** moves to the open position, with the flaps of the valve element collapsed inward. The artificial valve depicted in FIG. **3** depicts the preferred flap configuration, having three attachments points **56** and three flaps **58** spaced around the frame **20**. It is contemplated that other numbers of attachment points **56** (e.g., 2, 4, 5, 6, etc.) may be used without departing from the scope of the present invention. Although the valve element **22** may be attached to the band **40** using other means, the valve element of the preferred embodiment is attached to the band by adhesive bonding.

As illustrated in FIGS. **4** and **5**, the artificial valves **10**M, **10**A, respectively, are used in combination with instruments, generally designated by **70**M, **70**A, for inserting the artificial valve between the cusps C of damaged heart valves M, A. The instrument **70**M shown in FIG. **4** is intended for use when implanting the valve **10**M using an endothoracoscopic or transluminal procedure. It is envisioned this instrument would be used primarily when implanting an artificial valve in the mitral valve M, however similar instruments could be used to implant artificial valves in other native valves of the heart H such as the tricuspid or pulmonary valves. When used to implant an artificial valve in a mitral, tricuspid or pulmonary valve, the instrument could be introduced through a jugular or femoral vein. The endothoracoscopic instrument **70**M comprises a tubular holder **72**, and an elongate tubular manipulator **74** attached to the holder for manipulating the holder into position. Further, the instrument **70**M includes an ejector, generally designated by **76**, positioned in a hollow interior **78** of the holder **72** for ejecting the artificial heart valve **10**M from the holder. The hollow interior **78** of the holder **72** is sized for holding the artificial valve **10**M when the frame **20** is in the collapsed configuration (e.g., less than about 18 mm). Further, the hollow interior **78** may have axial grooves for receiving the anchors **34** of the valve to prevent the anchors from being tangled during valve implantation. Such grooves are described in greater detail below with respect to another embodiment. The manipulator **74** is a flexible tube attached to the holder **72** for manipulating the holder through an incision made in the heart H or selected vessel and into position adjacent the plurality of cusps C of the damaged heart valve. The ejector **76** includes a flat plunger tip **80** which engages the valve **10**M, a push rod **82** attached to the tip for moving the tip forward in the holder **72** for ejecting the valve from the holder, and a handle **84** attached to the push rod opposite the plunger tip for gripping the ejector when ejecting the valve from the holder.

To implant an artificial valve **10**M using the instrument **70**M via an endothoracoscopic procedure, a small opening is made in a chest wall (or another vascular access site) of a patient and a small incision is made in a heart H of the patient. The holder end **86** of the instrument **70**M is inserted through the opening made in the chest wall and the incision made in the heart H. The inserted end **86** of the instrument **70**M is positioned adjacent the cusps C of the damaged heart valve M and the artificial valve **10**M is ejected from the end of the instrument into a position between the cusps of the damaged valve as shown in FIG. **1**. When ejecting the valve **10**M from the end **86** of the instrument **70**M, it is envisioned that the handle **84** of the ejector **76** will be held in place while the manipulator **74** and holder **72** are withdrawn to push the valve out of the holder. Once the valve **10**M is in position, the instrument **70**M is withdrawn from the chest (or

another vascular access site) before the opening and incision are closed using conventional procedures. As will be appreciated by those skilled in the art, the valve **10**M may be implanted using this procedure with minimal trauma to the heart H and without removing the damaged heart valve from the heart.

The instrument **70**A shown in FIG. **5** is intended for use when implanting the valve **10**A by a transluminal procedure through a vessel. It is envisioned this instrument **70**A would be used when implanting an artificial valve in the aortic valve A. When used to implant an artificial valve **10**A in an aortic valve A, the instrument **70**A could be introduced through a femoral artery. The instrument **70**A comprises a holder **90** having a hollow interior **92** sized for holding the artificial valve **10**A when the frame **20** is in the collapsed configuration (e.g., less than about 6 mm) and an elongate flexible manipulator **94** attached to the holder for manipulating the holder through a vessel and into position adjacent the plurality of cusps C of the damaged heart valve A. Further, the instrument **70**A has a flexible ejector, generally designated by **96**, mounted in the hollow interior **92** of the holder **90** for ejecting the artificial heart valve **10**A from the hollow interior of the holder into position between the cusps C of the damaged heart valve A. The manipulator **94** is used to manipulate the instrument **70**A through the vessel. The ejector **96** includes a flat plunger tip **100** which engages the valve **10**A, a push rod **102** attached to the tip for moving the tip forward in the holder **90** for ejecting the valve from the holder, and a handle **104** attached to the push rod opposite the plunger tip for gripping the ejector when ejecting the valve from the holder. Both manipulators **74**,**94** may be configured to be long and flexible enough to be pushed or pulled through a vessel and/or over a conventional guidewire as discussed in greater detail below.

To implant an artificial valve **10**A using a transluminal procedure with instrument **70**A, a small incision is made in a vessel (e.g., the femoral artery) leading to a heart H. An end **106** of the instrument **70**A having the holder **90** is inserted through the incision made in the vessel and the end is pushed through the vessel and over a guidewire until the end is adjacent the cusps C of the damaged heart valve A. Once in position, the artificial valve **10**A is ejected from the end **106** of the instrument **70**A between the cusps C of the damaged heart valve A. As with the endothoracscopic procedure described above, the transluminal procedure may be performed with minimal trauma to the heart H and without removing the damaged heart valve from the heart and without cardiopulmonary bypass or heart arrest.

A second embodiment of the aortic valve is generally designated by **10**A' in FIG. **6**. This second embodiment is identical to the aortic valve of the first embodiment except that it includes a second band **110** surrounding the frame **20** downstream from the first band **40**. The second band **110** permits the frame elements **30** to be pushed together so the frame **20** can be collapsed to the collapsed configuration, but limits the maximum spacing between adjacent frame elements. It is envisioned that the second band **110** may be constructed similarly to the first band **40** and may be made from similar materials to the first band. As will be appreciated by those skilled in the art, the second band **100** of the aortic valve **10**A' supports the tissue surrounding the downstream region (i.e., the ascending aorta) and prevents the tissue from distending. An opening **112** provided between the first and second bands **40**, **110**, respectively, corresponds to openings of the right and left coronary arteries (designated by RC, LC, respectively) which enter the aorta immediately above the cusps C of the native valve so the replacement valve does not obstruct blood flow through these openings. Although the opening **112** may have other widths O without departing from the scope of the present invention, in one embodiment the opening has a width of between about 5 mm and about 10 mm. Although the second band **110** may have other lengths L without departing from the scope of the present invention, in one embodiment the second band **110** has a length of between about 6 cm and about 12 cm. It is further envisioned that hooks (not shown) may be provided along the frame elements **30** adjacent the second band **110** to engage the tissue to further prevent distention of the tissue.

In yet another embodiment of the present invention illustrated in FIGS. **8** and **9**, an artificial heart valve of another embodiment of the present invention, generally indicated by **210**, includes a flexibly resilient frame, generally indicated by **220**, having a plurality of peripheral anchors **234** for anchoring the frame in an expanded configuration, generally as set forth above. The flexibly resilient frame **220** includes frame elements **230** biased outward as set forth above. A central portion **236** of the frame **220** is centrally located between the plurality of peripheral anchors **234** of the frame. In addition, the artificial heart valve **210** includes a flexible valve element **222** attached to the central portion **236** of the frame having a convex upstream side **250** and a concave downstream side **252** opposite the upstream side. The valve element **222** moves in response to fluid pressure between an open position, with the valve element collapsed inward, and a closed position, with the element extended outward.

In addition, the artificial valve **210** may include a band, generally indicated by **240**, extending around the frame elements **230** to limit outward movement of the frame elements to the expanded configuration and to sealingly engage adjacent heart H tissue (FIGS. **7** and **8**). In one embodiment, the band **240** includes an inner portion **258** and an outer portion **260**. The inner portion **258** is formed to limit outward movement of the frame elements **230** and to act as a sealing surface for the valve element **222** in its closed position, where the element extends outward to seal against the inner portion. The outer portion **260** at least partially surrounds the inner portion **258** and has a memory, such that when the frame elements **230** are forced inward to a collapsed configuration, the outer portion urges the inner portion inward to a position inside the frame elements. Preferably, the frame elements **230** are biased outward by a spring force sufficient to overcome the inward force of the outer portion **260**, so that the frame elements maintain the frame **220** in the expanded configuration. The flexible valve element **222** is attached to the frame **220**, and more particularly to the band **240**, at several attachment points **256** around the frame. Thus, the valve element **222** forms flaps **257** extending between adjacent attachment points **256**. The preferred embodiment of the valve, shown in FIG. **13**, has three attachment points **256** and three flaps **257**. It is contemplated that other numbers of attachment points **256** (e.g., 2, 4, 5, 6, etc.) may also be used without departing from the scope of the present invention. FIG. **13**, however, shows a preferred embodiment having three equally spaced attachment points **256**, forming three flaps **257**. This configuration is thought to provide the maximum flow of blood through the valve **210** while maintaining flaps **257** that will close quickly when required. Flaps **257** of the three-flap preferred embodiment are also configured to be an optimal length circumferentially. The length of such flap **257** in the closed position, with the element extended outward, is approximately equal to 2.09r, where r is the radius of the valve. In the open position, with the valve element **222**

collapsed inward, the ideal length for the valve flap **257** is 2r, which is approximately equal to 2.09r. The substantial congruence of these two lengths (2r and 2.09r) facilitates proper support of the valve element **222** without undue stress due to incongruence of optimal flap length between the open and closed positions.

In addition, it is envisioned the valve element **222** may be longitudinally pleated as depicted in FIGS. **11–13**. Pleats **264** encourage proper folding of the valve element **222** when the valve **210** collapses (FIG. **10**). The pleats **264** may be of a wide range of numbers and spacing. For example, the valve **210** of FIGS. **10** and **11** includes a valve element **222** having many pleats of uniform size and shape. The number of pleats **264** may be reduced or increased from what is shown in FIGS. **11** and **12**, without departing from the scope of the present invention. Moreover, the spacing between the pleats **264** may be altered. For example, for an element **222** having pleats **264**, half of the pleats may have wide spacing while the other half may have narrow spacing. These pleats may be alternated, for example, wide-narrow-wide-narrow etc. Other combinations of pleats **264** having relatively different spacing are also contemplated as within the scope of the present invention. Without wishing to be bound by any particular theory, it is envisioned that longitudinal pleats **264** may encourage laminar flow through the valve when in the open position, with the valve element **222** collapsed inward, as shown in FIG. **13**.

The inner portion **258** preferably has a width B between about 4.0 mm and about 6.0 mm. The opposite sides of the band **240** are preferably spaced by a distance D of between about 21 mm and about 33 mm, depending upon the intended application of the artificial valve **210**. This yields an artificial valve **210** with a perimeter in the expanded configuration of between about 60 mm and about 100 mm. In the collapsed configuration, the opposite sides of the band **240** are preferably spaced by a distance of no more than between about 6.0 mm and about 8.0 mm.

The inner portion **258** may comprise a material selected from the group consisting of PTFE, Dacron® velour material, Dacron® porous cloth, a synthetic polymer and biological source tissue. Alternately, non-synthetic materials may be used for the inner portion **258**. Heterologous preserved tissues from bovine or porcine pericardium may be used as disclosed above. In addition, autologous tissues (i.e., those derived from a patient's own tissue) may be used as a substitute for synthetic or heterologous tissues. It is envisioned that the previously described band **240** and flexible valve element **222**, described below, could be made from autologous tissues, thereby eliminating the possibility of immune system or foreign body rejection complications sometimes caused by synthetic material or heterologous tissue.

The outer portion **260** has a width B' that is substantially similar, yet slightly wider than the inner portion. This larger width B' allows the outer portion **260** to attach to the frame elements **230** at several contact points **270** outside the opposite edges of the inner portion **258**. The outer portion **260** preferably attaches to the frame elements **230** by laser welding, epoxy bonding or other means as would be readily understood by one skilled in the art, such that the outer portion **260** can move independent from the inner portion **258**. Therefore, when the artificial valve **210** collapses or expands, the outer portion **260** and inner portion **258** are free to move independently, without binding upon one another. The outer portion **260** urges the inner portion **258** inward between the frame elements as shown in FIG. **15**. This ensures that the inner portion **258** of the band **240** folds into the proper shape upon collapse of the artificial valve **210**. The purpose of the outer portion **260** of the band **240** is to prevent the inner portion **258** from protruding outward beyond the frame elements **230** when the artificial valve **210** is collapsed. Without the outer portion **260**, segments of the inner portion **258** located between the frame elements **230** would be free to flex either inward or outward as the frame elements **230** move inward. With the outer portion **260**, the inner portion folds inward between the frame elements **230**. The outer portion **260** essentially prevents the inner portion **258** from prolapsing outwardly as the valve collapses, which could impede loading of the artificial valve **210** into a holder **276**, as will be described below. Folding the inner portion **258** inward also provides a smaller distance D between opposite sides of the band **240** when the artificial valve **210** is in the collapsed configuration. Moreover, the outer portion **260**, due to its inherent material properties, provides a lower friction surface for the artificial valve **210** as it moves to and from the holder **276**.

The outer portion **260** preferably comprises a braided mesh **282**, in which thin filaments **284** are braided into a woven fabric (FIGS. **8** and **9**). Such filaments **284** each preferably have a thickness of between about 0.05 mm and about 0.13 mm. The filaments **284** may comprise Nitinol superelastic alloy, stainless steel alloy, Elgiloy® alloy (available from Elgin National Watch Company of Elgin, Ill.), fiberglass, PTFE, polyester or Lycra® (available from E.I. duPont de Nemours and Company of Wilmington, Del.). The thin filaments **284** of the mesh **282** preferably move freely with respect to one another, such that the mesh may change its shape and size as the artificial valve **210** moves between its expanded and collapsed configurations. Where the material of the braided mesh **282** is a metal with shape memory, the outer portion **260** may be heat treated to set the unrestricted perimeter of the braided mesh to be smaller than the size of the desired collapsed configuration. Treating the braided mesh **282** to constrict to smaller than the collapsed configuration ensures that the braided mesh continues to exert a compressive force upon the artificial valve **210** irrespective of valve configuration. Therefore, for an artificial valve **210** having a collapsed dimension of between about 6.0 mm and about 8.0 mm, the braided mesh **282** preferably is heat treated to a dimension less than the collapsed valve dimension. Thus, by heat treating the braided mesh **282** of the outer portion **260** as described above, it biases the inner portion **258** and frame elements **230** inward in all configurations. Such inward forces caused by the outer portion **260** oppose the outward spring forces of the frame elements **230**. As such, the outwardly directed force of the frame elements **230** are preferably greater than the inwardly directed force of the band **240** to ensure the artificial valve **210** will expand to its expanded configuration when released from its holder **276**.

In an alternative embodiment depicted in FIG. **8**A, the valve **210'** comprises a thin strand **296**, instead of a band **240**, extending around the frame elements **230** to limit outward movement of the frame elements to their expanded configuration. The thin strand **296** functions in primarily the same way as the band **240**. The strand **296** includes an inner portion **258'** and an outer portion **260'** substantially as disclosed above with respect to the band **240**. The valve **210'** of the alternative embodiment is identical to the valve **210** of the previously described embodiment in all other respects.

The frame **220** preferably includes a post **310**, or more generally a mount, generally indicated by **300**, for selectively connecting the artificial valve **210** to an instrument,

generally indicated by **306** (FIG. **18**). In one embodiment, the post **310** mounts on the frame **220** (FIGS. **8**, **14**, **16** and **17**) and includes an opening **212** (FIG. **14**) to allow an implement **214**, such as a guide, or guidewire, as depicted in FIG. **16** and described in detail below, to pass through the valve **210**. The opening **212** extends through at least one of the frame **220** and the valve element **222** for receiving the implement **214** (FIGS. **8** and **16**). Although the opening **212** of the illustrated embodiment extends through the central portion **236** of the frame **220** and the valve element **222**, it is envisioned that the opening **212** could extend through other portions of the artificial valve **210** without departing from the scope of the present invention. After removal of the implement **214**, it is envisioned the opening **212** may provide surface washing to reduce a potential for blood to coagulate adjacent the downstream side (i.e., the concave side **252**) of the valve element **222**. It is further envisioned the opening **212** may be used even where an implement **214** is not needed to reduce potential for blood to coagulate adjacent the valve element **222**. Although this opening **212** may have other dimensions without departing from the scope of the present invention, in one embodiment the opening has a width of between about 0.5 mm and about 1 mm, and more preferably a width of about 1 mm.

The post **318** may additionally include a releasable fastener **314**. For example, the post **318** may include threads **320** (FIG. **16**) for attaching the valve **210** to the instrument **306**. Either the inside or outside of the post **318** may be threaded, but is preferably externally threaded, as shown in FIGS. **8** and **16**. Preferably, the post **318** has an inner diameter ID of about 1.0 mm (FIG. **16**) and an outer diameter OD of about 2.0 mm. The post **318** is also preferably right-hand threaded, although left-hand threads are contemplated as being within the scope of the present invention.

As illustrated in FIG. **18**, the instrument **306** of the present invention further includes the holder **276**, having a hollow interior **332** sized for holding the artificial valve **210** when the frame **220** of the valve is in the collapsed configuration. The holder **276** includes an outwardly flared end **336** for receiving the peripheral anchors **234** while the artificial valve **210** is within the holder. This shields the anchors **234** from engaging valvular or endocardial structures as the artificial valve **210** is retrieved into the holder **276** for repositioning, as will be discussed in greater detail below. In addition, the flared end **336** facilitates receiving the artificial valve **210** within the holder **276** by creating a smooth and gradual entry for the valve, such that the frame elements **230** may collapse more easily as the artificial valve is pulled into the holder by the instrument **306**. The holder **276** additionally includes internal, longitudinal grooves **338** extending the length of the holder (FIGS. **10** and **19**). This grooving **338** helps guide the frame elements **230** and anchors **234** into individual grooves as the valve **210** is ejected from or retrieved into the holder **276**. By providing a groove **338** for each frame element **230**, the valve **210** will collapse uniformly within the holder **276**, thereby ensuring that the valve element **222** collapses properly, as shown in FIG. **10**. The holder **276** is formed from a material sufficiently strong to limit outward movement of the frame elements **230** when the valve **210** is in the holder. An artificial valve **210** of the present invention is preferably collapsible to its collapsed configuration such that the dimension D' of the artificial valve is about 5 mm to about 8 mm. Thus, the holder **276** requires an inner dimension D' of at least about 5 mm to about 8 mm to receive the artificial valve **210** in its collapsed configuration. It is contemplated that the holder **276** will have an outer dimension OD'" of about 6 mm to about 9 mm along most of its length. The outwardly flared end **336** is formed to have a slightly larger dimension than the holder **276** (e.g., about 7 mm to about 10 mm) to accommodate the anchors **234**. Although the holder **276** must be sufficiently strong to limit outward movement of the frame elements **230**, once the valve **210** is removed, the holder may collapse slightly as it is removed from the body to ease its removal.

The instrument **306** further comprises an elongate manipulator **344** extending from the holder **276** for manipulating the holder into position between the upstream region and the downstream region. As shown in FIG. **18**, the holder **276** and elongate manipulator **344** are of unitary construction, although it is contemplated that they may be formed separately and then joined. Depending upon the size of the patient and the entry point of the elongate manipulator **344** (e.g., femoral artery, femoral vein, jugular vein, endoscopic trans-thoracic), manipulators of different length are needed. The manipulator **344** must be long enough to allow the artificial valve **210** to reach the damaged heart valve, without having additional unnecessary length which may hinder remote movement of the manipulator. The elongate manipulator **344** preferably has a minimum inner dimension ID' of about 2.5 mm to about 3.0 mm to accommodate an installer **328**, as described in detail below.

The elongate manipulator **344** is preferably formed of a material sufficiently flexible to allow bending as it passes through the body of the patient. In addition, the material is preferably sufficiently rigid such that the holder **276** at the end of the manipulator **344** moves in response to manual movements of the elongate manipulator. The elongate manipulator **344** is preferably both flexible for threading through the vessel of the patient, while still possessing the column strength required to push the elongate manipulator through the vessel. Materials capable of meeting such requirements include PTFE, polyurethane, polyvinyl or polyethylene combined with a radiopaque treatment. In addition, magnetically directed catheter guidance technology may also be applied to the elongate manipulator **344** to aid in guiding the manipulator through the vessel. One skilled in the art would readily understand how to apply such technology to the present invention. An example of magnetically directed catheter guidance technology is available from Stereotaxis, Inc. of St. Louis, Mo.

The elongate manipulator **344** further includes a hollow interior **348** shaped and sized to receive the installer **328**. The installer is releasably attachable to the artificial heart valve **210** for maneuvering the artificial heart valve from the hollow interior **332** of the holder **276** into position between the upstream region and the downstream region of the damaged heart H. In one embodiment, an end **352** of the installer **328** includes an internally threaded portion **354** for threadably receiving the externally threaded post **310** of the valve **210**. This allows the user to push the valve **210** from the holder **276** and selectively release the installer **328** from the post **310** of the valve by rotating the installer, thereby unscrewing the installer from the post. The installer **328** and elongate manipulator **344** may then be removed from the surgical field. Preferably, the internally threaded portion **354** would have an inner dimension ID" of about 2.0 mm to match the outer dimension OD of the externally threaded post **310**. In one embodiment, the end **352** of the installer **328** preferably has an outer dimension OD' of about 2.5 mm while the remaining portion of the installer has an outer dimension OD" of about 2.0 mm.

In a different installer and post embodiment, the post **310'** includes a bayonet fastener **360** as depicted in FIG. **17**.

Rather than threading onto the installer **328**, the bayonet fastener **360** includes a keyway **362** for receiving a key **364** extending from the post **310'**. The key **364** and keyway **362** cooperate to maintain the installer **328** connected to the post **310'**. To disengage the bayonet fastener **360**, the user simply rotates the installer **328** and pulls, thereby allowing the key **364** to pass through and escape from the keyway **362**. The positions of the keyway **362** and key **364** may switch, such that the post **310'** includes the keyway and the installer includes the key, without departing from the scope of the present invention.

Returning to the previous embodiment, illustrated in FIG. **16**, the installer **328** further includes an open central channel **370** passing through the length of the installer. This channel **370** permits passage of implements **214** (e.g., guides, catheters, etc.) to aid in installing the artificial valve **210**. Preferably, the channel **370** has an inner dimension ID'" of about 1.0 mm for accommodating implements **214** of up to that dimension. The ID'" and OD" may vary somewhat, however, depending upon the particular valvular implant procedure. The sizes indicated here are for illustrative purposes only, and one skilled in the art would readily understand that such dimensions may vary without departing from the scope of the present invention. The installer **328** is preferably fabricated from any type of biocompatible metallic or elastomeric material. Preferably, the installer **328** is also of a flexible construction and is radiopaque.

The guide **214** of the present invention aids in guiding the artificial valve **210** through a body of a patient and into position between the upstream region and the downstream region of the damaged heart H. The guide **214** is elongate, flexible and sized for receipt within the opening **212** to guide the valve **210** into position. As discussed above, the guide **214** is much smaller than the elongate manipulator **344**, preferably formed with a dimension no greater than about 1.0 mm. Because the guide **214** is much smaller than the manipulator **344**, it can be more easily maneuvered through the vessels of the patient to the heart H. Once the guide **214** is placed within the patient and guided to the area of interest, the manipulator **344** and installer **328** may be threaded onto the guide for passage to the area of surgical interest as explained below.

The present invention may further comprise an implement **214** functioning as a vascular catheter **214**. The vascular catheter **214** may include a sensor for registering and sending a signal through the vascular catheter for vascular monitoring. Such a sensor may preferably comprise a pressure sensor or an oximetry sensor. In addition, the vascular catheter **214** may comprise a dye injector for injecting dye into the heart H. Each of these vascular catheters **214** performs a specific function, readily understood by one skilled in the art.

The artificial valve **210** of the present invention is preferably installed in an antegrade orientation, meaning that the valve is ejected from the holder **276** in the direction of blood flow. Such antegrade applications include implantation to the mitral M, pulmonary or tricuspid valves via transvenous routes, typically via the femoral vein. For the mitral valve M implantation, the artificial valve **210** typically passes through the femoral vein and into the right atrium. From there, the surgeon performs a septostomy to create a small atrial septal perforation (i.e., atrial septal defect (ASD)) between the right atrium and left atrium LA to gain access to the left atrium. Such an ASD may require closure if unacceptable levels of shunting across the ASD are shown by testing (e.g., Doppler color flow imaging, blood oximetry, excessive pressure gradients). Such an antegrade orientation will apply to both endoscopic and open thoracotomy implants into the mitral valve M through a left closed atriotomy beating heart procedure without cardio pulmonary bypass and cardioplegia or a left open atriotomy with cardio pulmonary bypass and cardioplegia.

It is envisioned that the previously described instrument **306** would permit implantation of an artificial valve **210** by a transseptal procedure or a retrograde non-transseptal procedure. Transseptal access is conventionally used for balloon valvuloplasty of the mitral valve M with an Inoue single balloon catheter or another type of balloon catheter (e.g., Mansfield balloon catheter, available from Mansfield Scientific, Inc., of Mansfield, Mass.). Each of these procedures requires the intentional, controlled creation of an ASD between the right and left atria. Such a septostomy is required for the transseptal procedures noted above. The initial penetration of the atrial septum is typically performed using a Brockenbrough® catheter/needle (available from C.R. Bard, Inc. of Murray Hill, N.J.), which provides an atrial septal penetration of about 8.5 French (Fr.) (2.8 mm). Further dilation may then be provided using a 24 Fr. (8.0 mm) dilation catheter balloon about 30 mm in length. For the Inoue balloon, a 14 Fr. (4.7 mm) or 16 Fr. (5.3 mm) dialator sheath may be advanced through the septum after the initial penetration. Such procedures provide a relatively low incidence rate of a significant residual ASD. Such rates tend to fall in a range of about ten to about fifteen percent. Identifying such residual ASDs is readily accomplished by measuring transluminal pressure gradients or blood oximetry within the heart H. For example, an excessive left atrium to right atrium transmural pressure gradient may indicate a shunt between atria. Similarly, blood oximetry indicators, such as an oxygen saturation in the right atrium more than about seven percent by volume greater than blood in the superior vena cava, may also indicate a shunt. However, what may in fact be an insignificant residual ASD can present as a false positive on a color-flow Doppler study, but this can be further analyzed by a Valsalva maneuver bubble test, as one skilled in the art would appreciate. Finally, although the projected size of ASDs are quite large when considering the balloon dimensions noted above, the atrial septum in the area of penetration (i.e., fossa ovalis) is elastic, thereby contracting and closing the septostomy after removal of a balloon or other surgical tool. These surgically created defects typically close and heal spontaneously, but may also be closed with some type of closure device if required. One skilled in the art would readily understand how to make such determinations concerning possible shunts.

Aortic valve A access with an antegrade valve implant procedure is also possible by the method disclosed above (i.e., femoral vein to right atrium to left atrium LA) with the additional passage of the artificial valve through the mitral valve M and into the left ventricle LV. Alternately, access to the aortic valve A is possible in a retrograde configuration (e.g., from the femoral artery), as described above with respect to FIG. **5**. Such an installation would not include the use of a releasable fastener, but would incorporate a plunger tip **80** and push rod **82** as set forth above. The push rod **82** could be configured with a central channel, however, such that the advantages of the presently disclosed guide **214** may be adapted to retrograde applications. The artificial valve **210**, push rod **82** and manipulator **74** may be threaded onto the guide **214** to facilitate positioning the artificial valve adjacent the damaged aortic valve A. Such an arrangement also provides access for a vascular catheter **214** as described herein, such that pressure readings and dye injections may be made near the aortic valve A implant site.

In addition, the present invention is directed to an endothoracoscopic method of inserting the artificial valve **210** described above between a plurality of cusps C of a damaged heart valve. The method comprises multiple steps, some of which are not depicted in the figures because one skilled in the art would readily understand how to perform such steps by referencing the claims and specification only. First, an opening is made in a chest wall of a patient. Then, an incision is made in the heart H of the patient. Determining the location, orientation and size of such an opening and incision are well within the skill and understanding of one skilled in the art. The end **336** of the elongate instrument **306** is then inserted through the opening made in the chest wall and the incision made in the heart H. The surgeon may then position the inserted end **336** of the instrument adjacent the plurality of cusps C of the damaged heart valve. This procedure is particularly applicable to the mitral valve or the tricuspid valve. The artificial valve **210** within the instrument **306** may then be ejected from the end **336** of the instrument and positioned adjacent the plurality of cusps C of the damaged heart valve. If placed properly, this ejection will place the artificial valve **210** into a position between the plurality of cusps C of the damaged heart valve without removing the damaged heart valve from the heart H and without cardiopulmonary bypass or cardioplegia. With the artificial valve **210** properly placed within the heart H, the surgeon may then remove the instrument **306** from the patient and complete the surgery.

In some instances, however, the position of the artificial valve **210** in the heart H may not be optimal after the first ejection from the instrument **306**. In those cases, the surgeon may then retrieve the artificial valve **210** into the end **336** of the instrument **306**. Retrieving the artificial valve **210** into the instrument **306** is accomplished by advancing the elongate manipulator **344** over the installer **328**. Such relative movement between the installer **328** and the elongate manipulator **344** retrieves the artificial valve **210** to within the holder **276**, thereby forcing the valve from its expanded configuration to its collapsed configuration. The surgeon may then reposition the inserted end **336** of the instrument **306** adjacent the plurality of cusps C of the damaged heart valve and eject the repositioned artificial valve **210** from the end of the instrument again. This provides the surgeon with the flexibility to reposition the artificial valve **210** between the plurality of cusps C of the damaged heart valve multiple times until the positioning is optimal.

In yet another method of the present invention, an artificial valve **210** as described above may be inserted transluminally and placed between a plurality of cusps C of a damaged heart valve. Such a method is similar to the method disclosed immediately above, except that an incision is made in a vessel leading to the heart H, an end **336** of an elongate flexible instrument **306** is inserted through the incision made in the vessel and the end of the instrument is pushed through the vessel to be positioned adjacent the plurality of cusps C of the damaged heart valve. Once in position, the method is essentially the same. The method provides a surgeon with the flexibility to position and reposition the artificial valve **210** within the heart H.

In another method of the present invention, the artificial valve **210** is again inserted transluminally after making an incision in a vessel leading to the heart H. Here, however, an end **378** of the guide **214** is first inserted through the incision made in the vessel. The guide **214** is preferably smaller in its width dimension than the instrument **306** that will be inserted later. The smaller dimension of the guide **214** simplifies the task of pushing the guide through the vessel to the heart H of the patient, especially where the vein is of a smaller inner dimension. Once the guide **214** is in the proper position near the heart valve of the patient, the elongate flexible instrument **306** with hollow interior **348** is threaded onto the guide. The end **336** of the elongate flexible instrument **306** may then be threaded through the incision made in the vessel and pushed through the vessel along the guide **214** until the end is adjacent the plurality of cusps C of the damaged heart valve. Because the guide **214** has delineated a path for the instrument **306** to the heart H, the instrument may more easily pass through the vessel. Once in position, the artificial valve **210** may be ejected from the end **336** of the instrument **306** positioned adjacent the plurality of cusps C of the damaged heart valve into a position between the plurality of cusps of the damaged heart valve without removing the damaged heart valve from the heart H.

As will be appreciated by those skilled in the art, the valves and instruments described above permit "beating heart" procedures (i.e., without cardiopulmonary bypass or cardioplegic arrest) in part due to the relatively small size of the valves and instruments. Further, the valves described above permit implantation without removal of the native valves. The valves also permit some correction of valvular stenosis along with correction of regurgitant valvular disease. It is further envisioned that the valves described above may be coated with heparin or other protective coatings and immune suppressant coatings (e.g., rapamycin coating) to reduce coagulation or immune inflammatory response initiation.

It is envisioned that the valves of the present invention may be suitable for implant in pediatric patients due to their small size and substantially unrestricted flow characteristics. Further, because the valves adaptively expand, they are capable of expanding to fit a growing child.

It is further envisioned that rapidly implanting the valves of the present invention using an endothoracoscopic technique may provide a suitable remedy of acute papillary muscle dysfunction due to major chordal rupture or frank papillary muscle infarction.

In heavily calcified native valves, implantation of the valve described above could remedy regurgitant disease without disturbing the calcific deposits.

When used in the mitral M site, the valve described above avoids problems associated with valve cusp stents and fabric arms present in prior art bioprosthetic valves. Also use of the valve described above at the mitral M site eliminates removal of or damage to papillary muscles and all of the chordae tendinae thereby preserving systolic apical movement. Still further, the valve described above is compliant and capable of regurgitant control in cases of ischemic mitral regurgitation.

When used in the aortic valve A site, placement of the valve may be controlled using fluoroscopic guidance or echocardiographic guidance to ensure the native cusps C are positioned in the valve sinuses and the coronary openings above the valve site are not obstructed. It is envisioned that a conventional dye injection technique may be used to identify the coronary openings.

When used to implant the valve in either the Mitral or Atrial site, fluoroscopy and/or echocardiographic studies may be used to verify proper device positioning prior to release of the artificial valve.

In view of the above, it will be seen that the several objects of the invention are achieved and other advantageous results attained.

When introducing elements of the present invention or the preferred embodiment(s) thereof, the articles "a", "an",

"the" and "said" are intended to mean that there are one or more of the elements. The terms "comprising", "including" and "having" are intended to be inclusive and mean that there may be additional elements other than the listed elements.

As various changes could be made in the above constructions without departing from the scope of the invention, it is intended that all matter contained in the above description or shown in the accompanying drawings shall be interpreted as illustrative and not in a limiting sense.

What is claimed is:

1. An artificial valve for repairing a damaged heart valve having a plurality of cusps separating an upstream region from a downstream region, said artificial valve comprising:

a flexibly resilient frame sized and shaped for insertion in a position between the upstream region and the downstream region, the frame having a plurality of peripheral anchors for anchoring the frame in the position between the upstream region and the downstream region and a central portion located along a centerline extending between the plurality of peripheral anchors and between the upstream region and the downstream region when said frame is inserted in the position between the upstream region and the downstream region;

a flexible valve element attached to the central portion of the frame having an upstream side facing said upstream region when the frame is anchored in the position between the upstream region and the downstream region and a downstream side opposite the upstream side facing said downstream region when the frame is anchored in the position between the upstream region and the downstream region, said flexible valve element moving in response to a difference between fluid pressure in said upstream region and fluid pressure in said downstream region between an open position in which the flexible valve element permits downstream flow between said upstream region and said downstream region and a closed position in which the flexible valve element blocks flow reversal from said downstream region to said upstream region, wherein the flexible valve element moves to the open position when fluid pressure in said upstream region is greater than fluid pressure in said downstream region to permit downstream flow from said upstream region to said downstream region and the flexible valve element moves to the closed position when fluid pressure in said downstream region is greater than fluid pressure in said upstream region to prevent flow reversal from said downstream region to said upstream region; and

an opening extending through at least one of said frame and said flexible valve element for receiving an implement.

2. An artificial valve as set forth in claim **1** wherein said opening extends through the central portion of the frame and the flexible valve element.

3. An artificial valve as set forth in claim **2** further comprising a releasable fastener mounted on the frame for selectively connecting the valve to an instrument.

4. An artificial valve as set forth in claim **3** wherein the fastener comprises a hollow post mounted on the central portion of the frame coaxial with the opening.

5. An artificial valve as set forth in claim **4** wherein said fastener comprises a threaded fastener.

6. An artificial valve as set forth in claim **5** wherein said post is externally threaded.

7. An artificial valve as set forth in claim **4** wherein said fastener comprises a bayonet fastener.

8. An artificial valve as set forth in claim **1** wherein said flexibly resilient frame includes frame elements extending outward from the central portion, said frame elements being biased outward to engage the heart tissue and hold the frame in an expanded configuration in the position between the upstream region and the downstream region.

9. An artificial valve as set forth in claim **8** further comprising a band extending around the frame elements to limit outward movement of the frame elements to the expanded configuration and to sealingly engage adjacent heart tissue.

10. An artificial valve as set forth in claim **9** wherein said band includes an inner portion formed to limit outward movement of the frame elements, and an outer portion at least partially surrounding said inner portion and being biased inward, such that when the frame elements are forced inward to a collapsed configuration, the outer portion urges the inner portion inward to a position inside the frame elements.

11. An artificial valve as set forth in claim **10** wherein the frame elements are biased outward by a spring force sufficient to overcome the inward bias of the outer portion, so that the outward spring force maintains the frame in the expanded configuration.

12. An artificial valve as set forth in claim **11** wherein said outer portion comprises a braided mesh.

13. An artificial valve as set forth in claim **12** wherein said braided mesh comprises a woven fabric of filaments, each having a width of between about 0.05 mm and about 0.13 mm.

14. An artificial valve as set forth in claim **12** wherein said braided mesh comprises a material selected from the group consisting of Nitinol superelastic alloy, stainless steel alloy, Elgiloy® alloy, fiberglass, PTFE, polyester and Lycra®.

15. An artificial valve as set forth in claim **10** wherein said inner portion comprises a material selected from the group consisting of PTFE, Dacron® velour, Dacron® porous cloth, a synthetic polymer and biological source tissue.

16. A artificial valve as set forth in claim **8** further comprising a thin strand extending around the frame elements to limit outward movement of the frame elements to the expanded configuration.

17. An endothoracoscopic method of inserting an artificial valve as set forth in claim **1** between a plurality of cusps of a damaged heart valve, said method comprising the steps of:

making an opening in a chest wall of a patient;

making an incision in a heart of the patient;

inserting an end of an elongate instrument through the opening made in the chest wall and the incision made in the heart;

positioning the inserted end of the instrument adjacent the plurality of cusps of the damaged heart valve;

ejecting an artificial valve from the end of the instrument positioned adjacent the plurality of cusps of the damaged heart valve into a position between said plurality of cusps of the damaged heart valve without removing the damaged heart valve from the heart;

retrieving the artificial valve into the end of the instrument;

repositioning the inserted end of the instrument adjacent the plurality of cusps of the damaged heart valve; and

ejecting the repositioned artificial valve from the end of the instrument positioned adjacent the plurality of cusps of the damaged heart valve into position between said plurality of cusps of the damaged heart valve without removing the damaged heart valve from the heart.

18. A transluminal method of inserting an artificial valve as set forth in claim 1 between a plurality of cusps of a damaged heart valve, said method comprising the steps of:

making an incision in a vessel leading to the heart;

inserting an end of an elongate flexible instrument through the incision made in the vessel;

pushing the end of the instrument through the vessel;

positioning the end adjacent the plurality of cusps of the damaged heart valve;

ejecting an artificial valve from the end of the instrument positioned adjacent the plurality of cusps of the damaged heart valve into a position between said plurality of cusps of the damaged heart valve without removing the damaged heart valve from the heart;

retrieving the artificial valve into the end of the instrument;

repositioning the inserted end of the instrument adjacent the plurality of cusps of the damaged heart valve; and

ejecting the repositioned artificial valve from the end of the instrument positioned adjacent the plurality of cusps of the damaged heart valve into position between said plurality of cusps of the damaged heart valve without removing the damaged heart valve from the heart.

19. A transluminal method as set forth in claim 18 further comprising performing a septostomy between the atria of the heart and pushing the instrument through an atrial septal perforation created by the septostomy.

20. A transluminal method of inserting an artificial valve as set forth in claim 1 between a plurality of cusps of a damaged heart valve, said method comprising the steps of:

making an incision in a vessel leading to the heart;

inserting an end of a guide through the incision made in the vessel;

pushing the guide through the vessel;

threading an elongate flexible instrument having a hollow interior onto the guide;

inserting an end of the elongate flexible instrument through the incision made in the vessel;

pushing the end of the instrument through the vessel along the guide until the end is adjacent the plurality of cusps of the damaged heart valve; and

ejecting an artificial valve from the end of the instrument positioned adjacent the plurality of cusps of the damaged heart valve into a position between said plurality of cusps of the damaged heart valve without removing the damaged heart valve from the heart.

21. A transluminal method as set forth in claim 20 further comprising performing a septostomy between the atria of the heart and pushing the instrument through an atrial septal perforation created by the septostomy.

22. An artificial valve for repairing a damaged heart valve having a plurality of cusps separating an upstream region from a downstream region, said artificial valve comprising:

a flexibly resilient frame sized and shaped for insertion in a position between the upstream region and the downstream region, the frame having a plurality of peripheral anchors for anchoring the frame in the position between the upstream region and the downstream region;

a flexible valve element fixedly attached to the frame so that at least a portion of the element is substantially immobile with respect to at least a portion of the frame, said element having a convex upstream side facing said upstream region when the frame is anchored in the position between the upstream region and the downstream region and a concave downstream side opposite the upstream side facing said downstream region when the frame is anchored in the position between the upstream region and the downstream region, said flexible valve element moving in response to a difference between fluid pressure in said upstream region and fluid pressure in said downstream region between an open position in which the flexible valve element permits downstream flow between said upstream region and said downstream region and a closed position in which the flexible valve element blocks flow reversal from said downstream region to said upstream region, wherein the flexible valve element moves to the open position when fluid pressure in said upstream region is greater than fluid pressure in said downstream region to permit downstream flow from said upstream region to said downstream region and the flexible valve element moves to the closed position when fluid pressure in said downstream region is greater than fluid pressure in said upstream region to prevent flow reversal from said downstream region to said upstream region; and

an opening extending through at least one of said frame and the flexible valve element.

23. An artificial valve as set forth in claim 22 further comprising a releasable fastener mounted on the frame for selectively connecting the valve to an instrument.

24. An artificial valve as set forth in claim 23 wherein the fastener comprises a hollow post mounted on the frame coaxial with the opening.

25. An artificial valve as set forth in claim 24 wherein said fastener comprises a threaded fastener.

26. An artificial valve as set forth in claim 25 wherein said post is externally threaded.

27. An artificial valve as set forth in claim 24 wherein said fastener comprises a bayonet fastener.

28. An artificial valve as set forth in claim 27 wherein said flexibly resilient frame includes frame elements extending outward from the central portion, said frame elements being biased outward to engage the heart tissue and hold the frame in an expanded configuration in the position between the upstream region and the downstream region.

29. An artificial valve as set forth in claim 28 further comprising a band extending around the frame elements to limit outward movement of the frame elements to the expanded configuration and to sealingly engage adjacent heart tissue and form a seal with the heart.

30. An artificial valve as set forth in claim 29 wherein said band includes a inner portion formed to limit outward movement of the frame elements, and an outer portion at least partially surrounding said inner portion and being biased inward, such that when the frame elements are forced inward to a collapsed configuration, the outer portion urges the inner portion inward to a position inside the frame elements.

31. In combination, an artificial valve for repairing a damaged heart valve having a plurality of cusps separating an upstream region from a downstream region, and a guide for guiding the artificial valve between the upstream region and the downstream region, said combination comprising:

said artificial valve including

a flexibly resilient frame sized and shaped for insertion between the upstream region and the downstream region, the frame having a plurality of peripheral anchors for anchoring the frame between the upstream region and the downstream region and a central portion

located along a centerline extending between the plurality of peripheral anchors,

a flexible valve element fixedly attached to the central portion of the frame so that at least a portion of the element is substantially immobile with respect to the central portion of the frame, said element having an upstream side fading said upstream region when the frame is anchored between the upstream region and the downstream region and a downstream side opposite the upstream side facing said downstream region when the frame is anchored between the upstream region and the downstream region, said flexible valve element moving in response to a difference between fluid pressure in said upstream region and fluid pressure in said downstream region between an open position in which the flexible valve element permits downstream flow between said upstream region and said downstream region and a closed position in which the flexible valve element blocks flow reversal from said downstream region to said upstream region, wherein the flexible valve element moves to the open position when fluid pressure in said upstream region is greater than fluid pressure in said downstream region to permit downstream flow from said upstream region to said downstream region and the flexible valve element moves to the closed position when fluid pressure in said downstream region is greater than fluid pressure in said upstream region to prevent flow reversal from said downstream region to said upstream region, and

an opening extending through at least one of said frame and the flexible valve element; and

said flexible, elongate guide sized for receipt within the opening to guide the valve into position.

32. A combination as set forth in claim **31** further comprising a holder having a hollow interior sized for holding the artificial valve when the frame is in the collapsed configuration.

33. A combination as set forth in claim **32** further comprising an elongate manipulator attached to the holder for manipulating the holder into position between the upstream region and the downstream region.

34. A combination as set forth in claim **33** further comprising an installer received within the hollow interior of the holder and releasably attachable to the artificial heart valve for maneuvering the artificial heart valve from the hollow interior of the holder into position between the upstream region and the downstream region.

35. A combination as set forth in claim **32** wherein the holder comprises an outwardly flared end for receiving the artificial valve within the holder.

36. A combination as set forth in claim **32** wherein the holder comprises internal, longitudinal grooving for guiding the flexibly resilient frame.

37. A combination as set forth in claim **31** further comprising a vascular catheter.

38. In combination, an artificial valve for repairing a damaged heart valve having a plurality of cusps separating an upstream region from a downstream region, and an instrument for inserting the artificial valve between the upstream region and the downstream region, said combination comprising:

said artificial valve including

a flexibly resilient frame sized and shaped for insertion between the upstream region and the downstream region, the frame having a plurality of peripheral anchors for anchoring the frame between the upstream region and the downstream region and a central portion located between the plurality of peripheral anchors, and

a flexible valve element fixedly attached to the frame so that at least a portion of the element is substantially immobile with respect to the central portion of the frame, said element having an upstream side facing said upstream region when the frame is anchored between the upstream region and the downstream region and a downstream side opposite the upstream side facing said downstream region when the frame is anchored between the upstream region and the downstream region, said flexible valve element moving in response to a difference between fluid pressure in said upstream region and fluid pressure in said downstream region between an open position in which the flexible valve element permits downstream flow between said upstream region and said downstream region and a closed position in which the flexible valve element blocks flow reversal from said downstream region to said upstream region, wherein the flexible valve element moves to the open position when fluid pressure in said upstream region is greater than fluid pressure in said downstream region to permit downstream flow from said upstream region to said downstream region and the flexible valve element moves to the closed position when fluid pressure in said downstream region is greater than fluid pressure in said upstream region to prevent flow reversal from said downstream region to said upstream region, and

an opening extending through at least one of said frame and the flexible valve element; and

an instrument including

a holder having a hollow interior sized for holding the artificial valve when the frame is in a collapsed configuration,

an elongate manipulator attached to the holder for manipulating the holder into position between the upstream region and the downstream region, and

an installer received within the hollow interior of the holder and releasably attachable to the frame of the artificial heart valve for maneuvering the artificial heart valve from the hollow interior of the holder into position between the upstream region and the downstream region.

39. A combination as set forth in claim **38** wherein the frame includes a mount for selectively connecting the valve to the instrument.

40. A combination as set forth in claim **39** wherein the mount comprises a post mounted on the frame.

41. A combination as set forth in claim **40** wherein said post comprises a threaded fastener.

42. A combination as set forth in claim **41** wherein said post is externally threaded.

43. A combination as set forth in claim **42** wherein said installer includes an internally threaded portion for threadably receiving said externally threaded post.

44. A combination as set forth in claim **40** wherein said post comprises a bayonet fastener.

45. A combination as set forth in claim **38** wherein said holder has an outwardly flared end for receiving the peripheral anchors when the artificial valve is within the holder.

46. A combination as set forth in claim **38** wherein the holder comprises internal, longitudinal grooving for guiding the flexibly resilient frame.

* * * * *

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Paper No. 15
Filed: May 3, 2018

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ST. JUDE MEDICAL, LLC,
Petitioner,

v.

SNYDERS HEART VALVE LLC,
Patent Owner.

IPR2018-00105 (Patent 6,540,782 B1)
IPR2018-00106 (Patent 6,540,782 B1)
IPR2018-00107 (Patent 6,821,297 B1)
IPR2018-00109 (Patent 6,821,297 B2)[1]

Before PATRICK R. SCANLON, MITCHELL G. WEATHERLY, and JAMES A. WORTH, *Administrative Patent Judges.*[2]

SCANLON, *Administrative Patent Judge.*

DECISION
Denying Motion to Dismiss
37 C.F.R. §§ 42.5, 42.71

[1] This Decision addresses issues pertaining to multiple cases. The parties are not authorized to use this style heading for any subsequent papers.
[2] Director Andrei Iancu has taken no part in this Decision due to recusal.

I. INTRODUCTION

Patent Owner filed a Motion to Dismiss the Petition in each of these proceedings. Paper 13 ("Mot.")[3]. Patent Owner asserts that, prior to his appointment as Director of the U.S. Patent and Trademark Office, Mr. Andrei Iancu "represented the Petitioner (St. Jude Medical) as lead trial counsel in district court litigation related to the patents that are the subject of the IPR petitions," and "[a]pplicable ethical regulations bar Director Iancu from any participation in this IPR." Mot. 1. In view of this assertion, Patent Owner contends the Petition in each of these proceedings should be dismissed. *Id.* Petitioner filed an Opposition to each Motion. Paper 14 ("Opp.").

II. BACKGROUND

Patent Owner sets forth the following sequence of relevant events in its Motion:

Patent Owner filed a complaint for patent infringement against St. Jude Medical S.C., Inc. and St. Jude Medical, Cardiology Division, Inc. (wholly owned subsidiaries of Petitioner), asserting infringement of U.S. Patent Nos. 6,540,782 and 6,821,297 (the two patents challenged in these four proceedings) on October 25, 2016. Mot. 1 (citing Ex. 2017, Dkt. 1). On January 18 2017, Patent Owner filed an amended complaint adding Petitioner as a defendant. *Id.* at 1–2 (citing Ex. 2017, Dkt. 22).

[3] As the pertinent papers in all four proceedings are substantially similar, we refer herein to the papers filed in IPR2018-00105 for convenience.

On February 13, 2017, St. Jude[4] filed its first Notice of Appearance in the litigation, entering the appearance of Andrei Iancu, then managing partner of the law firm Irell & Manella, as its counsel of record. *Id.* at 2 (citing Ex. 2017, Dkt. 34). Additional attorneys from Irell & Manella also entered notices of appearance. *Id.* (citing Ex. 2017, Dkt. 35, 39, 179, 182, 208). On January 31, 2018, St. Jude filed a Motion of Withdrawal of Attorney, seeking to withdraw Mr. Iancu (but not other attorneys from Irell & Manella) as attorney in the litigation. *Id.* (citing Ex. 2017, Dkt. 293). The district court granted the motion on February 2, 2018. *Id.* (citing Ex. 2017, Dkt. 294).

The Petitions in these four proceedings were all filed on October 23, 2017. *Id.*

Mr. Iancu was confirmed as Director by the Senate on February 5, 2018 and sworn in on February 8, 2018. *Id.* at 3.

Petitioner does not dispute this sequence of events in its Oppositions. Opp. 1. Petitioner contends, however, that it is represented in these proceedings by the law firm Lerner David, and Irell & Manella has never entered an appearance in these proceedings. *Id.*

III. ANALYSIS

A. Participation by Director Iancu

Patent Owner argues that "[t]he inter partes review statute requires the Director to determine whether to institute an inter partes review," and "[t]he

[4] Patent Owner appears to use "St. Jude" to collectively refer to Petitioner and co-defendants St. Jude Medical S.C., Inc. and St. Jude Medical, Cardiology Division, Inc.

Board institutes the trial *on behalf of* the Director." Mot. 4 (citing 35 U.S.C. § 314; quoting 37 C.F.R. § 42.4(a) (emphasis added by Patent Owner)). According to Patent Owner, however, Director Iancu should be disqualified with respect to these proceedings pursuant to 5 C.F.R. § 2635.502. *Id.*

Director Iancu has recused himself from these proceedings. Accordingly, the Director's past representation of Petitioner in the related litigation is not a basis to dismiss the Petitions in these proceedings.

B. Participation by the Board

Patent Owner also argues that

> Even if another Patent Office employee were allowed to perform the role expressly assigned to the Director by 35 U.S.C. § 314, that employee would also have a conflict of interest. Those subordinate employees are subject to a significant risk that their representation of the U.S. Patent and Trademark Office in this particular matter will be limited by their loyalty to their boss, Director Iancu.

Mot. 6. Patent Owner asserts that because "of Director Iancu's direct involvement in the litigation and the authority that Director Iancu holds over subordinate employees, any employee who might perform the Director's duty would therefore also have a conflict of interest." *Id.* at 7; *see also id.* n.7 (citing the American Bar Association's Model Rules of Professional Conduct concept that disqualification of an attorney may extend to that attorney's subordinate employees).

In response, Petitioner argues that Patent Owner "fails to ground its allegation to any applicable legal standard, citing only a 'concept' under the ABA's Model Rules of Professional Conduct applicable to law firms," and [t]here is nothing to suggest that this Model Rule applies or was ever

intended to apply to an entire government agency." Opp. 5. Petitioner also argues that Patent Owner has not "pointed to any specific evidence that the minds of the members of the Board in the proceeding are 'irrevocably closed on a disputed issue.'" *Id.* (citing *NEC Corp. v. United States*, 151 F.3d 1361, 1373 (Fed. Cir. 1998). According to Petitioner, "[i]n the absence of any showing that the APJs of this Panel are 'not capable of judging a particular controversy fairly on the basis of its own circumstances,' the APJs should not be disqualified." *Id.* (citing *Hortonville Joint School Dist. v. Hortonville Educ. Assoc.*, 426 U.S. 482, 493 (1976)).

Petitioner also argues that Patent Owner effectively is "requesting that Petitioner be completely denied access to a statutorily prescribed decision on the merits in [these proceedings] as 'punishment' for hiring a particular private attorney in a separate, albeit related, matter." *Id.* at 6. Furthermore, Petitioner argues that "[a]ccepting [Patent Owner's] position would effectively require that Petitioner be denied access to *all* proceedings at the USPTO," noting that Patent Owner's position the Patent Office employees should be disqualified because of loyalty to the Director would apply to Patent Examiners as well as Administrative Patent Judges. *Id.* at 7.

Upon consideration of the parties' positions, we find Petitioner's arguments more persuasive. Patent Owner has not established sufficiently that Administrative Patent Judges are unable to carry out their pre-designated duties impartially. Accordingly, we disagree that Administrative Patent Judges should be disqualified with respect to these proceedings.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that Patent Owner's Motion to Dismiss in each of these proceedings is *denied*.

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Certificate of Filing and Service

I hereby certify that on December 2, 2019, I caused this Opening Brief of Appellant to be filed electronically with the Clerk of the Court using the CM/ECF system. All participants in the case are represented by registered CM/ECF users and will be served electronically by the CM/ECF system.

/s/ Matthew J. Antonelli
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Counsel for Appellant

Certificate of Compliance

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