IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the *Inter Partes* Review of: Trial Number: To Be Assigned

U.S. Patent No. 7,914,569

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Assignee: Medtronic CoreValve LLC

Title: HEART VALVE PROSTHESIS AND METHODS OF MANUFACTURE AND USE

Panel: To Be Assigned

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PETITION FOR *INTER PARTES* REVIEW UNDER 37 C.F.R. § 42.100

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On behalf of Troy R. Norred ("Norred") and in accordance with 35 U.S.C. § 311 and 37 C.F.R. § 42.100, *inter partes* review is respectfully requested for claims 1-18 of U.S. Patent No. 7,914,569 ("the '569 Patent") (Ex. 1001).

I. MANDATORY NOTICES UNDER 37 C.F.R. § 42.8(a)(1)

The following mandatory notices are provided as part of this Petition.

A. Real Party-In-Interest Under 37 C.F.R. § 42.8(b)(1)

Troy R. Norred is the real party-in-interest.

B. Related Matters Under 37 C.F.R. § 42.8(b)(2)

There are no related matters to this action.

C. Lead and Back-Up Counsel Under 37 C.F.R. § 42.8(b)(3)

Petitioner provides the following designation of counsel:

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D. Service Information Under 37 C.F.R. § 42.8(b)(4)

Service of any documents via hand-delivery may be made at the postal mailing address of the respective lead or back-up counsel designated above with courtesy email copies to the email addresses and ekdkdocket@kcpatentlaw.com.

II. PAYMENT OF FEES UNDER 37 C.F.R. § 42.103

The undersigned authorizes the Office to charge Deposit Account No. 502790 for the fee set forth in 37 C.F.R. § 42.15(a), or any other applicable fees, for this Petition for *inter partes* review. The undersigned further authorizes payment for any additional fees that might be due in connection with this Petition to be charged to the above-referenced Deposit Account.

III. SUMMARY OF THE '569 PATENT

A. Description of the Alleged Invention of the '569 Patent

The '569 Patent (Ex. 1001) contains 18 claims, including two independent apparatus claims (claims 1 and 18). The '569 Patent relates to a heart valve prosthesis that is placed by a catheter in the ascending aorta and held in place with a stent system. '569 Patent, 1: 6-12. Shown below is an annotated version of Figure 6 showing the valve prosthesis 10 frame 12 in the ascending aorta.

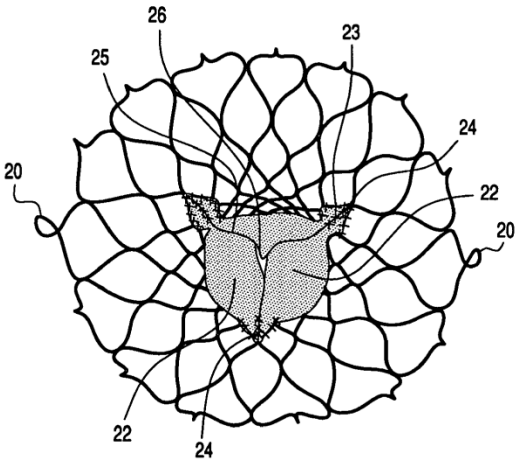


FIG.1C

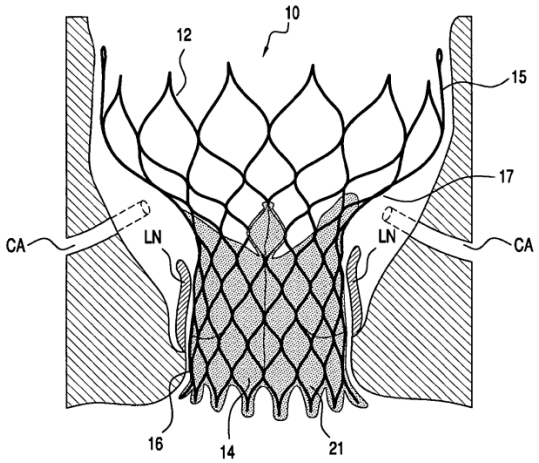


FIG.6

The ‘569 Patent discloses one valve prosthesis design that includes a self-expanding multi-level frame that supports a valve body with a skirt and coapting leaflets. The frame includes a contracted delivery configuration that allows transluminal delivery, and an expanded deployed configuration with an hourglass shape.

With respect to independent claim 1 and its dependent claims 2-17, the ‘569 Patent’s alleged invention is a valve prosthesis (see Figs. 1 and 6 above) with a self-expanding multi-level frame that supports a valve body comprising a skirt and plurality of coapting leaflets. The frame transitions between a contracted delivery configuration that enables percutaneous transluminal delivery, and an expanded deployed configuration having an asymmetric hourglass shape. The valve body skirt and leaflets are constructed so that the center of coaptation may be selected to reduce horizontal forces applied to the commissures of the valve, and to efficiently distribute and transmit forces along the leaflets and to the frame. ‘569 Patent, Ab-

stract.

B. Summary of the Prosecution History of the ‘569 Patent

Referring to the prosecution history of the ‘569 Patent (Ex. 1002), the ‘569 Patent was filed as U.S. App. Serial No. 11/128,826 on May 13, 2005 (see Ex. 1002, paper 1). The ‘569 Patent does not claim priority to any earlier filed applications. The application for the ‘569 Patent was rejected several times over nearly six years. The first IDS filed with the application only cited five prior art references. Patent Owner filed a second IDS with five additional references before the first office action. Patent Owner then filed four additional IDSs disclosing 177 references. Finally, Patent Owner filed a seventh IDS with 541 additional references

Claims 1-40 were rejected in the first Office Action mailed on Aug. 10, 2007. In response to the August 10, 2007 Office Action, applicants cancelled claims 1-20 and amended claims 21, 25, 27 and 34, on February 11, 2008. In the Office Action mailed on May 13, 2008, claims 21-25 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,037,434 to Lane et al. Further, claims 26-40 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Lane in view of Bailey.

In response to the May 13, 2008 Office Action and final rejection, applicants conducted a telephonic interview with the examiner on September 3, 2008 and dis-

cussed claim 21 as well as the Lane reference. No agreement was reached with respect to the patentability of claim 21. *See* November 13, 2008, Summary of Interview. Further, applicants amended claim 21 and added dependent claim 41.

In the Office Action mailed January 27, 2009, claims 21-41 were rejected. Claims 21, 22 and 25 were rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 4,340,977 to Brownlee et al.; claims 23 and 24 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Brownlee in view of Lane; and claims 26-41 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Brownlee in view of Lane and Bailey. Claims 23, 24 and 27-41 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Cai in view of U.S. Pub. No. 2003/0114913 to Spenser et al. Claims 38-41 were further rejected under 35 U.S.C. § 103(a) as being unpatentable over Cai in view of Spenser and Bailey.

In response, applicants amended claims 21, 25 and 41, and added claim 42, on June 29, 2009. The patent office issued a final rejection in the Office Action mailed November 10, 2009, rejecting claims 21, 22, 25, 26 and 42 under 35 U.S.C. § 102(b) as being unpatentable over U.S. Patent No. 6,562,069 to Cai et al.

Applicants filed a response on January 11, 2010 that was not considered by the Patent Office for failure to place the application in condition for allowance. *See* January 20, 2010 Advisory Action. Applicants filed a response and RCE on February 9, 2010, amending claims 21, 26, 28 and 29, and adding new claim 43.

In the Office Action mailed February 19, 2010, claims 21-42 were rejected under 35 U.S.C. § 112 paragraph 1 as failing to meet the written description requirement, and § 112 paragraph 2 as being indefinite. Claims 21-37 and 42-43 were again rejected under 35 U.S.C. § 103(a) as being unpatentable over Cai in view of Spenser. Claims 38-41 were further rejected under 35 U.S.C. § 103(a) as being unpatentable over Cai in view of Spenser and Bailey.

On June 21, 2010, applicants filed a reply to the February 19, 2010 Office Action amending claims 21 and 43, and adding claim 44. An interview with the examiner was held on June 21, 2010 to discuss claims 21 and 43, and Bailey, but no agreement with respect to the claims was reached. *See* Interview Summary mailed June 29, 2010. Although required to file a statement of the substance of the interview, none was filed by applicants. *Id.*

In the Office Action mailed on October 6, 2010, amended claim 43 and new claim 44 were allowed without comment from the examiner, and claims 21-42 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,562,069 to Cai et al. in view of U.S. Pub. No. 2003/0114913 to Spenser et al. and Bailey. In response to the October 6, 2010 Office Action, applicants filed an amendment an December 13, 2010, amending claims 22-28, 30, 31, 33-37, and 40-41 to depend from allowed claim 43, and cancelling claims 29, 32, 38, 39 and 42. Claim 43 issued as claim 1, and claim 44 issued as claim 18.

IV. REQUIREMENTS FOR INTER PARTES REVIEW UNDER 37 C.F.R. § 42.104

As set forth below and pursuant to 37 C.F.R. § 42.104, each requirement for *inter partes* review of the '569 Patent is satisfied.

A. Grounds for Standing Under 37 C.F.R. § 42.104(a)

Petitioner hereby certifies that the '569 Patent is available for *inter partes* review and that the Petitioner is not barred or estopped from requesting *inter partes* review challenging the claims of the '569 Patent on the grounds identified herein. More particularly, Petitioner certifies that: (1) Petitioner is not the owner of the '569 Patent; (2) Petitioner has not filed a civil action challenging the validity of a claim of the '569 Patent; (3) Petitioner has not been served with a complaint alleging infringement of the '569 Patent; (4) the estoppel provisions of 35 U.S.C. § 315(e)(1) do not prohibit this *inter partes* review; and (5) this Petition is filed after the later of (a) the date that is nine months after the date of the grant of the '569 Patent or (b) the date of termination of any post-grant review of the '569 Patent.

B. Identification of Challenge Under 37 C.F.R. § 42.104(b) and Relief Requested

The precise relief requested by Petitioner is that claims 1-18 of the '569 Patent be found unpatentable.

C. Claims for Which Inter Partes Review Is Requested Under 37 CFR § 42.104(b)(1)

Inter partes review of claims 1-18 of the '569 Patent is requested.

D. The Specific Art and Statutory Ground(s) on Which the Challenge Is Based Under 37 C.F.R. § 42.104(b)(2)

Inter partes review is requested in view of the following references and specific grounds for rejection under 35 U.S.C. §102:

No.	Grounds
1	Claims 1-18 are anticipated by U.S. Patent No. 7,044,966 to Svanidze
2	Claims 1-18 are anticipated by U.S. Patent No. 7,201,772 to Schwammenthal
3	Claims 1-18 are anticipated by U.S. Patent No. 6,730,118 to Spenser
4	Claims 1-18 are anticipated by U.S. Patent No. 7,044,966 to Svanidze
5	Claims 1-18 are obvious under § 103(a) over Svanidze in view of U.S. Patent No. 7,320,704 to Lashinski
6	Claims 1-18 are obvious under § 103(a) over U.S. Patent No. 7,201,772 to Schwammenthal in view of Svanidze
7	Claims 1-18 are obvious under § 103(a) over U.S. Patent No. 6,730,118 to Spenser in view of Schwammenthal
8	Claims 1-18 are obvious under § 103(a) over U.S. Patent No. 7,201,772 to Schwammenthal in view of Svanidze, further in view of Lashinski
9	Claims 1-18 are obvious under § 103(a) over U.S. Patent No. 6,730,118 to Spenser in view of Schwammenthal, further in view of Lashinski

Each reference and grounds listed above establishes a reasonable likelihood that Petitioner will prevail on at least one claim and thus this petition for *inter partes* review should be granted.

E. How the Challenged Claims Are to Be Construed Under 37 C.F.R. §42.104(b)(3)

Petitioner notes that a claim is given the "broadest reasonable construction in light of the specification" in *inter partes* review. See 37 C.F.R. § 42.100(b). As described in Section III.A above, the '569 Patent is directed to a heart valve prosthesis and describes one embodiment. Petitioner's claim construction herein should not be taken to mean that Petitioner agrees or admits that any claim element of the challenged claims should receive the benefits of the doctrine of equivalents, that Petitioner is precluded from propounding alternative claim constructions, or that Petitioner agrees or believes that the claims at issue are amendable to a meaningful construction or satisfy the requirements of 35 U.S.C. § 112. All claim terms not specifically addressed in this section have been accorded their broadest reasonable interpretation in light of the patent specification.

1. **"commissure"**

Petitioner submits that the term "commissure," which appears in claims 1, 3 and 18, is a "seam where two materials are joined together." This is a straightforward reading of the claims in the context of the specification under the broadest reasonable interpretation standard, and supported by the specification. *See* '569

Patent Abstract; 4:27-38; 7:6-54; 8:25 – 9:2.

2. "coaptation"

Petitioner submits that the term "coaptation," which appears in claims 1, 10 and 18, is a "free edge where two materials come together." This is a straightforward reading of the claims in the context of the specification under the broadest reasonable interpretation standard, and supported by the specification. *See* '569 Patent Abstract; 4:27-38; 5:17-29; 7:2-5, 14-29, 43-54.

3. "catenary"

Petitioner submits that the term "catenary," which appears in claims 1, 2 and 18, is a "natural U-shaped curve assumed by a free edge when supported at its ends." This is a straightforward reading of the claims in the context of the specification under the broadest reasonable interpretation standard, and supported by the specification. *See* '569 Patent; 7:43-54; Ex. 1007, ¶7, 8.

F. How the Construed Claim(s) Are Unpatentable Under 37 C.F.R. § 42.104(b)(4)

An explanation of how construed claims 1-18 of the '569 Patent are un- patentable under the statutory grounds identified above, including identification of where each element of the claim is found in the prior art patents, is provided in Section V and in claim charts A-1 to A-4.

A claimed invention may be rejected under 35 U.S.C. 102 when the invention is anticipated (or is "not novel") over a disclosure that is available as prior art.

To anticipate a claim, the disclosure must teach every element of the claim. MPEP § 2131.

"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. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987). "When a claim covers several structures or compositions, either generically or as alternatives, the claim is deemed anticipated if any of the structures or compositions within the scope of the claim is known in the prior art." *Brown v. 3M*, 265 F.3d 1349, 1351(Fed. Cir. 2001). See also MPEP § 2131.02. "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236 (Fed. Cir. 1989). The elements must be arranged as required by the claim, but this is not an *ipsissimis verbis* test, i.e., identity of terminology is not required. *In re Bond*, 910 F.2d 831 (Fed. Cir. 1990).

A patent is invalid as obvious when "the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains." 35 U.S.C. § 103(a); see *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398 (2007). Under *KSR*, an invention is obvious if the claimed improvement amounts to no more than

"the predictable use of prior art elements according to their established functions." *Id*. at 417; MPEP § 2141. "[I]f a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious", unless such use would require skill beyond that of a person of ordinary skill in the art. *KSR* at 417. Simply put, if a person of ordinary skill in the art would be able to implement a predictable variation of the prior art, that variation is obvious. *Id*.

Rejecting the need for an explicitly stated motivation to combine prior art elements, KSR held that in determining whether there was an apparent reason to combine, the court should look to a variety of factors, including the teachings of the prior art patents, the effects of marketplace demand, and the background knowledge of a person of ordinary skill in the art. *Id*. at 418. This analysis should not rely solely upon explicit teachings of the claimed subject matter, but also the inferences that a person of ordinary skill in the art might exercise. *Id*. Purported inventions arising from ordinary innovation, ordinary skill, or common sense should not be patentable. *Id*. at 400, 403-04, 418-22, 427-428. That is, "the combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." *Id*. at 416.

G. Supporting Evidence Under 37 C.F.R. § 42.104(b)(5)

The exhibit numbers of the supporting evidence relied upon to support the

challenge and the relevance of the evidence to the challenge, including identification of specific portions of the evidence that support the challenge, are provided below in Section V and in claim charts A-1 to A-7.

V. DETAILED EXPLANATION OF PERTINENCE AND MANNER OF APPLYING CITED PRIOR ART TO EVERY CLAIM FOR WHICH REVIEW IS REQUESTED UNDER 37 C.F.R. § 42.104(b)(4)

A. Claims 1-18 are Anticipated under 35 U.S.C. §102(a) by U.S. Patent No. 7,044,966 to Svanidze et al. (Ex. 1003)

Claim 1:

U.S. Patent No. 3,548,417 to Svanidze et al issued on issued on May 16, 2016 and published on April 7, 2005 and thus qualifies as prior art under § 102(a). Svanidze was not cited during prosecution of the '569 Patent or considered by the Examiner, and was listed on an IDS submitted by applicants years after filing the '569 Patent application along with 436 other U.S. references. Svanidze discloses heart valve prosthesis with a self-expanding multi-level frame (70) that supports a valve body comprising a skirt (37) and plurality of coapting leaflets (36). The frame transitions between a contracted delivery configuration that enables percutaneous transluminal delivery, and an expanded deployed configuration having an asymmetric hourglass shape (Figs. 11 - 14). The valve body skirt and leaflets are constructed so that the center of coaptation may be selected to reduce

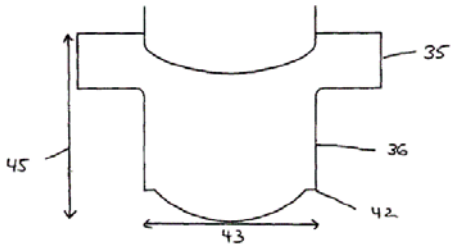


FIG. 9

horizontal forces applied to the commissures of the valve (Figs. 11 - 14), and to efficiently distribute and transmit forces along the leaflets and to the frame. Svanidze discloses a valve body comprising a plurality of leaflets (36) sewn to a skirt (6), adjoining leaflets sewn together to form commissures (9). Figs. 2, 9, 11, 12.

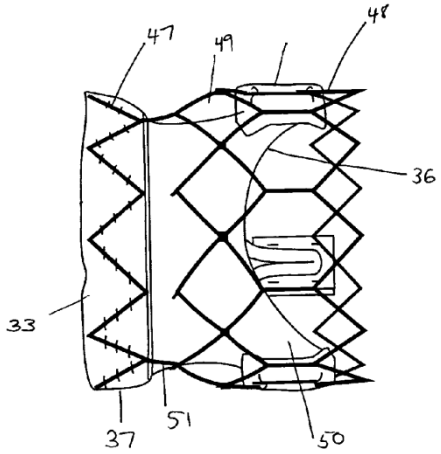


FIG. 11

Svanidze discloses a valve body 32 comprising a plurality of leaflets 36 sewn to a skirt 6, adjoining leaflets sewn together to form commissures 35. Figs. 2, 9, 11, 12.

Svanidze discloses a self-expanding frame comprised of a plurality of cells 49, 50, the frame has a substantially conical inflow section, a flared outflow section, and a constriction region between the inflow and outflow sections (Figs. 11, 12; 13:5-40) wherein the constriction region is configured to avoid blocking blood flow to the coronary arteries when the frame is implanted in a body, wherein the frame supporting supports the valve body, wherein the frame has a longitudinal axis, wherein the frame has a contracted delivery configuration and an expanded deployed configuration. Figs. 11-12; 11:64 – 12:21; 15:26-32.

Svanidze discloses when the frame is in the expanded deployed configuration, the inflow section, the outflow section, and the constriction region have substantially circular cross-sections, the outflow section has a larger diameter than the

inflow section, and the inflow section has a larger diameter than the constriction region. Figs. 11, 12, 26. Svanidze discloses a skirt with a bottom edge, the inflow section of the frame has an inflow edge, and the bottom edge of the skirt is sewn to the inflow edge of the inflow section. Figs. 11, 12, 24-26; 9:38-56; 13:5-40; 16:41-17:40. Svanidze discloses commissures sewn to the frame along a region of the frame that increases in diameter along the longitudinal axis in an intended direction of blood flow. Figs 11-12; 13:5-40.

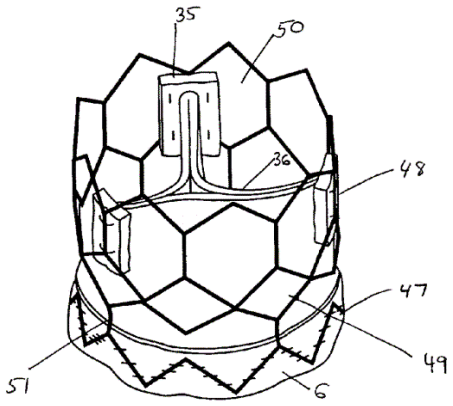


FIG. 12

Svanidze discloses commissures configured to span a cell 60 of the frame to distribute force within the commissures and to the frame, and wherein a plurality of cells of the frame are positioned between the cells spanned by commissures. Figs. 11, 12, 14; 13:5-40; 14:12-35; Ex. 1007, ¶¶ 11-14. At least a portion of the commissures are longitudinally offset from the center of coaptation, and each leaflet has a free edge that is suspended from the leaflet's respective commissures to define coaptation edges and a center of coaptation. Figs. 11-12. The length of each free edge

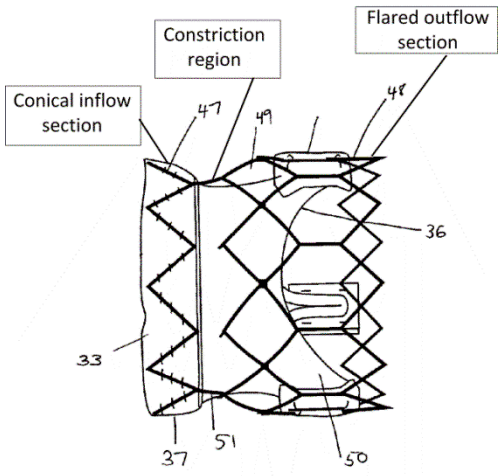


FIG. 11

forms a substantially continuous curve extending downwardly between the respective commissures so that the free edges of the leaflets generally define the shape of catenaries to substantially uniformly distribute loads over the leaflets. The free edges of the leaflets naturally define the shape of catenaries to uniformly distribute loads over the leaflets. Figs. 11, 12; Ex. 1007, ¶¶ 7-14.

Claims 2-17:

Svanidze discloses catenaries configured to reduce horizontal loads applied to the commissures. Catenaries naturally reduce the horizontal loads applied to the commissures. *See also*, Figs. 11-12; Ex. 1007, ¶¶ 7-14.

Svanidze discloses each leaflet is individually formed and comprises an enlarged lateral end having a plurality of flaps that are folded over to increase the durability of the commissures. Figs. 9, 11, 12, 13; 12:48 – 13:4. The skirt includes a plurality of longitudinally-oriented reinforcing tabs. Figs. 9, 11, 12, 13; 12:48 – 13:4.

Svanidze discloses reinforcing tabs affixed to the frame. Figs. 9, 11, 12, 13; 6:57-7:2; 9:38-56; 12:48 – 13:40; 15:42-44; 16:54-17:3; 17:26-40.

The leaflets are made of porcine, bovine, equine or other mammalian pericardial tissue, synthetic material, or polymeric material. 9:38-46. The leaflets sewn to the skirt at joints, and the joints are affixed to the frame to evenly distribute forces through the valve body to the frame. Joints affixed to a frame evenly

distribute forces through the valve body to the frame. Figs. 9, 11-12; 9:38-56; 13:5-40; Ex. 1007, ¶¶ 11-14.

Svanidze discloses a frame with a cell pattern that defines a contour configured to support the joints. Figs. 5, 9, 11-14; 6:57-7:2; 7:59-8:31; 9:6-20; 11:18-38; 12:48-59. The frame has a cell pattern defined by unequal length zig-zags. Figs. 5-8, 11-13; 8:11 – 9:14; 10:1-37; 10:58 – 11:38.

Commissures are affixed to the frame at a location proximal of the center of coaptation. Figs. 11-13; Ex. 1007, ¶¶ 11-14.

Svanidze discloses a skirt with a plurality of end tabs adapted to be affixed to a proximal-most row of cells of the frame. Figs. 9, 11-13.

Svanidze discloses a valve body deployed superannularly of a patient's aortic annulus when the valve prosthesis is delivered within a patient's aortic valve and the frame is in the expanded deployed configuration. 11:64 – 12:35. The frame is configured to hold a patient's native valve permanently open in the expanded deployed configuration. 11:64 – 12:35. The frame is configured to permit access to a patient's coronary arteries in the expanded deployed configuration. Figs. 11-13; 11:64 – 12:35; 13:5-40; 13:58-14:11. The frame with proximal and distal ends and a plurality of cell patterns that vary in size between the proximal and distal ends. Figs. 6C, 11-14.

Svanidze discloses a constriction region with a plurality of cell patterns con-

figured to provide a pre-determined radius of curvature for a transition from the constricted region to the outflow section. Figs. 11, 12, 14. The diameter of the constriction region with a predetermined diameter. Figs. 6C, 11, 12, 14.

Claim 18:

Svanidze discloses a valve prosthesis with a valve body 32 comprising a plurality of leaflets 36 sewn to a skirt 6, adjoining leaflets sewn together to form commissures 35. Figs. 9, 12; 6:57-7:2; 9:6-14, 38-56; 12:48-59; 17:26-40.

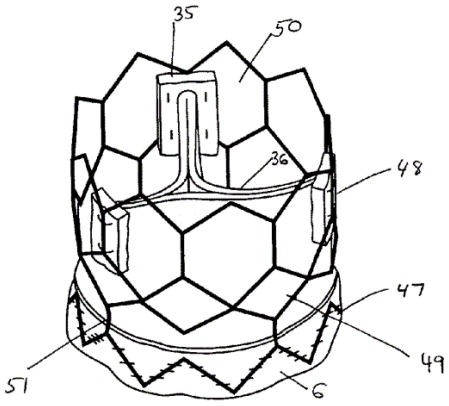


FIG. 12

Svanidze discloses a self-expanding frame comprising a plurality of cells comprising struts, the frame having a contracted delivery configuration and an expanded deployed configuration, wherein the frame supports the valve body, and wherein the frame has a longitudinal axis. Figs. 11, 12; 13:5-40.

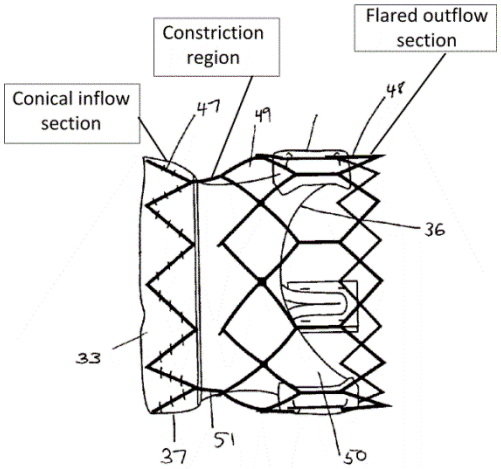


FIG. 11

Svanidze discloses when the frame is in the expanded deployed configuration, the frame has a tri-level asymmetric hourglass shape including a conical inflow section, an enlarged distal section, and a constriction region, wherein the constriction region

has a predefined curvature when the frame is in the expanded deployed configuration. Figs. 11-12; 7:59-67; 11:64 – 12:21; 13:19-22; 15:26-32; 17:47-51; 18:65-19:43.

Svanidze discloses a skirt with a bottom edge, the inflow section of the frame has an inflow edge, and the bottom edge of the skirt is sewn to the inflow edge of the inflow section. Figs. 11-13; 6:66-7:2; 9:38-56; 13:5-40; 15:42-44.

Svanidze discloses commissures sewn to the frame along a region of the frame that increases in diameter along the longitudinal axis in an intended direction of blood flow. Figs 11-12; 13:5-40.

Svanidze discloses each commissure configured to span a cell 60 of the frame to distribute force within the commissures and to the frame, and wherein a plurality of cells of the frame are positioned between the cells spanned by commissures. Figs. 11, 12, 14; 7:9-19; 9:15-22; 11:18-38; 13:5-40; 13:58-14:35.

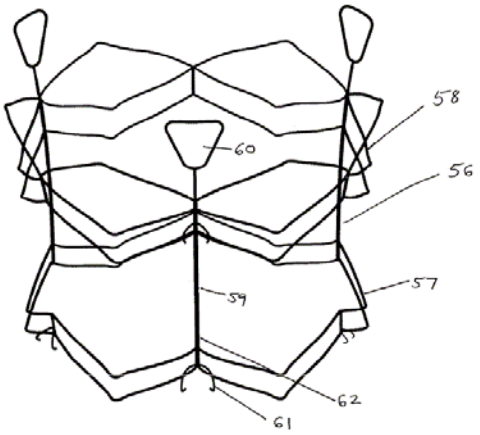


FIG. 14

Svanidze discloses at least a portion of the commissures are longitudinally offset from the center of coaptation, and each leaflet has a free edge that is suspended from the leaflet's respective commissures to define coaptation edges and a center of coaptation. Figs. 11-12; Ex. 1007, ¶¶ 7-14.

Svanidze discloses the length of each free edge forms a substantially continuous curve extending downwardly between the respective commissures so that the free edges of the leaflets generally define the shape of catenaries to substantially uniformly distribute loads over the leaflets. The free edges of the leaflets naturally define the shape of catenaries to uniformly distribute loads over the leaflets. Figs. 11, 12; Ex. 1007, ¶¶ 7-14.

Svanidze discloses the joints between the leaflets and the skirt are substantially aligned with and sewn to a curved contour defined by the struts of the frame such that the joints are supported by the frame over at least a substantial portion of the length of the joints. Figs. 11-12; 9:38-56; 13:5-40.

B. Claims 1-18 are Anticipated under 35 U.S.C. §102(a) by U.S. Patent No. 7,201,772 to Schwammenthal et al. (Ex. 1004)

Claim 1:

U.S. Patent No. 7,201,722 to Schwammenthal et al. was filed on December 30, 2004 and thus qualifies as prior art under § 102(e). Schwammenthal was not cited during prosecution of the ‘569 Patent or considered by the Examiner, and was listed on an IDS submitted by applicants years after filing the ‘569 Patent application along with 436 other U.S. references.

Schwammenthal discloses heart valve prosthesis with a self-expanding multi-level frame (10) that supports a valve body comprising a skirt (11) and plurality of coapting leaflets (16). The frame transitions between a contracted delivery con-

figuration that enables percutaneous transluminal delivery, and an expanded deployed configuration having an asymmetric hourglass shape (Figs. 15, 16 and 17). The valve body skirt and leaflets are constructed so that the center of coaptation may be selected to reduce horizontal forces applied to the commissures of the valve (Figs. 18a and 19a), and to efficiently distribute and transmit forces along the leaflets and to the frame. Schwammenthal discloses a valve body 16 comprising a plurality of leaflets sewn to a skirt 11, adjoining leaflets sewn together to form commissures. Figs. 4 (annotated below), 5 7, 9, 11A-C; 7:4-13; 8:8-19.

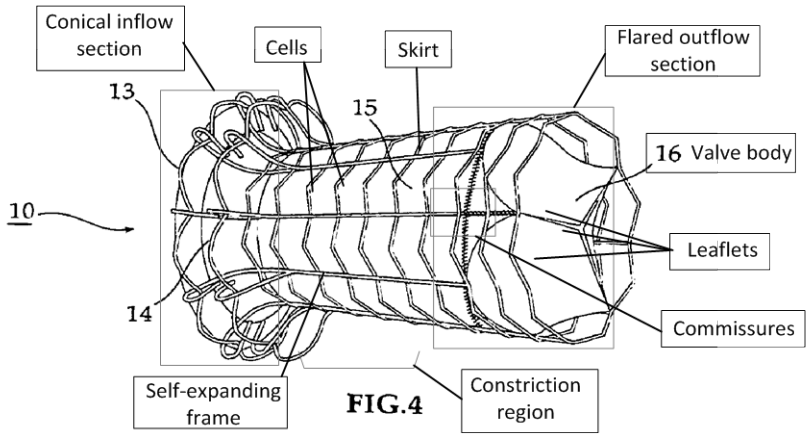


FIG.4

Schwammenthal discloses a self-expanding frame 10 comprising a plurality of cells, the frame has a substantially conical inflow section, a flared outflow section, and a constriction region between the inflow and outflow sections (Figs. 4, 5, 7, 10, 11, 11A-C; 3:1-5; 7:22-28); wherein the constriction region is configured to avoid blocking blood flow to the coronary arteries when the frame is implanted in a body, wherein the frame supporting supports the valve body, wherein the frame has a longitudinal axis, wherein the frame has a contracted delivery configuration

and an expanded deployed configuration. Figs. 10, 11A-C, 16a-f; 7:4-9; 7:31-34; 7:61 – 8:7; 8:61-67; 10:8-18; 11:7-24. When the frame is in the expanded de

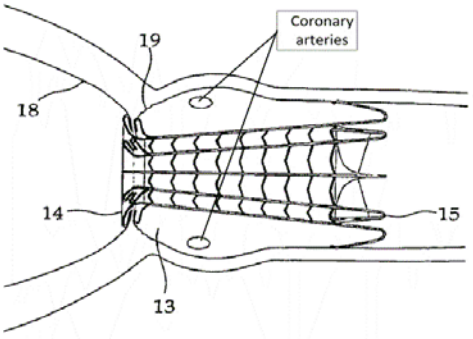


FIG.10

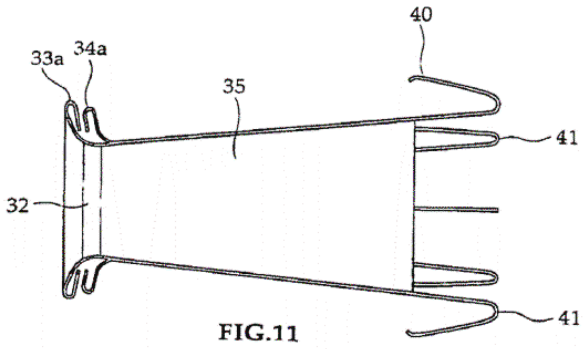


FIG.11

ployed configuration, the inflow section, the outflow section, and the constriction region have substantially circular cross-sections, the outflow section has a larger diameter than the inflow section, and the inflow section has a larger diameter than the constriction region. Figs. 6, 11A-C; 5:45-6:9.

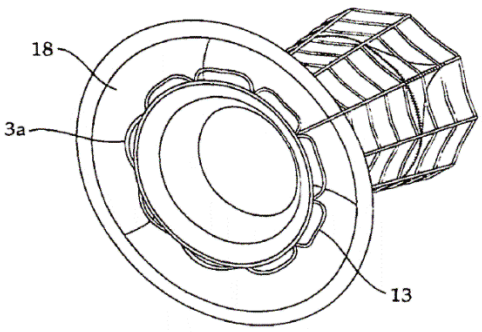


FIG.6

Schwammenthal discloses a skirt with a bottom edge and the inflow section of the frame has an inflow edge. Figs. 4, 5, 19b; 8:18-19. Although Schwammenthal does not expressly state that the bottom edge of the skirt is sewn to the inflow edge of the inflow section, Schwammenthal discloses sewing the liner to the frame, and sewing a skirt to the frame was known in the art at the time of filing the ‘569 patent.

Schwammenthal discloses commissures sewn to the frame along a region of

the frame that increases in diameter along the longitudinal axis in an intended direction of blood flow. Figs. 4, 5, 18a, 19b.

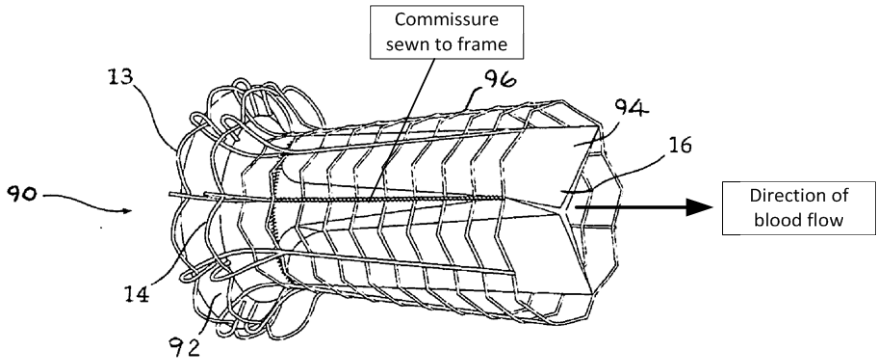


FIG.19b

Schwammenthal discloses each commissure configured to span a cell of the frame to distribute force within the commissures and to the frame, and wherein a plurality of cells of the frame are positioned between the cells spanned by commissures. Figs. 4, 5, 18a, 19b. At least a portion of the commissures are longitudinally offset from the center of coaptation, and each leaflet has a free edge that is suspended from the leaflet's respective commissures to define coaptation edges and a center of coaptation. Figs. 4, 5, 7, 11A-C.

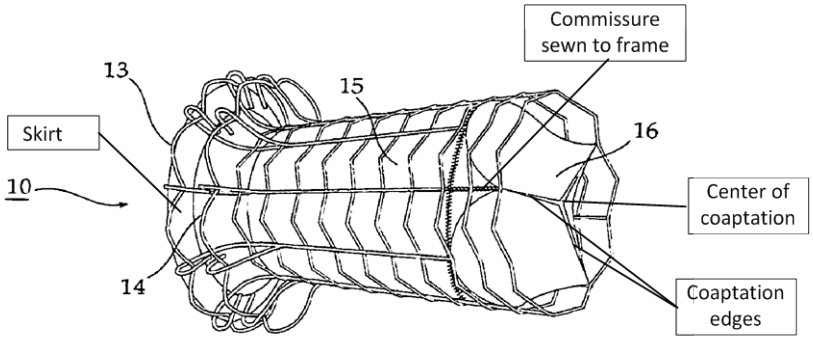


FIG.4

Schwammenthal discloses the length of each free edge forms a substantially continuous curve extending downwardly between the respective commissures so that the free edges of the leaflets generally define the shape of catenaries to substantially uniformly distribute loads over the leaflets. The free edges of the leaflets naturally define the shape of catenaries to uniformly distribute loads over the leaflets 16. Figs. 4, 5, 7, 9, 11A-C; Ex. 1007, ¶¶ 7-14.

Claims 2-17:

Schwammenthal discloses catenaries configured to reduce horizontal loads applied to the commissures. Catenaries reduce the horizontal loads applied to the commissures. See also Figs. 4, 5, 7, 9, 11A-C; Ex. 1007, ¶¶ 11-14.

Schwammenthal discloses each leaflet is individually formed and comprises an enlarged lateral end having a plurality of flaps that are folded over to increase the durability of the commissures. Figs. 4, 5, 7, 9, 11A-C.

Schwammenthal discloses a skirt. However, Schwammenthal does not expressly disclose longitudinally-oriented reinforcing tabs affixed to the frame. However, Schwammenthal discloses leaflets attached to the frame which would inherently include reinforcing tabs. *See* Figs. 4, 5 and 7.

Schwammenthal discloses leaflets of porcine, bovine, equine or other mammalian pericardial tissue, synthetic material, or polymeric material. 3:20-27; 7:35-54.

Schwammenthal discloses leaflets sewn to the skirt at joints, and the joints are affixed to the frame to evenly distribute forces through the valve body to the frame. Figs. 4, 5, 7, 11A-C, 18a, 19c; Ex. 1007, ¶¶ 11-14. The frame has a cell pattern that defines a contour configured to support the joints and has unequal length zig-zags. Figs. 4, 5, 7, 9, 11A-C, 18a-b, 19b.

Schwammenthal discloses commissures affixed to the frame at a location proximal of the center of coaptation. The commissures are affixed to the frame at a location proximal of the center of coaptation. Figs. 4, 5, 7, 9, 11A-C, 18a-b, 19b; Ex. 1007, ¶¶ 11-14.

Schwammenthal discloses a skirt with a plurality of end tabs adapted to be affixed to a proximal-most row of cells of the frame. Figs. 4, 5, 19b; 8:18-19. Although Schwammenthal does not expressly state that the bottom edge of the skirt is affixed to the proximal-most row of cells of the frame, Schwammenthal discloses sewing the liner to the frame, and sewing skirt to the frame was known in the art at the time of filing the ‘569 patent.

Schwammenthal discloses a valve body deployed superannularly of a patient's aortic annulus when the valve prosthesis is delivered within a patient's aortic valve and the frame is in the expanded deployed configuration. Figs. 10, 11A-C, 15a-h. The frame is configured to hold a patient's native valve permanently open in the expanded deployed configuration. Figs. 10, 11A-C, 15a-h; 12:36-46. The

frame is configured to permit access to a patient's coronary arteries in the expanded deployed configuration. Figs. 10, 11A-C; 8:61-67; 11:21-24; 12:9-13. The frame with proximal and distal ends and a plurality of cell patterns that vary in size between the proximal and distal ends. Figs. 4, 5, 7, 10.

Schwammenthal discloses a constriction region with a plurality of cell patterns configured to provide a pre-determined radius of curvature for a transition from the constricted region to the outflow section. Figs. 4, 5, 7, 10. The diameter of the constriction region with a predetermined diameter. Figs. 4-7, 10.

Claim 18:

Schwammenthal discloses a valve prosthesis with a valve body 16 comprising a plurality of leaflets sewn to a skirt 11, adjoining leaflets sewn together to form commissures. Figs. 4, 5 7, 9, 11A-C; 2:59-63; 7:4-13; 8:8-19.

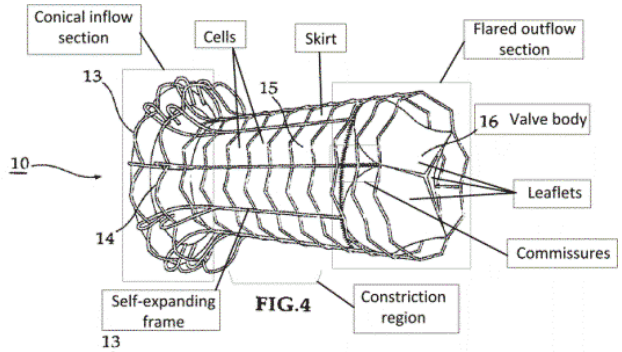


FIG.4

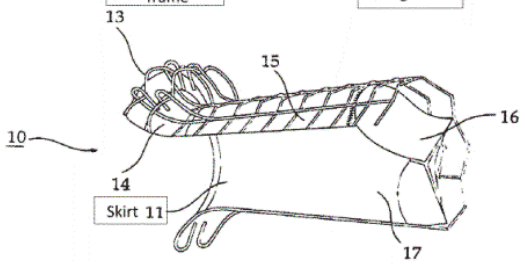


FIG.5

Schwammenthal discloses a self-expanding frame comprising a plurality of cells comprising struts, the frame having a contracted delivery configuration and an expanded deployed configuration, wherein the frame supports the valve body, and wherein the frame has a longitudinal axis. Figs. 4, 15a-h.

Schwammenthal discloses when the frame is in the expanded deployed configuration, the frame has a tri-level asymmetric hourglass shape including a conical inflow section, an enlarged distal section, and a constriction region, wherein the constriction region has a predefined curvature when the frame is in the expanded deployed configuration. Figs. 4, 5, 11.

Schwammenthal discloses a skirt with a bottom edge, the inflow section of the frame has an inflow edge, and the bottom edge of the skirt is sewn to the inflow edge of the inflow section. Figs. 4, 5, 19b; 8:18-19. Although Schwammenthal does not expressly state that the bottom edge of the skirt is sewn to the inflow edge of the inflow section, Schwammenthal discloses sewing the liner to the frame, and sewing a skirt to the frame was known in the art at the time of filing the ‘569 patent.

Schwammenthal discloses commissures sewn to the frame along a region of the frame that increases in diameter along the longitudinal axis in an intended direction of blood flow. Figs. 4, 5, 18a, 19b. Each commissure is configured to span a cell of the frame to help distribute force within the commissures and to the frame, and wherein a plurality of cells are positioned between the cells spanned by commissures. Figs. 4, 5, 18a, 19b. At least a portion of the commissures are longitudinally offset from the center of coaptation, and each leaflet has a free edge that is suspended from the leaflet's respective commissures to define coaptation edges and

a center of coaptation. Figs. 4, 5, 7, 11A-C.

Schwammenthal discloses the length of each free edge forming a substantially continuous curve extending downwardly between the respective commissures so that the free edges of the leaflets generally define the shape of catenaries to substantially uniformly distribute loads over the leaflets. The free edges of the leaflets naturally define the shape of catenaries to uniformly distribute loads over the leaflets 16. Figs. 4, 5, 7, 9, 11A-C.

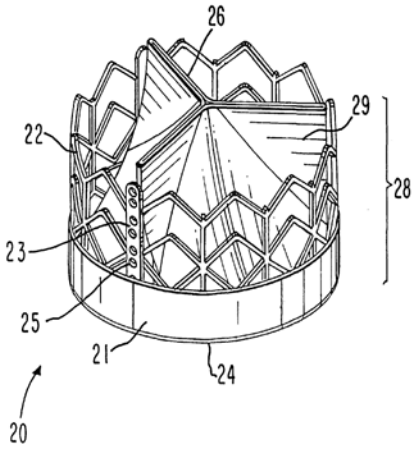
Schwammenthal discloses joints between the leaflets and the skirt substantially aligned with and sewn to a curved contour defined by the struts of the frame such that the joints are supported by the frame over at least a substantial portion of the length of the joints. Joints affixed to a frame evenly distribute forces through the valve body to the frame. Figs. 4, 5, 7, 11A-C, 18a, 19c; Ex. 1007, ¶¶ 11-14.

C. Claims 1-18 are Anticipated under 35 U.S.C. §102(a) by U.S. Patent No. 6,730,118 to Spenser et al. (Ex. 1005)

Claim 1:

U.S. Patent No. 6,730,118 to Spenser et al. ("Spenser") was filed on October 11, 2002 and issued on May 4, 2004 and thus qualifies as prior art under § 102(a).

FIG.1

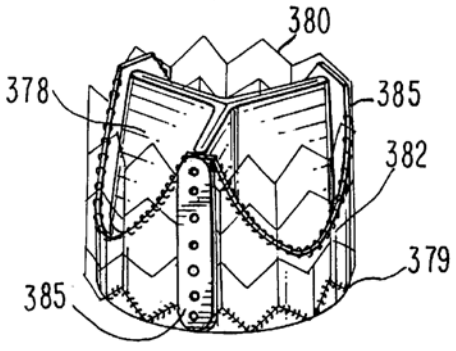


Spenser discloses heart valve prosthesis with

a self-expanding multi-level frame (Figs. 1, 9a, 11a, 17a, b) that supports a valve body comprising a skirt (21) and plurality of coapting leaflets (29). The frame transitions between a contracted delivery configuration that enables percutaneous transluminal delivery, and an expanded deployed configuration having an asymmetric hourglass shape (Figs. 17a, b). The valve body skirt and leaflets are constructed so that the center of coaptation may be selected to reduce horizontal forces applied to the commissures of the valve, and to efficiently distribute and transmit forces along the leaflets and to the frame. Figs. 20b, 23e, 40a, 41a, b 15:8-28; 16:1-24; 22:51-65); Ex. 1007, ¶¶ 11-14. Spenser discloses a valve body comprising a plurality of leaflets sewn to a skirt, adjoining leaflets sewn together to form commissures (23). Figs. 1, 9, 11, 23e, 25, 32a, 37c, 40a, 43a, 44a; 19:57 – 20:15.

Spenser discloses a self-expanding frame comprised of a plurality of cells 22, 380, the frame has a substantially conical inflow section 24, a flared outflow section 26, and a constriction region between the inflow and outflow sections (Fig. 41b), wherein the constriction region is configured to avoid blocking blood flow to the coronary arteries when the frame is implanted in a body, wherein the frame supporting supports the valve body, wherein the frame has a longitudinal axis, wherein the frame has a contracted delivery configu-

FIG. 23e



ration and an expanded deployed configuration. Figs. 16a – 17b; 12:40-49; 18:11-36.

Spenser discloses when the frame is in the expanded deployed configuration, the inflow section, the outflow section, and the constriction region have substantially circular cross-sections, the outflow section has a larger diameter than the inflow section, and the inflow section has a larger diameter than the constriction region. Figs. 17b, 20a, 20b, 44a.

Spenser discloses a skirt with a bottom edge, the inflow section of the frame has an inflow edge, and the bottom edge of the skirt is sewn to the inflow edge of the inflow section. Figs. 23e, 28, 37c. Spenser discloses commissures sewn to the frame along a region of the frame that increases in diameter along the longitudinal axis in an intended direction of blood flow. Figs. 17a – 17b. Each commissure is configured to span a cell 60 of the frame to distribute force within the commissures and to the frame, and wherein a plurality of cells of the frame are positioned between the cells spanned by commissures. Figs. 28, 31b, 32a, 33a, 33b, 37c; 15:8-29; 16:1-24; 22:51-65.

Spenser discloses at least a portion of the commissures are longitudinally offset from the center of coaptation, and each leaflet has a free edge that is sus-

pended from the leaflet's respective commissures to define coaptation edges and a center of coaptation. Figs. 1, 23e. Spenser discloses the length of each free edge forms a substantially continuous curve extending downwardly between the respective commissures so that the free edges of the leaflets generally define the shape of catenaries to substantially uniformly distribute loads over the leaflets. The free edges of the leaflets naturally define the shape of catenaries to uniformly distribute loads over the leaflets. Figs. 1, 23e, 26a.

Claims 2-17:

Spenser discloses catenaries configured to reduce horizontal loads applied to the commissures. Catenaries reduce the horizontal loads applied to the commissures. Figs. 23a-23f, 30a-30c, 31a-31b, 36a-36b, 37a-37c; 19:57 – 20:15; 22:51 – 23:14; 24:28-53; Ex. 1007, ¶¶ 7-14.

Spenser discloses each leaflet is individually formed and comprises an enlarged lateral end having a plurality of flaps that are folded over to increase the durability of the commissures. Figs. 23a-23f, 30a-30c, 31a-31b, 36a-36b, 37a-37c; 19:57 – 20:15; 22:51 – 23:14; 24:28-53.

Spenser discloses a skirt with a plurality of longitudinally-oriented reinforcing tabs. Figs. 23a-23f, 30a-30c, 31a-31b, 36a-36b, 37a-37c; 19:57 – 20:15; 22:51 – 23:14; 24:28-53. The reinforcing tabs are affixed to the frame. Figs. 23a-23f, 30a-30c, 31a-31b, 36a-36b, 37a-37c; 19:57 – 20:15; 22:51 – 23:14; 24:28-53.

Spenser discloses leaflets of porcine, bovine, equine or other mammalian pericardial tissue, synthetic material, or polymeric material. 2:55-60; 12:30-39. The leaflets are sewn to the skirt at joints, and the joints are affixed to the frame to evenly distribute forces through the valve body to the frame. Joints affixed to a frame evenly distribute forces through the valve body to the frame. Figs. 23a-23f, 30a-30c, 31a-31b, 36a-36b, 37a-37c; 19:57 – 20:15; 22:51 – 23:14; 24:28-53; Ex. 1007, ¶¶ 11-14. The frame has a cell pattern that defines a contour configured to support the joints. Figs. 23a-23f, 30a-30c, 31a-31b, 36a-36b, 37a-37c; 19:57 – 20:15; 22:51 – 23:14; 24:28-53. The frame has a cell pattern defined by unequal length zig-zags. Figs. 9a, 21, 41a.

Spenser discloses commissures affixed to the frame at a location proximal of the center of coaptation. Commissures are affixed to the frame at a location proximal of the center of coaptation. Fig. 23e; Ex. 1007, ¶¶ 11-14.

Spenser discloses a skirt with a plurality of end tabs adapted to be affixed to a proximal-most row of cells of the frame. Figs. 23a-23e.

Spenser discloses a valve body deployed superannularly of a patient's aortic annulus when the valve prosthesis is delivered within a patient's aortic valve and the frame is in the expanded deployed configuration. Figs. 16a-16c, 17a-17b.

Spenser discloses a frame configured to hold a patient's native valve permanently open in the expanded deployed configuration. Figs. 17a – 17b; 18:11-36.

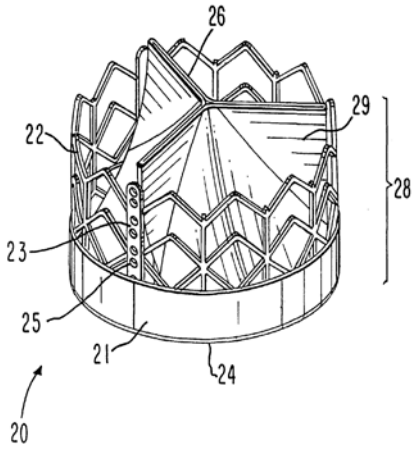
Spenser discloses frame configured to permit access to a patient's coronary arteries in the expanded deployed configuration. Figs. 17a – 17b; 18:11-36.

Spenser discloses a frame with proximal and distal ends and a plurality of cell patterns that vary in size between the proximal and distal ends. Figs. 1, 23e, 26a.

Spenser discloses a constriction region with a plurality of cell patterns configured to provide a pre-determined radius of curvature for a transition from the constricted region to the outflow section. Fig. 44a.

Spenser discloses a diameter of the constriction region with a predetermined diameter. Fig. 44a.

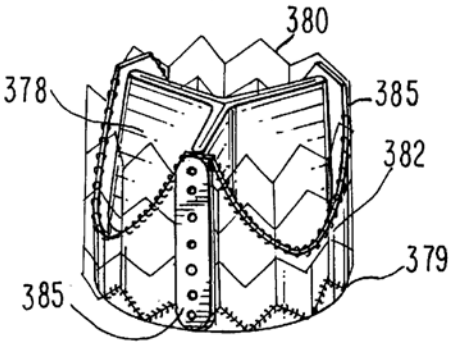
FIG.1



Claim 18:

Spenser discloses a valve prosthesis with a valve body 20 comprising a plurality of leaflets 29 sewn to a skirt 382, adjoining leaflets sewn together to form commissures Figs. 1, 23e, 25, 32a, 37c, 40a, 43a, 44a. 19:57 – 20:15.

FIG. 23e



Spenser discloses a self-expanding frame comprising a plurality of cells comprising struts, the frame having a contracted delivery configuration and an expanded deployed configuration,

wherein the frame supports the valve body, and wherein the frame has a longitudinal axis. Figs. 16a – 17b; 12:40-49; 18:11-36.

When the frame is in the expanded deployed configuration, the frame has a tri-level asymmetric hourglass shape including a conical inflow section, an enlarged distal section, and a constriction region, wherein the constriction region has a predefined curvature when the frame is in the expanded deployed configuration. Figs. 16a – 17b; 12: 40-49; 18-11-36.

Spenser discloses a skirt with a bottom edge, the inflow section of the frame has an inflow edge, and the bottom edge of the skirt is sewn to the inflow edge of the inflow section. Figs. 16a – 17b; 12: 40-49; 18-11-36. The commissures are sewn to the frame along a region of the frame that increases in diameter along the longitudinal axis in an intended direction of blood flow. Figs. 16a – 17b, 20a, 20b, 44a; 12: 40-49; 18-11-36. The commissures are configured to span a cell of the frame to help distribute force within the commissures and to the frame, and wherein a plurality of cells are positioned between the cells spanned by commissures. Fig. 28, 31b, 32a, 33a, 33b, 37c; 15:8-29; 16:1-24; 22:51-65.

Spenser discloses at least a portion of the commissures are longitudinally offset from the center of coaptation, and each leaflet has a free edge that is suspended from the leaflet's respective commissures to define coaptation edges and a center of coaptation. Figs. 1, 23e.

Spenser discloses the length of each free edge forms a substantially continuous curve extending downwardly between the respective commissures so that the free edges of the leaflets generally define the shape of catenaries to substantially uniformly distribute loads over the leaflets. Figs. 1, 23e, 26a; Ex. 1007, ¶¶ 7-14. The joints between the leaflets and the skirt are substantially aligned with and sewn to a curved contour defined by the struts of the frame such that the joints are supported by the frame over at least a substantial portion of the length of the joints. Figs. 16a – 17b; 12: 40-49; 18-11-36.

D. Claims 1-18 are Obvious under 35 U.S.C. §103(a) over Svanidze (Ex. 1003) in view of U.S. Patent No. 7,320,704 to Lashinski et al. (Ex. 1006)

Claims 1, 7 and 18:

To the extent that Svanidze does not disclose that the free edges of the leaflets generally define the shape of catenaries to substantially uniformly distribute loads over the leaflets, Lashinski discloses coapting leaflets that distribute stress evenly over the entire leaflet cusp from commissure to commissure to evenly distribute the attachment forces. Figs. 1-16B, 25E, 25F; 25:44 – 26:9. It would have been obvious to one of ordinary skill in the art at the time of the filing the ‘569 Patent to utilize natural catenaries to distribute loads in view of the teachings of Lashinski. Further, uniform distribution of force by catenaries is inherent in the shape. Ex. 1007, ¶¶ 7-14.

Claim 6:

To the extent that Svanidze does not disclose procine, bovine, equine or other mammalian pericardial tissue, Lashinski discloses procine, bovine, equine or other mammalian pericardial tissue. 26:51 – 28:34. It would have been obvious to one of ordinary skill in the art at the time of the filing the '569 Patent to utilize natural valve tissue in view of the teachings of Lashinski.

E. Claims 1-18 are Obvious under 35 U.S.C. §103(a) over U.S. Patent No. 7,201,772 to Schwammenthal et al. (Ex. 1004) in view of Svanidze (Ex. 1003)

Claim 1:

Svanidze shows a skirt with a bottom edge sewn to the inflow edge of the inflow section. *Svanidze*, Figs. 11, 12, 24-26; 9:38-56; 13:5-40; 16:41-17:40. It would have been obvious to one of ordinary skill in the art at the time of the filing the '569 Patent to sew the skirt disclosed in Schwammenthal to the frame in view of the teachings of Svanidze.

Claim 4:

Svanidze discloses a plurality of longitudinally reinforcing tabs affixed to the frame. *Svanidze*, Figs. 9, 11, 12, 13; 6:57-7:2; 9:38-56; 12:48 – 13:40; 15:42-44; 16:54-17:3; 17:26-40. It would be obvious to one of ordinary skill in the art at the time of filing the '569 Patent to utilize the leaflets with reinforcing tabs disclosed in Svanidze in combination with the frame of Schwammenthal.

Claim 18:

Svanidze shows a skirt with a bottom edge sewn to the inflow edge of the inflow section. *Svanidze*, Figs. 11, 12, 24-26; 9:38-56; 13:5-40; 16:41-17:40. Therefore it would have been obvious to one of ordinary skill in the art at the time of the filing the '569 Patent to sew the skirt shown in Schwammenthal to the frame in view of the teachings of Svanidze.

F. Claims 1-18 are Obvious under 35 U.S.C. §103(a) over U.S. Patent No. 6,730,118 to Spenser et al. (Ex. 1005) in view of Schwammenthal (Ex. 1004)

Claim 1:

To the extent that Spenser does not show a larger diameter outflow section than the diameter of the inflow section, and the inflow section having a larger diameter than the constriction region, Schwammenthal discloses a larger diameter outflow section than the diameter of the inflow section, and the inflow section having a larger diameter than the constriction region. *Schwammenthal,* Figs. 2, 3, 6, 11A-C; 5:45-6:9, 6:29-57. It would be obvious to one of ordinary skill in the art at the time of filing of the '569 Patent to configure Spenser as taught by Schwammenthal.

Claim 16:

To the extent that Spenser does not disclose a constriction region with a plurality of cell patterns configured to provide a pre-determined radius of curvature

for a transition from the constricted region to the outflow section, Schwammenthal discloses a constriction region with a plurality of cell patterns configured to provide a pre-determined radius of curvature for a transition from the constricted region to the outflow section. *Schwammenthal*, Figs. 4-7, 10, 11A, 18b. It would be obvious to configure the cells of Spenser as taught by Schwammenthal.

Claim 18:

To the extent that Spenser does not show tri-level asymmetric hourglass shape, Schwammenthal discloses when the frame is in the expanded deployed configuration, the frame has a tri-level asymmetric hourglass shape including a conical inflow section, an enlarged distal section, and a constriction region, wherein the constriction region has a predefined curvature when the frame is in the expanded deployed configuration. *Schwammenthal,* Figs. 4, 5, 11.

G. Claims 1-18 are Obvious under 35 U.S.C. §103(a) over U.S. Patent No. 7,201,772 to Schwammenthal et al. (Ex. 1004) in view of Svanidze (Ex. 1003), further in view of Lashinski (Ex. 1006)

Claims 1, 7 and 18:

To the extent that Schwammenthal does not disclose that the free edges of the leaflets generally define the shape of catenaries to substantially uniformly distribute loads over the leaflets, Lashinski discloses coapting leaflets that distribute stress evenly over the entire leaflet cusp from commissure to commissure to evenly distribute the attachment forces. Figs. 1-16B, 25E, 25F; 25:44 – 26:9. It would

have been obvious to one of ordinary skill in the art at the time of the filing the ‘569 Patent to utilize natural catenaries to distribute loads in view of the teachings of Lashinski. Further, uniform distribution of force by catenaries is inherent in the shape. Ex. 1007, ¶¶7-14.

H. Claims 1-18 are Obvious under 35 U.S.C. §103(a) over U.S. Patent No. 6,730,118 to Spenser et al. (Ex. 1005) in view of Schwammenthal (Ex. 1004), further in view of Lashinski (Ex. 1006)

Claims 1, 7 and 18:

To the extent that Schwammenthal does not disclose that the free edges of the leaflets generally define the shape of catenaries to substantially uniformly distribute loads over the leaflets, Lashinski discloses coapting leaflets that distribute stress evenly over the entire leaflet cusp from commissure to commissure to evenly distribute the attachment forces. Figs. 1-16B, 25E, 25F; 25:44 – 26:9. It would have been obvious to one of ordinary skill in the art at the time of the filing the ‘569 Patent to utilize natural catenaries to distribute loads in view of the teachings of Lashinski. Further, uniform distribution of force by catenaries is inherent in the shape. Ex. 1007, ¶¶7-14.

VI. CONCLUSION

Based on the foregoing, it is clear that claims 1-18 of the '569 Patent define subject matter that is anticipated and/or obvious. The art cited above establishes a reasonable likelihood that Petitioner will prevail on at least one claim. Accordingly, *inter partes* review of claims 1-18 of U.S. Patent No. 7,914,569 is respectfully requested.

Respectfully submitted,
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Attachments: Appendices A-1 – A-7 (Claim Charts)
Exhibits 1001-1012

APPENDIX A-1

U.S. Patent No. 7,914,569 **Anticipation by U.S. Patent No. 7,044,966 to Svanidze (Ex. 1003)**
1. A valve prosthesis comprising: To the extent that the preamble is a limitation, Svanidze discloses a valve prosthesis.
a valve body comprising a plurality of leaflets sewn to a skirt, adjoining leaflets sewn together to form commissures; and
Svanidze discloses a valve body 32 comprising a plurality of leaflets 36 sewn to a skirt 6, adjoining leaflets sewn together to form commissures 35. Figs. 9, 12; 6:57-7:2; 9:6-14, 38-56; 12:48-59; 17:26-40.
a self-expanding frame comprising a plurality of cells, the frame having a substantially conical inflow section, a flared outflow section, and a constriction region between the inflow section and the outflow section, wherein the constriction region is configured to avoid blocking blood flow to the coronary arteries when the frame is implanted in a body, wherein the frame supporting supports the valve body, wherein the frame has a longitudinal axis, wherein the frame has a contracted delivery configuration and an expanded deployed configuration,
Svanidze discloses a self-expanding frame comprised of a plurality of cells 49, 50, the frame has a substantially conical inflow section, a flared outflow section, and a constriction region between the inflow and outflow sections. Figs. 11, 12; 7:32-43; 12:17-21; 13:5-40; 14:26-28; and wherein the constriction region is configured to avoid blocking blood flow to the coronary arteries when the frame is implanted in a body, wherein the frame supporting supports the valve body, wherein the frame has a longitudinal axis, wherein the frame has a contracted delivery configuration and an expanded deployed configuration. Figs. 11-12; 7:59-67; 11:64 – 12:21; 13:19-22; 15:26-32; 17:47-51; 18:65-19:43.
wherein, when the frame is in the expanded deployed configuration, the inflow section, the outflow section, and the constriction region have substantially circular cross-sections, the outflow section has a larger diameter than the inflow section, and the inflow section has a larger diameter than the constriction region,
Svanidze discloses when the frame is in the expanded deployed configuration, the inflow section, the outflow section, and the constriction region have substantially circular cross-sections, the outflow section has a larger diameter than the inflow section, and the inflow section has a larger diameter than the constriction region. Figs. 3, 6A, 6C, 11, 12, 13, 27B, 28B.
wherein the skirt has a bottom edge, the inflow section of the frame has an inflow edge, and the bottom edge of the skirt is sewn to the inflow edge of the inflow section,

Svanidze discloses a skirt with a bottom edge, the inflow section of the frame has an inflow edge, and the bottom edge of the skirt is sewn to the inflow edge of the inflow section. Figs. 11-13; 6:66-7:2; 9:38-56; 13:5-40; 15:42-44.
wherein the commissures are sewn to the frame along a region of the frame that increases in diameter along the longitudinal axis in an intended direction of blood flow,
Svanidze discloses commissures sewn to the frame along a region of the frame that increases in diameter along the longitudinal axis in an intended direction of blood flow. Figs 11-12; 13:5-40.
wherein each commissure is configured to span a cell of the frame to distribute force within the commissures and to the frame, and wherein a plurality of cells of the frame are positioned between the cells spanned by commissures,
Svanidze discloses each commissure configured to span a cell 60 of the frame to distribute force within the commissures and to the frame, and wherein a plurality of cells of the frame are positioned between the cells spanned by commissures. Figs. 11, 12, 14; 7:9-19; 9:15-22; 11:18-38; 13:5-40; 13:58-14:35.
wherein at least a portion of the commissures are longitudinally offset from the center of coaptation, and each leaflet has a free edge that is suspended from the leaflet's respective commissures to define coaptation edges and a center of coaptation, and
Svanidze discloses at least a portion of the commissures are longitudinally offset from the center of coaptation, and each leaflet has a free edge that is suspended from the leaflet's respective commissures to define coaptation edges and a center of coaptation. Figs. 11, 12.
wherein the length of each free edge forms a substantially continuous curve extending downwardly between the respective commissures so that the free edges of the leaflets generally define the shape of catenaries to substantially uniformly distribute loads over the leaflets.
Svanidze discloses the length of each free edge forms a substantially continuous curve extending downwardly between the respective commissures so that the free edges of the leaflets generally define the shape of catenaries to substantially uniformly distribute loads over the leaflets. The free edges of the leaflets naturally define the shape of catenaries to uniformly distribute loads over the leaflets. Figs. 11, 12, 13.
2. The valve prosthesis of claim 1 wherein the catenaries are configured to reduce horizontal loads applied to the commissures.
Svanidze discloses catenaries configured to reduce horizontal loads applied to the commissures. Catenaries reduce the horizontal loads applied to the commissures. *See also,* Figs. 11-12; Ex. 1007, ¶¶ 7-14.

3. The valve prosthesis of claim 1 wherein each leaflet is individually formed and comprises an enlarged lateral end having a plurality of flaps that are folded over to increase the durability of the commissures.
Svanidze discloses each leaflet is individually formed and comprises an enlarged lateral end having a plurality of flaps that are folded over to increase the durability of the commissures. Figs. 9, 11, 12, 13; 12:48 – 13:4.
4. The valve prosthesis of claim 1 wherein the skirt further comprises a plurality of longitudinally-oriented reinforcing tabs.
Svanidze discloses a skirt with a plurality of longitudinally-oriented reinforcing tabs. Figs. 9, 11, 12, 13; 12:48 – 13:4.
5. The valve prosthesis of claim 4 wherein the reinforcing tabs are affixed to the frame.
Svanidze discloses reinforcing tabs affixed to the frame. Figs. 9, 11, 12, 13; 6:57-7:2; 9:38-56; 12:48 – 13:40; 15:42-44; 16:54-17:3; 17:26-40.
6. The valve prosthesis of claim 1 wherein the leaflets comprise porcine, bovine, equine or other mammalian pericardial tissue, synthetic material, or polymeric material.
Svanidze discloses leaflets of porcine, bovine, equine or other mammalian pericardial tissue, synthetic material, or polymeric material. 9:38-46.
7. The valve prosthesis of claim 1 wherein the leaflets are sewn to the skirt at joints, and the joints are affixed to the frame to evenly distribute forces through the valve body to the frame.
Svanidze discloses leaflets sewn to the skirt at joints, and the joints are affixed to the frame to evenly distribute forces through the valve body to the frame. Joints affixed to a frame evenly distribute forces through the valve body to the frame. Figs. 9, 11-12; 9:38-56; 13:5-40; Ex. 1007, ¶¶ 11-14.
8. The valve prosthesis of claim 7 wherein the frame further comprises a cell pattern that defines a contour configured to support the joints.
Svanidze discloses a frame with a cell pattern that defines a contour configured to support the joints. Figs. 5, 9, 11-14; 6:57-7:2; 7:59-8:31; 9:6-20; 11:18-38; 12:48-59.
9. The valve prosthesis of claim 1 wherein the frame comprises a cell pattern defined by unequal length zig-zags.
Svanidze discloses a frame with a cell pattern defined by unequal length zig-zags. Figs. 5-8, 11-13; 8:11 – 9:14; 10:1-37; 10:58 – 11:38.
10. The valve prosthesis of claim 1 wherein the commissures are affixed to the frame at a location proximal of the center of coaptation.
Svanidze discloses commissures affixed to the frame at a location proximal of the center of coaptation. Commissures are affixed to the frame at a location proximal

of the center of coaptation. Figs. 11-13; Ex. 1007, ¶¶ 11-14.
11. The valve prosthesis of claim 1 wherein the skirt further comprises a plurality of end tabs adapted to be affixed to a proximal-most row of cells of the frame.
Svanidze discloses a skirt with a plurality of end tabs adapted to be affixed to a proximal-most row of cells of the frame. Figs. 9, 11-13.
12. The valve prosthesis of claim 1 wherein the valve body is deployed superannularly of a patient's aortic annulus when the valve prosthesis is delivered within a patient's aortic valve and the frame is in the expanded deployed configuration.
Svanidze discloses a valve body deployed superannularly of a patient's aortic annulus when the valve prosthesis is delivered within a patient's aortic valve and the frame is in the expanded deployed configuration. 11:64 – 12:35.
13. The valve prosthesis of claim 1 wherein the frame is configured to hold a patient's native valve permanently open in the expanded deployed configuration.
Svanidze discloses a frame configured to hold a patient's native valve permanently open in the expanded deployed configuration. 11:64 – 12:35.
14. The valve prosthesis of claim 1 wherein the frame is configured to permit access to a patient's coronary arteries in the expanded deployed configuration.
Svanidze discloses a frame configured to permit access to a patient's coronary arteries in the expanded deployed configuration. Figs. 11-13; 11:64–12:35; 13:5-40; 13:58-14:11.
15. The valve prosthesis of claim 1 wherein the frame has proximal and distal ends and a plurality of cell patterns that vary in size between the proximal and distal ends.
Svanidze discloses a frame with proximal and distal ends and a plurality of cell patterns that vary in size between the proximal and distal ends. Figs. 6C, 11-14.
16. The valve prosthesis of claim 1 wherein the constriction region comprises a plurality of cell patterns configured to provide a pre-determined radius of curvature for a transition from the constricted region to the outflow section.
Svanidze discloses a constriction region with a plurality of cell patterns configured to provide a pre-determined radius of curvature for a transition from the constricted region to the outflow section. Figs. 11, 12, 14.
17. The valve prosthesis of claim 1 wherein the diameter of the constriction region is a predetermined diameter.
Svanidze discloses a diameter of the constriction region with a predetermined diameter. Figs. 6C, 11, 12, 14.
18. A valve prosthesis comprising: To the extent that the preamble is a limitation, Svanidze discloses a valve prosthesis.
a valve body comprising a plurality of leaflets sewn to a skirt to form joints between the leaflets and the skirt, adjoining leaflets sewn together to form commis-

sures; and
Svanidze discloses a valve body 32 comprising a plurality of leaflets 36 sewn to a skirt 6, adjoining leaflets sewn together to form commissures 35. Figs. 9, 12; 6:57-7:2; 9:6-14, 38-56; 12:48-59; 17:26-40.
a self-expanding frame comprising a plurality of cells comprising struts, the frame having a contracted delivery configuration and an expanded deployed configuration, wherein the frame supports the valve body, and wherein the frame has a longitudinal axis,
Svanidze discloses a self-expanding frame comprising a plurality of cells comprising struts, the frame having a contracted delivery configuration and an expanded deployed configuration, wherein the frame supports the valve body, and wherein the frame has a longitudinal axis. Figs. 11, 12; 13:5-40.
wherein, when the frame is in the expanded deployed configuration, the frame has a tri-level asymmetric hourglass shape including a conical inflow section, an enlarged distal section, and a constriction region, wherein the constriction region has a predefined curvature when the frame is in the expanded deployed configuration,
Svanidze discloses when the frame is in the expanded deployed configuration, the frame has a tri-level asymmetric hourglass shape including a conical inflow section, an enlarged distal section, and a constriction region, wherein the constriction region has a predefined curvature when the frame is in the expanded deployed configuration. Figs. 11-12; 7:59-67; 11:64 – 12:21; 13:19-22; 15:26-32; 17:47-51; 18:65-19:43.
wherein the skirt has a bottom edge, the inflow section of the frame has an inflow edge, and the bottom edge of the skirt is sewn to the inflow edge of the inflow section,
Svanidze discloses a skirt with a bottom edge, the inflow section of the frame has an inflow edge, and the bottom edge of the skirt is sewn to the inflow edge of the inflow section. Figs. 11-13; 6:66-7:2; 9:38-56; 13:5-40; 15:42-44.
wherein the commissures are sewn to the frame along a region of the frame that increases in diameter along the longitudinal axis in an intended direction of blood flow,
Svanidze discloses commissures sewn to the frame along a region of the frame that increases in diameter along the longitudinal axis in an intended direction of blood flow. Figs 11-12; 13:5-40.
wherein each commissure is configured to span a cell of the frame to help distribute force within the commissures and to the frame, and wherein a plurality of cells are positioned between the cells spanned by commissures,
Svanidze discloses each commissure configured to span a cell 60 of the frame to

distribute force within the commissures and to the frame, and wherein a plurality of cells of the frame are positioned between the cells spanned by commissures. Figs. 11, 12, 14; 7:9-19; 9:15-22; 11:18-38; 13:5-40; 13:58-14:35.
wherein at least a portion of the commissures are longitudinally offset from the center of coaptation, and each leaflet has a free edge that is suspended from the leaflet's respective commissures to define coaptation edges and a center of coaptation,
Svanidze discloses at least a portion of the commissures are longitudinally offset from the center of coaptation, and each leaflet has a free edge that is suspended from the leaflet's respective commissures to define coaptation edges and a center of coaptation. Figs. 11-12.
wherein the length of each free edge forms a substantially continuous curve extending downwardly between the respective commissures so that the free edges of the leaflets generally define the shape of catenaries to substantially uniformly distribute loads over the leaflets, and
Svanidze discloses the length of each free edge forms a substantially continuous curve extending downwardly between the respective commissures so that the free edges of the leaflets generally define the shape of catenaries to substantially uniformly distribute loads over the leaflets. The free edges of the leaflets naturally define the shape of catenaries to uniformly distribute loads over the leaflets. Figs. 11, 12.
wherein the joints between the leaflets and the skirt are substantially aligned with and sewn to a curved contour defined by the struts of the frame such that the joints are supported by the frame over at least a substantial portion of the length of the joints.
Svanidze discloses the joints between the leaflets and the skirt are substantially aligned with and sewn to a curved contour defined by the struts of the frame such that the joints are supported by the frame over at least a substantial portion of the length of the joints. Figs. 11-12; 9:38-56; 13:5-40.

APPENDIX A-2

Anticipation by U.S. Patent No. 7,201,772 to Schwammenthal (Ex. 1004)
1. *A valve prosthesis comprising:* To the extent that the preamble is a limitation, Schwammenthal discloses a valve prosthesis. Figures; 2:59-63.
a valve body comprising a plurality of leaflets sewn to a skirt, adjoining leaflets sewn together to form commissures; and
Schwammenthal discloses a valve body 16 comprising a plurality of leaflets sewn to a skirt 11, adjoining leaflets sewn together to form commissures. Figs. 4, 5, 7,

9, 11A-C; 7:4-13, 41-44; 8:8-19.
a self-expanding frame comprising a plurality of cells, the frame having a substantially conical inflow section, a flared outflow section, and a constriction region between the inflow section and the outflow section, wherein the constriction region is configured to avoid blocking blood flow to the coronary arteries when the frame is implanted in a body, wherein the frame supporting supports the valve body, wherein the frame has a longitudinal axis, wherein the frame has a contracted delivery configuration and an expanded deployed configuration,
Schwammenthal discloses a self-expanding frame 10 comprising a plurality of cells, the frame has a substantially conical inflow section, a flared outflow section, and a constriction region between the inflow and outflow sections (Figs. 4, 5, 7, 10, 11, 11A-C; 3:1-5; 7:22-28), wherein the constriction region is configured to avoid blocking blood flow to the coronary arteries when the frame is implanted in a body, wherein the frame supporting supports the valve body, wherein the frame has a longitudinal axis, wherein the frame has a contracted delivery configuration and an expanded deployed configuration. Figs. 10, 11A-C, 16a-f; 7:4-9; 7:31-34; 7:61 – 8:7; 8:61-67; 10:8-18; 11:7-24; 13:21-26.
wherein, when the frame is in the expanded deployed configuration, the inflow section, the outflow section, and the constriction region have substantially circular cross-sections, the outflow section has a larger diameter than the inflow section, and the inflow section has a larger diameter than the constriction region,
Schwammenthal discloses when the frame is in the expanded deployed configuration, the inflow section, the outflow section, and the constriction region have substantially circular cross-sections, the outflow section has a larger diameter than the inflow section, and the inflow section has a larger diameter than the constriction region. Figs. 2, 3, 6, 11A-C; 5:45-6:9; 6:29-57.
wherein the skirt has a bottom edge, the inflow section of the frame has an inflow edge, and the bottom edge of the skirt is sewn to the inflow edge of the inflow section,
Schwammenthal discloses a skirt with a bottom edge, the inflow section of the frame has an inflow edge, and the bottom edge of the skirt is attached to the inflow edge of the inflow section. Fig. 4, 5, 19b; 8:18-19.
wherein the commissures are sewn to the frame along a region of the frame that increases in diameter along the longitudinal axis in an intended direction of blood flow,
Schwammenthal discloses commissures sewn to the frame along a region of the frame that increases in diameter along the longitudinal axis in an intended direction of blood flow. Figs. 4, 5, 18a, 19b; 8:8-19.
wherein each commissure is configured to span a cell of the frame to distribute

force within the commissures and to the frame, and wherein a plurality of cells of the frame are positioned between the cells spanned by commissures,
Schwammenthal discloses each commissure configured to span a cell of the frame to distribute force within the commissures and to the frame, and wherein a plurality of cells of the frame are positioned between the cells spanned by commissures. Figs. 4, 5, 18a, 19b; 8:8-19.
wherein at least a portion of the commissures are longitudinally offset from the center of coaptation, and each leaflet has a free edge that is suspended from the leaflet's respective commissures to define coaptation edges and a center of coaptation, and
Schwammenthal discloses at least a portion of the commissures are longitudinally offset from the center of coaptation, and each leaflet has a free edge that is suspended from the leaflet's respective commissures to define coaptation edges and a center of coaptation. Figs. 4, 5, 7, 11A-C; 19b.
wherein the length of each free edge forms a substantially continuous curve extending downwardly between the respective commissures so that the free edges of the leaflets generally define the shape of catenaries to substantially uniformly distribute loads over the leaflets.
Schwammenthal discloses the length of each free edge forms a substantially continuous curve extending downwardly between the respective commissures so that the free edges of the leaflets generally define the shape of catenaries to substantially uniformly distribute loads over the leaflets. The free edges of the leaflets naturally define the shape of catenaries to uniformly distribute loads over the leaflets 16. Figs. 4, 5, 7, 9, 11A-C.
2. The valve prosthesis of claim 1 wherein the catenaries are configured to reduce horizontal loads applied to the commissures.
Schwammenthal discloses catenaries configured to reduce horizontal loads applied to the commissures. Catenaries reduce the horizontal loads applied to the commissures. See also Figs. 4, 5, 7, 9, 11A-C; Ex. 1007, ¶¶ 11-14.
3. The valve prosthesis of claim 1 wherein each leaflet is individually formed and comprises an enlarged lateral end having a plurality of flaps that are folded over to increase the durability of the commissures.
Schwammenthal discloses each leaflet is individually formed and comprises an enlarged lateral end having a plurality of flaps that are folded over to increase the durability of the commissures. Figs. 4, 5, 7, 9, 11A-C.
4. The valve prosthesis of claim 1 wherein the skirt further comprises a plurality of longitudinally-oriented reinforcing tabs.
Schwammenthal discloses a skirt with a plurality of longitudinally-oriented reinforcing tabs. Figs. 4, 5 and 7.

5. The valve prosthesis of claim 4 wherein the reinforcing tabs are affixed to the frame.
Schwammenthal discloses reinforcing tabs affixed to the frame. Figs. 4, 5 and 7.
6. The valve prosthesis of claim 1 wherein the leaflets comprise porcine, bovine, equine or other mammalian pericardial tissue, synthetic material, or polymeric material.
Schwammenthal discloses leaflets of porcine, bovine, equine or other mammalian pericardial tissue, synthetic material, or polymeric material. 3:20-27; 7:35-54.
7. The valve prosthesis of claim 1 wherein the leaflets are sewn to the skirt at joints, and the joints are affixed to the frame to evenly distribute forces through the valve body to the frame.
Schwammenthal discloses leaflets sewn to the skirt at joints, and the joints are affixed to the frame to evenly distribute forces through the valve body to the frame. Figs. 4, 5, 7, 11A-C, 18a, 19c; Ex. 1007, ¶¶ 11-14.
8. The valve prosthesis of claim 7 wherein the frame further comprises a cell pattern that defines a contour configured to support the joints.
Schwammenthal discloses a frame with a cell pattern that defines a contour configured to support the joints. Figs. 4, 5, 7, 911A-C; 18a-b, 19b.
9. The valve prosthesis of claim 1 wherein the frame comprises a cell pattern defined by unequal length zig-zags.
Schwammenthal discloses a frame with a cell pattern defined by unequal length zig-zags. Figs. 4, 5, 7, 911A-C; 18a-b, 19b.
10. The valve prosthesis of claim 1 wherein the commissures are affixed to the frame at a location proximal of the center of coaptation.
Schwammenthal discloses commissures affixed to the frame at a location proximal of the center of coaptation. Commissures are affixed to the frame at a location proximal of the center of coaptation.Figs. 4, 5, 7, 911A-C; 18a-b, 19b; Ex. 1007, ¶¶ 11-14.
11. The valve prosthesis of claim 1 wherein the skirt further comprises a plurality of end tabs adapted to be affixed to a proximal-most row of cells of the frame.
Schwammenthal discloses a skirt with a plurality of end tabs adapted to be affixed to a proximal-most row of cells of the frame. Tabs (skirt) are affixed to the frame; Ex. 1007, ¶¶ 11-14.
12. The valve prosthesis of claim 1 wherein the valve body is deployed superannularly of a patient's aortic annulus when the valve prosthesis is delivered within a patient's aortic valve and the frame is in the expanded deployed configuration.
Schwammenthal discloses a valve body deployed superannularly of a patient's aortic annulus when the valve prosthesis is delivered within a patient's aortic valve and the frame is in the expanded deployed configuration. Figs. 10, 11A-C, 15a-h.

13. The valve prosthesis of claim 1 wherein the frame is configured to hold a patient's native valve permanently open in the expanded deployed configuration.
Schwammenthal discloses a frame configured to hold a patient's native valve permanently open in the expanded deployed configuration. Figs. 10, 11A-C, 15a-h; 12:36-46.
14. The valve prosthesis of claim 1 wherein the frame is configured to permit access to a patient's coronary arteries in the expanded deployed configuration.
Schwammenthal discloses a frame configured to permit access to a patient's coronary arteries in the expanded deployed configuration. Figs. 10, 11A-C; 8:61-67; 11:21-24; 12:9-13.
15. The valve prosthesis of claim 1 wherein the frame has proximal and distal ends and a plurality of cell patterns that vary in size between the proximal and distal ends.
Schwammenthal discloses a frame with proximal and distal ends and a plurality of cell patterns that vary in size between the proximal and distal ends. Figs. 4, 5, 7, 10.
16. The valve prosthesis of claim 1 wherein the constriction region comprises a plurality of cell patterns configured to provide a pre-determined radius of curvature for a transition from the constricted region to the outflow section.
Schwammenthal discloses a constriction region with a plurality of cell patterns configured to provide a pre-determined radius of curvature for a transition from the constricted region to the outflow section. Figs. 4, 5, 7, 10.
17. The valve prosthesis of claim 1 wherein the diameter of the constriction region is a predetermined diameter.
Schwammenthal discloses a diameter of the constriction region with a predetermined diameter. Figs. 4-7, 10.
18. A valve prosthesis comprising: To the extent that the preamble is a limitation, Schwammenthal discloses a valve prosthesis. Figures; 2:59-63.
a valve body comprising a plurality of leaflets sewn to a skirt to form joints between the leaflets and the skirt, adjoining leaflets sewn together to form commissures; and
Schwammenthal discloses a valve body 16 comprising a plurality of leaflets sewn to a skirt 11, adjoining leaflets sewn together to form commissures. Figs. 4, 5 7, 9, 11A-C; 7:4-13; 8:8-19.
a self-expanding frame comprising a plurality of cells comprising struts, the frame having a contracted delivery configuration and an expanded deployed configuration, wherein the frame supports the valve body, and wherein the frame has a longitudinal axis,
Schwammenthal discloses a self-expanding frame comprising a plurality of cells

comprising struts, the frame having a contracted delivery configuration and an expanded deployed configuration, wherein the frame supports the valve body, and wherein the frame has a longitudinal axis. Figs. 4, 15a-h.
wherein, when the frame is in the expanded deployed configuration, the frame has a tri-level asymmetric hourglass shape including a conical inflow section, an enlarged distal section, and a constriction region, wherein the constriction region has a predefined curvature when the frame is in the expanded deployed configuration,
Schwammenthal discloses when the frame is in the expanded deployed configuration, the frame has a tri-level asymmetric hourglass shape including a conical inflow section, an enlarged distal section, and a constriction region, wherein the constriction region has a predefined curvature when the frame is in the expanded deployed configuration. Figs. 4, 5, 11.
wherein the skirt has a bottom edge, the inflow section of the frame has an inflow edge, and the bottom edge of the skirt is sewn to the inflow edge of the inflow section,
Schwammenthal discloses a skirt with a bottom edge, the inflow section of the frame has an inflow edge, and the bottom edge of the skirt is attached to the inflow edge of the inflow section. Figs. 4, 5, 19b; 8:18-19.
wherein the commissures are sewn to the frame along a region of the frame that increases in diameter along the longitudinal axis in an intended direction of blood flow,
Schwammenthal discloses commissures sewn to the frame along a region of the frame that increases in diameter along the longitudinal axis in an intended direction of blood flow. Figs. 4, 5, 18a, 19b.
wherein each commissure is configured to span a cell of the frame to help distribute force within the commissures and to the frame, and wherein a plurality of cells are positioned between the cells spanned by commissures,
Schwammenthal discloses each commissure configured to span a cell of the frame to help distribute force within the commissures and to the frame, and wherein a plurality of cells are positioned between the cells spanned by commissures. Figs. 4, 5, 18a, 19b.
wherein at least a portion of the commissures are longitudinally offset from the center of coaptation, and each leaflet has a free edge that is suspended from the leaflet's respective commissures to define coaptation edges and a center of coaptation,
Schwammenthal discloses at least a portion of the commissures are longitudinally offset from the center of coaptation, and each leaflet has a free edge that is suspended from the leaflet's respective commissures to define coaptation edges and a

center of coaptation. Figs. 4, 5, 7, 11A-C.
wherein the length of each free edge forms a substantially continuous curve extending downwardly between the respective commissures so that the free edges of the leaflets generally define the shape of catenaries to substantially uniformly distribute loads over the leaflets, and
Schwammenthal discloseswherein the length of each free edge forms a substantially continuous curve extending downwardly between the respective commissures so that the free edges of the leaflets generally define the shape of catenaries to substantially uniformly distribute loads over the leaflets. The free edges of the leaflets naturally define the shape of catenaries to uniformly distribute loads over the leaflets 16. Figs. 4, 5, 7, 9, 11A-C.
wherein the joints between the leaflets and the skirt are substantially aligned with and sewn to a curved contour defined by the struts of the frame such that the joints are supported by the frame over at least a substantial portion of the length of the joints.
Schwammenthal discloses joints between the leaflets and the skirt substantially aligned with and sewn to a curved contour defined by the struts of the frame such that the joints are supported by the frame over at least a substantial portion of the length of the joints. Joints affixed to a frame evenly distribute forces through the valve body to the frame. Figs. 4, 5, 7, 11A-C, 18a, 19c; Ex. 1007, ¶¶ 11-14.

APPENDIX A-3

Anticipation by U.S. Patent No. 6,730,118 to Spenser (Ex. 1005)
1. A valve prosthesis comprising: To the extent that the preamble is a limitation, Spenser discloses a valve prosthesis.
a valve body comprising a plurality of leaflets sewn to a skirt, adjoining leaflets sewn together to form commissures; and
Spenser discloses a valve body 20 comprising a plurality of leaflets 29 sewn to a skirt 382, adjoining leaflets sewn together to form commissures Figs. 1, 23e, 25, 32a, 37c, 40a, 43a, 44a. 19:57 – 20:15.
a self-expanding frame comprising a plurality of cells, the frame having a substantially conical inflow section, a flared outflow section, and a constriction region between the inflow section and the outflow section, wherein the constriction region is configured to avoid blocking blood flow to the coronary arteries when the frame is implanted in a body, wherein the frame supporting supports the valve body, wherein the frame has a longitudinal axis, wherein the frame has a contracted delivery configuration and an expanded deployed configuration,
Spenser discloses a self-expanding frame comprised of a plurality of cells 22, 380,

the frame has a substantially conical inflow section 24, a flared outflow section 26, and a constriction region between the inflow and outflow sections (Fig. 41b), wherein the constriction region is configured to avoid blocking blood flow to the coronary arteries when the frame is implanted in a body, wherein the frame supporting supports the valve body, wherein the frame has a longitudinal axis, wherein the frame has a contracted delivery configuration and an expanded deployed configuration. Figs. 16a – 17b; 12:40-49; 18:11-36.
wherein, when the frame is in the expanded deployed configuration, the inflow section, the outflow section, and the constriction region have substantially circular cross-sections, the outflow section has a larger diameter than the inflow section, and the inflow section has a larger diameter than the constriction region,
Spenser discloses when the frame is in the expanded deployed configuration, the inflow section, the outflow section, and the constriction region have substantially circular cross-sections, the outflow section has a larger diameter than the inflow section, and the inflow section has a larger diameter than the constriction region. Figs. 17b, 20a, 20b, 44a.
wherein the skirt has a bottom edge, the inflow section of the frame has an inflow edge, and the bottom edge of the skirt is sewn to the inflow edge of the inflow section,
Spenser discloses a skirt with a bottom edge, the inflow section of the frame has an inflow edge, and the bottom edge of the skirt is sewn to the inflow edge of the inflow section. Figs. 23e, 28, 37c.
wherein the commissures are sewn to the frame along a region of the frame that increases in diameter along the longitudinal axis in an intended direction of blood flow,
Spenser discloses commissures sewn to the frame along a region of the frame that increases in diameter along the longitudinal axis in an intended direction of blood flow. Figs. 17a – 17b.
wherein each commissure is configured to span a cell of the frame to distribute force within the commissures and to the frame, and wherein a plurality of cells of the frame are positioned between the cells spanned by commissures,
Spenser discloses each commissure configured to span a cell 60 of the frame to distribute force within the commissures and to the frame, and wherein a plurality of cells of the frame are positioned between the cells spanned by commissures. Fig. 28, 31b, 32a, 33a, 33b, 37c; 15:8-29; 16:1-24; 22:51-65.
wherein at least a portion of the commissures are longitudinally offset from the center of coaptation, and each leaflet has a free edge that is suspended from the leaflet's respective commissures to define coaptation edges and a center of coaptation, and

Spenser discloses at least a portion of the commissures are longitudinally offset from the center of coaptation, and each leaflet has a free edge that is suspended from the leaflet's respective commissures to define coaptation edges and a center of coaptation. Figs. 1, 23e.
wherein the length of each free edge forms a substantially continuous curve extending downwardly between the respective commissures so that the free edges of the leaflets generally define the shape of catenaries to substantially uniformly distribute loads over the leaflets.
Spenser discloses the length of each free edge forms a substantially continuous curve extending downwardly between the respective commissures so that the free edges of the leaflets generally define the shape of catenaries to substantially uniformly distribute loads over the leaflets. The free edges of the leaflets naturally define the shape of catenaries to uniformly distribute loads over the leaflets. Figs. 1, 23e, 26a.
2. The valve prosthesis of claim 1 wherein the catenaries are configured to reduce horizontal loads applied to the commissures.
Spenser discloses catenaries configured to reduce horizontal loads applied to the commissures. Catenaries reduce the horizontal loads applied to the commissures. Figs. 23a-23f, 30a-30c, 31a-31b, 36a-36b, 37a-37c; 19:57 – 20:15; 22:51 – 23:14; 24:28-53; Ex. 1007, ¶¶ 7-14.
3. The valve prosthesis of claim 1 wherein each leaflet is individually formed and comprises an enlarged lateral end having a plurality of flaps that are folded over to increase the durability of the commissures.
Spenser discloses each leaflet is individually formed and comprises an enlarged lateral end having a plurality of flaps that are folded over to increase the durability of the commissures. Figs. 23a-23f, 30a-30c, 31a-31b, 36a-36b, 37a-37c; 19:57 – 20:15; 22:51 – 23:14; 24:28-53.
4. The valve prosthesis of claim 1 wherein the skirt further comprises a plurality of longitudinally-oriented reinforcing tabs.
Spenser discloses a skirt with a plurality of longitudinally-oriented reinforcing tabs. Figs. 23a-23f, 30a-30c, 31a-31b, 36a-36b, 37a-37c; 19:57 – 20:15; 22:51 – 23:14; 24:28-53.
5. The valve prosthesis of claim 4 wherein the reinforcing tabs are affixed to the frame.
Spenser discloses reinforcing tabs affixed to the frame. Figs. 23a-23f, 30a-30c, 31a-31b, 36a-36b, 37a-37c; 19:57 – 20:15; 22:51 – 23:14; 24:28-53.
6. The valve prosthesis of claim 1 wherein the leaflets comprise porcine, bovine, equine or other mammalian pericardial tissue, synthetic material, or polymeric material.

Spenser discloses leaflets of porcine, bovine, equine or other mammalian pericardial tissue, synthetic material, or polymeric material. 2:55-60; 12:30-39.
7. The valve prosthesis of claim 1 wherein the leaflets are sewn to the skirt at joints, and the joints are affixed to the frame to evenly distribute forces through the valve body to the frame.
Spenser discloses leaflets sewn to the skirt at joints, and the joints are affixed to the frame to evenly distribute forces through the valve body to the frame. Joints affixed to a frame evenly distribute forces through the valve body to the frame. Figs. 23a-23f, 30a-30c, 31a-31b, 36a-36b, 37a-37c; 19:57 – 20:15; 22:51 – 23:14; 24:28-53; Ex. 1007, ¶¶ 11-14.
8. The valve prosthesis of claim 7 wherein the frame further comprises a cell pattern that defines a contour configured to support the joints.
Spenser discloses a frame with a cell pattern that defines a contour configured to support the joints. Figs. 23a-23f, 30a-30c, 31a-31b, 36a-36b, 37a-37c; 19:57 – 20:15; 22:51 – 23:14; 24:28-53.
9. The valve prosthesis of claim 1 wherein the frame comprises a cell pattern defined by unequal length zig-zags.
Spenser discloses a frame with a cell pattern defined by unequal length zig-zags. Figs. 9a, 21, 41a.
10. The valve prosthesis of claim 1 wherein the commissures are affixed to the frame at a location proximal of the center of coaptation.
Spenser discloses commissures affixed to the frame at a location proximal of the center of coaptation. Commissures are affixed to the frame at a location proximal of the center of coaptation. Fig. 23e; Ex. 1007, ¶¶ 11-14.
11. The valve prosthesis of claim 1 wherein the skirt further comprises a plurality of end tabs adapted to be affixed to a proximal-most row of cells of the frame.
Spenser discloses a skirt with a plurality of end tabs adapted to be affixed to a proximal-most row of cells of the frame. Figs. 23a-23e.
12. The valve prosthesis of claim 1 wherein the valve body is deployed superannularly of a patient's aortic annulus when the valve prosthesis is delivered within a patient's aortic valve and the frame is in the expanded deployed configuration.
Spenser discloses a valve body deployed superannularly of a patient's aortic annulus when the valve prosthesis is delivered within a patient's aortic valve and the frame is in the expanded deployed configuration. Figs. 16a-16c, 17a-17b.
13. The valve prosthesis of claim 1 wherein the frame is configured to hold a patient's native valve permanently open in the expanded deployed configuration.
Spenser discloses a frame configured to hold a patient's native valve permanently open in the expanded deployed configuration. Figs. 17a – 17b; 18:11-36.
14. The valve prosthesis of claim 1 wherein the frame is configured to permit ac-

cess to a patient's coronary arteries in the expanded deployed configuration.
Spenser discloses frame configured to permit access to a patient's coronary arteries in the expanded deployed configuration. Figs. 17a – 17b; 18:11-36.
15. The valve prosthesis of claim 1 wherein the frame has proximal and distal ends and a plurality of cell patterns that vary in size between the proximal and distal ends.
Spenser discloses a frame with proximal and distal ends and a plurality of cell patterns that vary in size between the proximal and distal ends. Figs. 1, 23e, 26a.
16. The valve prosthesis of claim 1 wherein the constriction region comprises a plurality of cell patterns configured to provide a pre-determined radius of curvature for a transition from the constricted region to the outflow section.
Spenser discloses a constriction region with a plurality of cell patterns configured to provide a pre-determined radius of curvature for a transition from the constricted region to the outflow section. Fig. 44a.
17. The valve prosthesis of claim 1 wherein the diameter of the constriction region is a predetermined diameter.
Spenser discloses a diameter of the constriction region with a predetermined diameter. Fig. 44a.
18. A valve prosthesis comprising: To the extent that the preamble is a limitation, Spenser discloses a valve prosthesis.
a valve body comprising a plurality of leaflets sewn to a skirt to form joints between the leaflets and the skirt, adjoining leaflets sewn together to form commissures; and
Spenser discloses a valve body 20 comprising a plurality of leaflets 29 sewn to a skirt 382, adjoining leaflets sewn together to form commissures Figs. 1, 23e, 25, 32a, 37c, 40a, 43a, 44a. 19:57 – 20:15.
a self-expanding frame comprising a plurality of cells comprising struts, the frame having a contracted delivery configuration and an expanded deployed configuration, wherein the frame supports the valve body, and wherein the frame has a longitudinal axis,
Spenser discloses a self-expanding frame comprising a plurality of cells comprising struts, the frame having a contracted delivery configuration and an expanded deployed configuration, wherein the frame supports the valve body, and wherein the frame has a longitudinal axis. Figs. 16a – 17b; 12:40-49; 18:11-36.
wherein, when the frame is in the expanded deployed configuration, the frame has a tri-level asymmetric hourglass shape including a conical inflow section, an enlarged distal section, and a constriction region, wherein the constriction region has a predefined curvature when the frame is in the expanded deployed configuration,

Spenser discloses when the frame is in the expanded deployed configuration, the frame has a tri-level asymmetric hourglass shape including a conical inflow section, an enlarged distal section, and a constriction region, wherein the constriction region has a predefined curvature when the frame is in the expanded deployed configuration. Figs. 16a – 17b; 12: 40-49; 18-11-36.
wherein the skirt has a bottom edge, the inflow section of the frame has an inflow edge, and the bottom edge of the skirt is sewn to the inflow edge of the inflow section,
Spenser discloses a skirt with a bottom edge, the inflow section of the frame has an inflow edge, and the bottom edge of the skirt is sewn to the inflow edge of the inflow section. Figs. 16a – 17b; 12: 40-49; 18-11-36.
wherein the commissures are sewn to the frame along a region of the frame that increases in diameter along the longitudinal axis in an intended direction of blood flow,
Spenser discloses commissures sewn to the frame along a region of the frame that increases in diameter along the longitudinal axis in an intended direction of blood flow. Figs. 16a – 17b, 20a, 20b, 44a; 12: 40-49; 18-11-36.
wherein each commissure is configured to span a cell of the frame to help distribute force within the commissures and to the frame, and wherein a plurality of cells are positioned between the cells spanned by commissures,
Spenser discloses each commissure is configured to span a cell of the frame to help distribute force within the commissures and to the frame, and wherein a plurality of cells are positioned between the cells spanned by commissures. Fig. 28, 31b, 32a, 33a, 33b, 37c; 15:8-29; 16:1-24; 22:51-65.
wherein at least a portion of the commissures are longitudinally offset from the center of coaptation, and each leaflet has a free edge that is suspended from the leaflet's respective commissures to define coaptation edges and a center of coaptation,
Spenser discloses at least a portion of the commissures are longitudinally offset from the center of coaptation, and each leaflet has a free edge that is suspended from the leaflet's respective commissures to define coaptation edges and a center of coaptation. Figs. 1, 23e.
wherein the length of each free edge forms a substantially continuous curve extending downwardly between the respective commissures so that the free edges of the leaflets generally define the shape of catenaries to substantially uniformly distribute loads over the leaflets, and
Spenser discloses the length of each free edge forms a substantially continuous curve extending downwardly between the respective commissures so that the free edges of the leaflets generally define the shape of catenaries to substantially uni-

formly distribute loads over the leaflets. Figs. 1, 23e, 26a.
wherein the joints between the leaflets and the skirt are substantially aligned with and sewn to a curved contour defined by the struts of the frame such that the joints are supported by the frame over at least a substantial portion of the length of the joints.
Spenser discloses the joints between the leaflets and the skirt are substantially aligned with and sewn to a curved contour defined by the struts of the frame such that the joints are supported by the frame over at least a substantial portion of the length of the joints. Figs. 16a – 17b; 12: 40-49; 18-11-36.

APPENDIX A-4

Obviousness over Svanidze (Ex. 1003) in view of Lashinski (Ex. 1006)
In claim 1: Lashinski discloses coapting leaflets that distribute stress evenly over the entire leaflet cusp from commissure to commissure to evenly distribute the attachment forces. Figs. 1-16B, 25E, 25F; 25:44 – 26:9. Further, uniform distribution of force by catenaries is inherent in the shape. Ex. 1007, ¶¶7-14.
Claim 6: Lashinski discloses procine, bovine, equine or other mammalian pericardial tissue. 26:51 – 28:35. Further, uniform distribution of force by catenaries is inherent in the shape. Ex. 1007, ¶¶7-14.
Claim 7: Lashinski discloses coapting leaflets that distribute stress evenly over the entire leaflet cusp from commissure to commissure to evenly distribute the attachment forces. Figs. 1-16B, 25E, 25F; 25:44 – 26:9. Further, uniform distribution of force by catenaries is inherent in the shape. Ex. 1007, ¶¶7-14.
In claim 18: Lashinski discloses coapting leaflets that distribute stress evenly over the entire leaflet cusp from commissure to commissure to evenly distribute the attachment forces. Figs. 1-16B, 25E, 25F; 25:44 – 26:9. Further, uniform distribution of force by catenaries is inherent in the shape. Ex. 1007, ¶¶7-14.

APPENDIX A-4

Obviousness of U.S. Patent No. 7,201,772 to Schwammenthal et al. (Ex. 1004) in view of Svanidze (Ex. 1003)
In claim 1: Svanidze discloses a skirt with a bottom edge, the inflow section of the frame has an inflow edge, and the bottom edge of the skirt is sewn to the inflow edge of the inflow section. *Svanidze*, Figs. 11-13; 6:66-7:2; 9:38-56; 13:5-40; 15:42-44.
In claim 18: Svanidze discloses a skirt with a bottom edge, the inflow section of the frame has an inflow edge, and the bottom edge of the skirt is sewn to the in-

flow edge of the inflow section. *Svanidze*, Figs. 11-13; 6:66-7:2; 9:38-56; 13:5-40; 15:42-44.

APPENDIX A-5

Obviousness of U.S. Patent No. 6,730,118 to Spenser (Ex. 1005) in view of Schwammenthal (Ex. 1004)
In claim 1: Schwammenthal discloses a larger diameter outflow section than the diameter of the inflow section, and the inflow section having a larger diameter than the constriction region. *Schwammenthal*, Figs. 2, 3, 6, 11A-C; 5:45-6:9, 6:29-57.
In claim 17: Schwammenthal discloses a constriction region with a plurality of cell patterns configured to provide a pre-determined radius of curvature for a transition from the constricted region to the outflow section. *Schwammenthal*, Figs. 4-7, 10, 11A, 18b.
In claim 18: Schwammenthal discloses when the frame is in the expanded deployed configuration, the frame has a tri-level asymmetric hourglass shape including a conical inflow section, an enlarged distal section, and a constriction region, wherein the constriction region has a predefined curvature when the frame is in the expanded deployed configuration. *Schwammenthal*, Figs. 4, 5, 11.

APPENDIX A-6

Obviousness over Schwammenthal (Ex. 1004) in view of Svanidze (Ex. 1003), further in view of Lashinski (Ex. 1006)
In claim 1: Svanidze discloses a skirt with a bottom edge, the inflow section of the frame has an inflow edge, and the bottom edge of the skirt is sewn to the inflow edge of the inflow section. *Svanidze*, Figs. 11-13; 6:66-7:2; 9:38-56; 13:5-40; 15:42-44.
In claim 1: Lashinski discloses coapting leaflets that distribute stress evenly over the entire leaflet cusp from commissure to commissure to evenly distribute the attachment forces. Figs. 1-16B, 25E, 25F; 25:44 – 26:9. Further, uniform distribution of force by catenaries is inherent in the shape. Ex. 1007, ¶¶7-14.
Claim 7: Lashinski discloses coapting leaflets that distribute stress evenly over the entire leaflet cusp from commissure to commissure to evenly distribute the attachment forces. Figs. 1-16B, 25E, 25F; 25:44 – 26:9. Further, uniform distribution of force by catenaries is inherent in the shape. Ex. 1007, ¶¶7-14.
In claim 18: Svanidze discloses a skirt with a bottom edge, the inflow section of the frame has an inflow edge, and the bottom edge of the skirt is sewn to the inflow edge of the inflow section. *Svanidze*, Figs. 11-13; 6:66-7:2; 9:38-56; 13:5-40;

15:42-44.
In claim 18: Lashinski discloses coapting leaflets that distribute stress evenly over the entire leaflet cusp from commissure to commissure to evenly distribute the attachment forces. Figs. 1-16B, 25E, 25F; 25:44 – 26:9. Further, uniform distribution of force by catenaries is inherent in the shape. Ex. 1007, ¶¶7-14.

APPENDIX A-7

Obviousness of U.S. Patent No. 6,730,118 to Spenser (Ex. 1005) in view of Schwammenthal (Ex. 1004), further in view of Lashinski (Ex. 1006)
In claim 1: Schwammenthal discloses a larger diameter outflow section than the diameter of the inflow section, and the inflow section having a larger diameter than the constriction region. *Schwammenthal*, Figs. 2, 3, 6, 11A-C; 5:45-6:9, 6:29-57.
In claim 1: Lashinski discloses coapting leaflets that distribute stress evenly over the entire leaflet cusp from commissure to commissure to evenly distribute the attachment forces. Figs. 1-16B, 25E, 25F; 25:44 – 26:9. Further, uniform distribution of force by catenaries is inherent in the shape. Ex. 1007, ¶¶7-14.
In claim 17: Lashinski discloses coapting leaflets that distribute stress evenly over the entire leaflet cusp from commissure to commissure to evenly distribute the attachment forces. Figs. 1-16B, 25E, 25F; 25:44 – 26:9. Further, uniform distribution of force by catenaries is inherent in the shape. Ex. 1007, ¶¶7-14.
In claim 18: Schwammenthal discloses when the frame is in the expanded deployed configuration, the frame has a tri-level asymmetric hourglass shape including a conical inflow section, an enlarged distal section, and a constriction region, wherein the constriction region has a predefined curvature when the frame is in the expanded deployed configuration. *Schwammenthal*, Figs. 4, 5, 11.
In claim 18: Lashinski discloses coapting leaflets that distribute stress evenly over the entire leaflet cusp from commissure to commissure to evenly distribute the attachment forces. Figs. 1-16B, 25E, 25F; 25:44 – 26:9. Uniform distribution of force by catenaries is inherent in the shape. Ex. 1007, ¶¶7-14.

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. §§ 42.6 and 42.105, I hereby certify that a true copy of the PETITION FOR *INTER PARTES* REVIEW UNDER 37 C.F.R. § 42.100 with Appendices A-1 – A-7 and Exhibits 1001-1012 were served by FEDERAL EXPRESS this 18th day of December, 2014 on the IP Legal Department of Medtronic CardioVascular owner of the subject patent, at the USPTO correspondence address of record listed below:

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