UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MEDTRONIC, INC., MEDTRONIC VASCULAR, INC.,
and MEDTRONIC COREVALVE, LLC
Petitioner

v.

TROY R. NORRED, M.D.
Patent Owner

Case IPR2014-00395
Patent 6,482,228

Attorney Docket No. 058888-0000019

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

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Inter partes review is respectfully requested for claims 16 and 19-24 of U.S. Patent No. 6,482,228 to Norred ("the '228 Patent") (Exh. 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)

Medtronic, Inc., Medtronic Vascular, Inc., and Medtronic CoreValve, LLC (collectively "Petitioner") are the real parties-in-interest. On or about April 9, 2009, CoreValve, Inc. merged into Medtronic-CoreValve, Inc., which was subsequently renamed Medtronic CoreValve, LLC, and is therefore not identified as a separate petitioner.

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

The '228 Patent is presently the subject of litigation brought by the Patent Owner against Petitioner in the U.S. District Court for the District of Kansas in a case titled *Troy R. Norred M.D. v. Medtronic, Inc., et al.*, No. 2:13-cv-02061 (February 6, 2013). In that matter, Petitioner's motion to stay the district court proceedings pending *inter partes* review of the '228 Patent has been fully briefed and is currently before the court. In addition, the '228 Patent is the subject of IPR2014-00110 and IPR2014-00111, which were filed concurrently on October 31, 2013.

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

Petitioner provides the following designation of counsel:

Lead Counsel	Back-Up Counsel
Jack Barufka (Reg. No. 37,087) PILLSBURY WINTHROP SHAW PITTMAN LLP Postal and Hand Delivery Address 1650 Tysons Boulevard McLean, Virginia 22102 Telephone: 703.770.7712 Facsimile: 703.906.2500 Email: jack.barufka@pillsburylaw.com	Evan Finkel (Reg. No. 49,059) PILLSBURY WINTHROP SHAW PITTMAN LLP Postal and Hand Delivery Address 725 S. Figueroa Street, Suite 2800 Los Angeles, California 90017 Telephone: 213.488.7307 Facsimile: 213.226.4058 Email: evan.finkel@pillsburylaw.com

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 docket_ip@pillsburylaw.com.

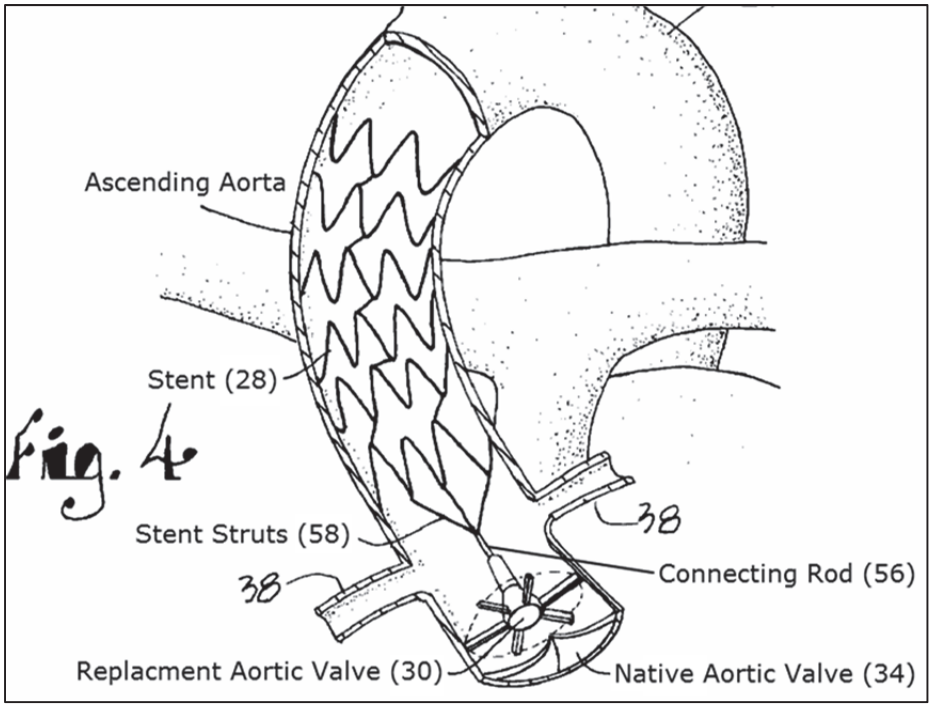
II. PAYMENT OF FEES UNDER 37 C.F.R. § 42.103

The undersigned authorizes the Office to charge Deposit Account No. 033975 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 '228 PATENT

A. Description of the Alleged Invention of the '228 Patent

The '228 Patent (Exh. 1001) contains 24 claims, including four independent apparatus claims (claims 1, 12, 16, and 20). The '228 Patent relates to a percutaneous aortic heart valve replacement that is placed by a catheter in the ascending aorta and anchored by a stent. *'228 Patent*, 1: 6-9; 2:63-3:13. Shown below is an annotated version of Figure 4 showing the location of Replacement Aortic Valve 30 and Stent 28 in a cut-away view of the ascending aorta.



The '228 Patent discloses four replacement valve designs that can be anchored with a stent: an umbrella valve 30 (Figs. 1-9); a conical valve 66 (Figs. 10-13); a trihedral valve 82 (Figs. 14-17); and biological tissue valves 100, such as cadaver or porcine (Figs. 18-19). The '228 Patent explains what is well known in

the art: that the replacement valves operate like a native aortic valve. That is, when the heart contracts (systole) the valve opens to allow blood exiting the left ventricle to flow through the valve, and when the heart relaxes (diastole) the valve closes to prevent regurgitation. The ’228 Patent discloses that each of these replacement valve designs, when anchored by a stent, would be disposed against the aortic wall to reduce or eliminate peri-valvular leaks.

With respect to claims 16 and 19, the ‘228 Patent’s alleged invention is a valve (see annotated Figures 10 and 16 below) for controlling blood flow through an aortic channel. *‘228 Patent*, 7:59- 8:12.

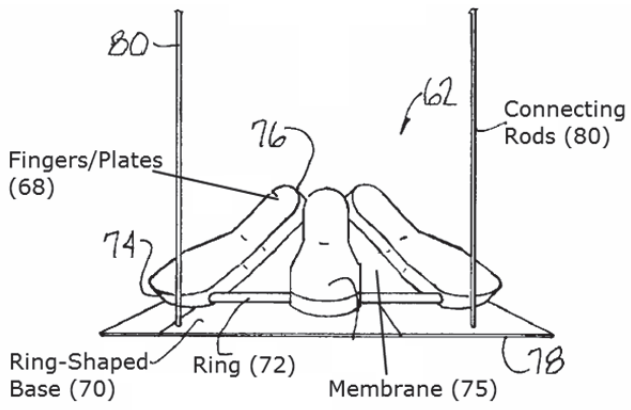


Fig. 10: Conical Valve in Closed Position

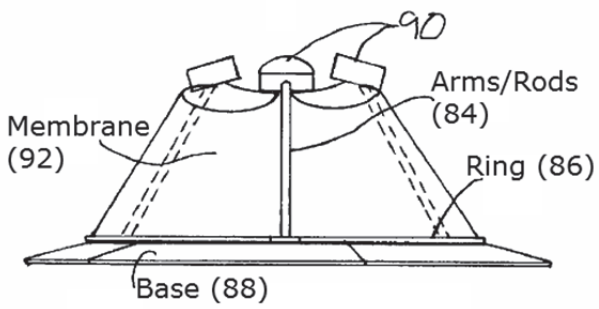


Fig. 16: Trihedral Valve in Open Position

Figure 10 above shows a conical valve which has a Ring-Shaped Base 70 made of a pliable biocompatible material with a circumference adapted to seat about an aortic wall surrounding an aortic channel such that blood flows through a center opening in Ring-Shaped Base 70. *‘228 Patent*, 5:9-20. Fingers 68 are generally wedge or bowling pin-shaped, constructed of stainless steel, plastic or other

biocompatible material, and are hingedly secured together with Ring 72, which is attached to Ring-Shaped Base 70. *'228 Patent*, 4:57-64. A "biocompatible, durable, flexible generally conically-shaped fabric 75 membrane" is secured to the inside surfaces of Fingers 68 and is used to interconnect Fingers 68. *Id*. The valve is anchored along the root of the aortic valve with Connecting Rods 80 which are connected to an aortic stent. *'228 Patent*, 5:21-23.

Figure 16 above shows a trihedral valve with similar structures and operation to the conical valve, including Arms/Rods 84 hingedly connected to Ring 86, which is attached to Base 88. *'228 Patent,* 5:33-62. Arms/Rods 84 are interconnected to each other by Membrane 92. *Id.* Each Arm/Rod 84 has a crescent-shaped pad 90 at its free end. *Id*. The trihedral valve is also anchored along the root of the aortic valve with connecting rods (not shown). *'228 Patent,* 5:48-51.

Figure 10 above shows the conical valve in closed position with the tips 76 of Fingers 68 contacting each adjacent tip to prevent regurgitation (*i.e.*, the flow of blood from the aorta back into the left ventricle). *'228 Patent*, 4:65-67. During systole the valve expands or opens to allow blood ejected from the left ventricle to flow through the center of the valve. *'228 Patent*, 5:9-14. Fingers 68 pivot on Ring 72 and tips 76 separate to allow blood to flow through the center of the valve. Membrane 75 prevents Fingers 68 from overextending to block coronary arteries

38. *Id*. The trihedral valve operates in a similar manner and is shown in the open position in Figure 16 above. *'228 Patent,* 5:43-47.

With respect to claims 20-24, the '228 Patent's alleged invention is an aortic tissue valve. *'228 Patent,* 8:27-59. As shown in Figure 18 below, the tissue valve comprises a Cadaver/Porcine Valve 100 retained in a Base Ring 102 made of pliable biocompatible material with an outer circumference adapted to seat the Base Ring 102 about an aortic wall surrounding an aortic channel. *'228 Patent,* 6:1-8. The tissue valve is anchored along the root of the aortic valve with Connecting Rods 104. *Id*.

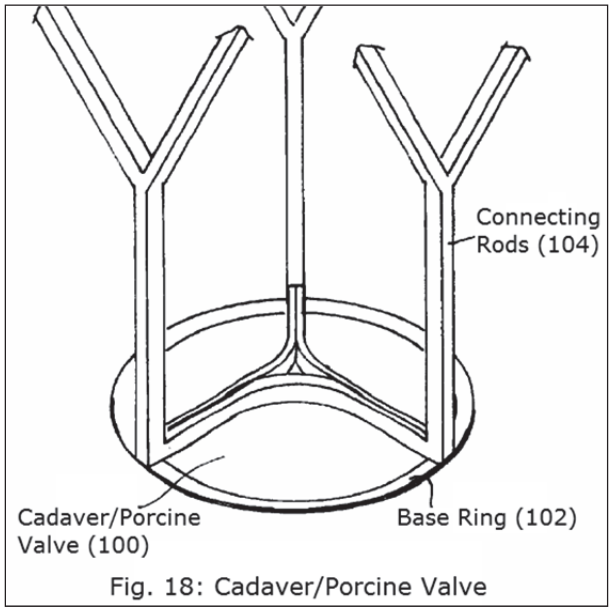


Fig. 18: Cadaver/Porcine Valve

B. Summary of the Prosecution History of the '228 Patent

Referring to the prosecution history of the '228 Patent (Exh. 1002), the '228 Patent was filed as U.S. App. Serial No. 09/712,121 on November 14, 2000 (see Exh. 1002, paper 1). The '228 Patent does not claim priority to any earlier filed

applications. Although claims 16-24 (originally claims 19-27) were not addressed in the first Office Action mailed on August 9, 2001 (*id.*, paper 3, "August 2001 Office Action"), the Examiner stated in a January 30, 2002 personal interview (*id.*, paper 4) with applicant that "Claims 19-27 should have been stated as allowable in the 8/9/01 action." In response to the August 2001 Office Action, applicant filed an amendment on February 26, 2002 (*id.*, paper 5) that, among other things, ostensibly made non-substantive grammatical amendments to improve the language of claims 16-24. *Id*. at page 9 ("Applicant has also amended all the claims, including the allowed claims 19-27, to improve the language therein. No substantive changes have been made by these grammatical amendments.") However, it should be noted that at least one of applicant's amendments potentially broadened the scope of claim 20 (originally claim 23) beyond what was approved by the Examiner in that it deletes the "means for moving" language, as shown below:

> "23. (Amended) An aortic valve for controlling a blood flow through an aortic channel upon placement therein, said valve comprising:
> a tissue valve having an interior member [and circumference;] made of a tissue material and presenting an opening movable between open and closed positions;
> a ring member [secured to] surrounding said tissue valve, [along said tissue valve circumference and] said ring member having an outer circumference adapted to seat said ring member about an aortic wall surrounding an aortic channel;

means for maintaining said ring member in said seated position about the aortic wall, [; and]

[means for moving] said tissue valve interior member responsive to changes of conditions within the aorta for movement of said opening between a first closed position and a second open position." (*Id.* at page 8).

The Examiner subsequently issued a Notice of Allowability on April 2, 2002 (*id.*, paper 4) that included a few Examiner amendments to the claim language.

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 '228 Patent is satisfied.

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

Petitioner hereby certifies that the '228 Patent is available for *inter partes* review and that Petitioner is not barred or estopped from requesting *inter partes* review challenging the claims of the '228 Patent on the grounds identified herein. More particularly, Petitioner certifies that: (1) Petitioner is not the owner of the '228 Patent; (2) Petitioner has not filed a civil action challenging the validity of a claim of the '228 Patent; (3) this Petition is filed less than one year after the date on which the Petitioner, the Petitioner's real party-in-interest, or a privy of the Petitioner was served with a complaint alleging infringement of the '228 Patent; (4) the estoppel provisions of 35 U.S.C. § 315(e)(1) do not prohibit this *inter partes* re-

view; 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 '228 Patent or (b) the date of termination of any post-grant review of the '228 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 16 and 19-24 of the '228 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 16 and 19-24 of the '228 Patent is requested.

D. The Specific Art and Statutory Grounds 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 16 and 19-24 are anticipated under 35 U.S.C. §102(b) by US 5,957,949 to Leonhardt et al. ("Leonhardt")
2	Claims 16 and 19-24 are anticipated under 35 U.S.C. §102(b) by US 5,411,552 to Andersen et al. ("Andersen")
3	Claims 16 and 19-24 are anticipated under 35 U.S.C. §102(e) by US 6,458,153 to Bailey ("Bailey")

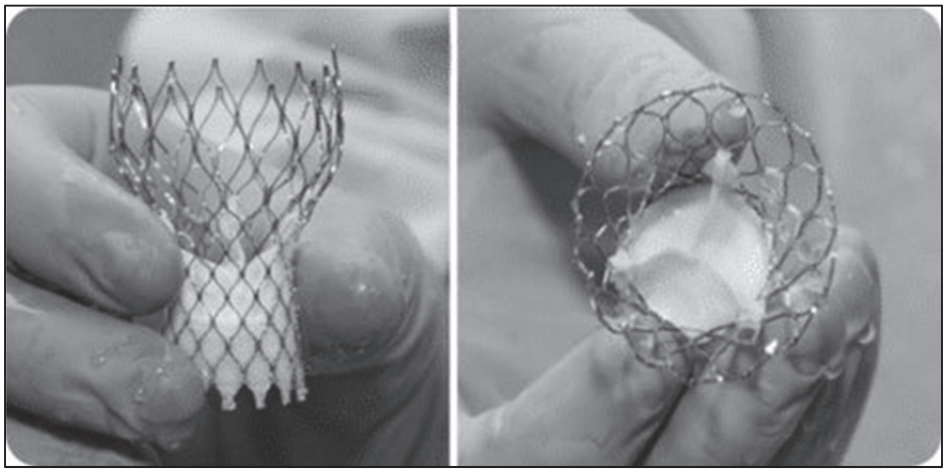
No.	Grounds
4	Claims 16 and 19 are anticipated under 35 U.S.C. §102(b) by DE App. No. 195 46 692 to Figulla ("Figulla")
5	Claims 16 and 19 are under anticipated 35 U.S.C. §102(b) by US 5,855,597 to Jayaraman ("Jayaraman")
6	Claims 16 and 19 are under anticipated 35 U.S.C. §102(b) by US 3,657,744 to Ersek ("Ersek")

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)

A claim receives 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 '228 Patent is directed to artificial aortic heart valve replacements that can be anchored in place with a stent and discloses four such replacement valve embodiments. In construing the challenged claims, Petitioner relies upon the implicit claim constructions within Patent Owner's Initial Infringement Contentions (Exh. 1003), which were served as part of Patent Owner's litigation against

Petitioner.[1] There the Patent Owner contends that the claims of the '228 Patent cover a manufactured tissue valve sutured within a stent as shown in the following pictures.



It must be noted, however, that in order to make such infringement claims, Patent Owner has stretched the meaning of the claim limitations beyond their broadest reasonable interpretation and ignored others altogether, particularly in the context of litigation. Although Petitioner disagrees with Patent Owner's proposed

[1] The Initial Infringement Contentions (Ex. 1003) are also attached at Exhibit 1 to the Declaration of Nicholas Mathews (Exh. 1020), Petitioner's counsel in Norred v. Medtronic, Inc., et al., Case No. 2:13-cv-02061 (D. Kan.). Figures from the Infringement Contentions are reproduced in the body of the Declaration of Russell Hodge (Exh. 1019), Medtronic CoreValve's Senior Program Director, for the purpose of identifying structures of Medtronic's CoreValve that the Patent Owner has labeled with limitations from the claims of the '228 Patent.

constructions, for the purposes of this *inter partes* review only, Petitioner accepts Patent Owner's proposed constructions. The bottom line is this: if a tissue valve in a stent satisfies all the limitations of the claims of the '228 Patent as Patent Owner contends, then any one of the prior art references detailed below anticipate those same claims.

1. "Membrane"

The term "membrane" is used in claim 16. Patent Owner has construed the meaning of this term to not only refer to materials such as fabric or fibrous polymer, but also to include "tissue." *See* Exh. 1003, p. 3; Exh. 1019, pp. 3-4. Although Petitioner disagrees with Patent Owner's construction, that is the construction applied to this term for purposes of this *inter partes* review. However, it should be noted that the '228 Patent draws a distinction between the terms "membrane" and "tissue." The specification only refers to a "membrane" in describing the cone-shaped valve embodiments, with the first cone-shaped valve embodiment having "a biocompatible, durable, flexible generally conically-shaped fabric 75 membrane" and the second cone-shaped valve embodiment having "[a] cone-shaped membrane 92 of fibrous polymer." *'228 Patent,* 4:59-62 and 5:40-41(emphasis added). In contrast, the specification's only reference to "tissue" is in the context of describing "other valvular designs" that "include the usage of biological tissue incorporated valves, such as cadaver/porcine valves." *'228 Patent*, 5:64-65. Thus, the

term "membrane" in the '228 Patent should be more narrowly construed in the context of litigation to include fabric or fibrous polymer, but not tissue.

2. "Means for mounting"

Claim 16 recites a "means for mounting" limitation. The limitation begins, a "means for mounting said first open end of said membrane about said ring aperture with said second open end displaced therefrom." The limitation continues, "said [mounting] means moving said membrane second end between a first open position to allow a blood flow therethrough and a second closed position to preclude a blood flow therethrough." Thus, the claimed means performs a mounting function and a moving function. Patent Owner seems to have ignored the means plus function strictures of the claim limitation and has instead broadly construed this limitation as being met by sutures for attaching the membrane to interior of a stent. *See* Exh. 1003, p. 4; Exh. 1019, pp. 4-5. It is presumed that Patent Owner intends for the sutures to be a structure that meets both the mounting and moving functions of the limitation, even though the sutures are stationary. Although Petitioner disagrees with Patent Owner's construction, that is the construction applied to this limitation for purposes of this *inter partes* review. It should be noted, however, that this limitation should be more narrowly construed in the context of litigation under the rules for construing a "means plus function" limitation under 35 U.S.C. § 112, ¶ 6.

3. "Tissue Valve"

Petitioner submits that the phrase "tissue valve," which appears in claims 20-23, is an "exogenous, biological tissue valve, such as cadaver and porcine tissue valves." This is a straightforward reading of the claim in the context of the specification under the broadest reasonable interpretation standard as the sole reference to "tissue" in the '228 Patent specification is "biological tissue incorporated valves, such as cadaver/porcine valves." *'228 Patent*, 5:64-65.

4. "Means for maintaining"

Claims 19 and 20 recite a "means for maintaining said ring member in said seated position about the aortic wall." Patent Owner seems to have ignored the means plus function strictures of this claim and has instead broadly construed this limitation to include a valve in a stent anchored to the aortic wall. *See* Exh. 1003, p. 6; Exh. 1019, p. 6-7. Although Petitioner disagrees with Patent Owner's construction, that is the construction applied to this limitation for purposes of this *inter partes* review. It should be noted, however, that this limitation should be more narrowly construed in the context of litigation under the rules for construing a "means plus function" limitation under 35 U.S.C. § 112, ¶ 6.

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

An explanation of how construed claims 16 and 19-24 of the '228 Patent are unpatentable under the statutory grounds identified above, including identification

of where each element of the claim is found in the prior art patents or printed publications, is provided below in Section V and in claim charts A-1 to A-6.

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-6.

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 16 and 19-24 are Anticipated Under 35 U.S.C. §102(b) by US 5,957,949 to Leonhardt et al. (Exh. 1004)

U.S. Patent No. 5,957,949 to Leonhardt et al. ("Leonhardt") issued on September 28, 1999 and thus qualifies as prior art under § 102(b). Although Leonhardt was considered during prosecution of the '228 Patent, in view of applicant's post-allowance amendments and Patent Owner's proposed claim constructions, Leonhardt warrants reconsideration given that it describes an aortic heart valve prosthesis made of a biological tissue valve, such as porcine tissue valve, for use within a stent. The claim chart attached as Appendix A-1 details how each element recited in claims 16 and 19-24 is anticipated by Leonhardt.

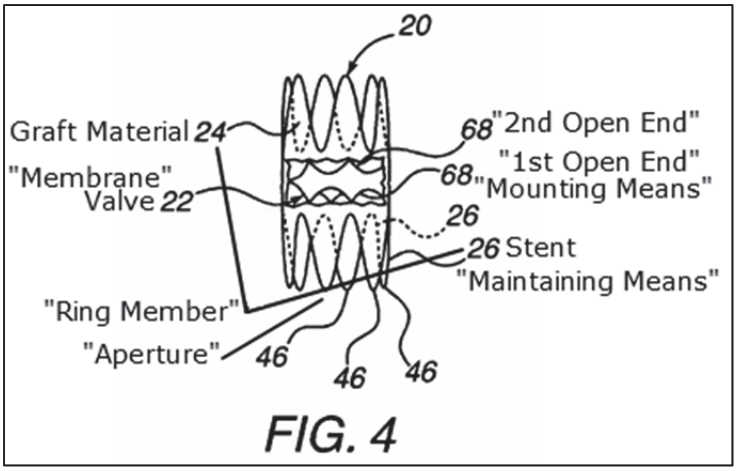


FIG. 4

Referring to annotated Figure 4 above, Leonhardt discloses a valve stent 20 for implantation in the aorta comprised of three elements: stent 26, biological valve 22, and graft material 24. *Leonhardt*, 4:14-16. Graft material 24 is a thin-walled biocompatible, flexible and expandable, low-porosity woven fabric (e.g., polyester or PTFE) that is attached to and encloses stent 26 to form a cylindrical fluid passageway. *Leonhardt*, 3:33-45; 5:53-59. Stent 26 is a made of a nitinol wire. *Leonhardt*, 4:66-67. The stent coerces graft material 24 to conform to the tissue surface at the implant site. *Leonhardt*, 5:53-59. Leonhardt further discloses that the prosthesis may be completely sealed to the implant site tissue by light activated biocompatible tissue adhesive. *Leonhardt*, Abstract; 3:42-45; 4:63-65; 12:54-57.

Biological valve 22 is preferably a porcine valve that is attached within the cylindrical fluid passageway formed by stent 26 and graft material 24 by sutures, biocompatible adhesive, or a combination of the two. *Leonhardt*, 6:23-33. Leon-

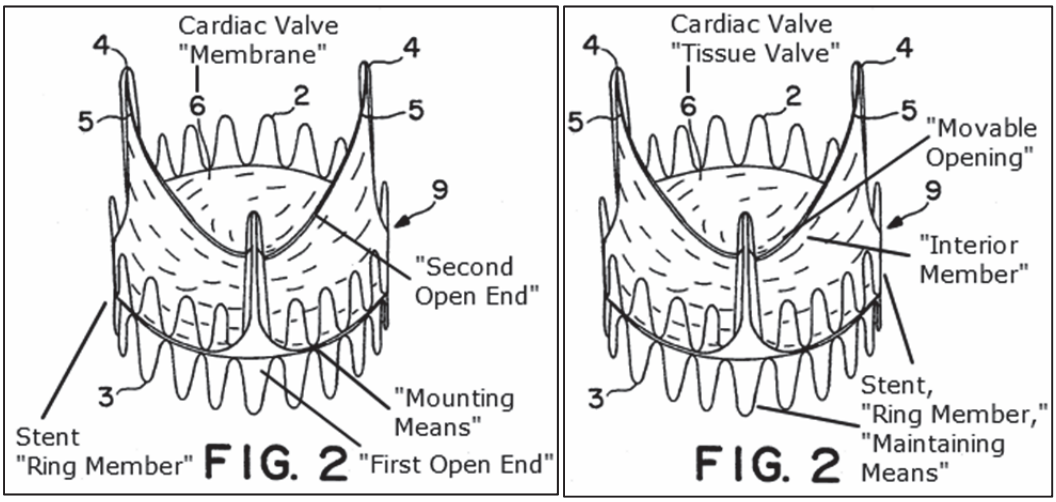
hardt further discloses that biological valve 22 opens and closes with pressure and/or flow changes to maintain bodily fluid flow in a single direction. *Leonhardt*, 1:11-14.

As explained in the accompanying Vassiliades Declaration (Exh. 1018), it is readily apparent and inherent that the biological valve disclosed by Leonhardt moves between a closed position and an open position in response to pressure changes in the aorta. Natural heart valves utilize the pressure gradient created during systole and diastole to open and close the valve. A prosthetic heart valve, whether of a mechanical design or a tissue design as disclosed in Leonhardt, must necessarily function in the same manner as the natural heart valve it replaces. Thus, prosthetic valves, including the one disclosed in Leonhardt, must necessarily utilize the pressure gradient created during systole and diastole to open and close the prosthetic valve such that the blood flow controlling function of the natural valve is replaced.

B. Claims 16 and 19-24 are Anticipated Under 35 U.S.C. §102(b) by US 5,411,552 to Andersen et al. (Exh. 1005)

U.S. Patent No. 5,411,552 to Andersen et al. ("Andersen") issued on May 2, 1995 and thus qualifies as prior art under § 102(b). Although a patent related to Andersen (U.S. Patent No. 6,168,614) was considered during prosecution of the '228 Patent, in view of applicant's post-allowance amendments and Patent Owner's proposed claim constructions, Andersen warrants consideration given that it

describes an aortic heart valve prosthesis made of a biological tissue valve, such as porcine tissue valve, for use within a stent. The claim chart attached as Appendix A-2 details how each element recited in claims 16 and 19-24 is anticipated by Andersen.



Referring to annotated Figure 2 above, Andersen discloses valve prosthesis 9 for implantation in the aorta comprising a stent made from an expandable cylinder-shaped thread structure and a biological (pig) cardiac valve 6 that is glued, welded or sutured within the stent. *Andersen*, Abstract; 2:35-37; 4:3-11; 5:11-14, 29-30, 33-35; 7:3-12. Andersen further discloses that the stent abuts the inner wall of the aorta to ensure the securing of the valve prosthesis in the aorta. *Andersen*, Abstract; 4:3-11; 5:9-28; 6:30-36; 7:3-12; Figs. 5-10.

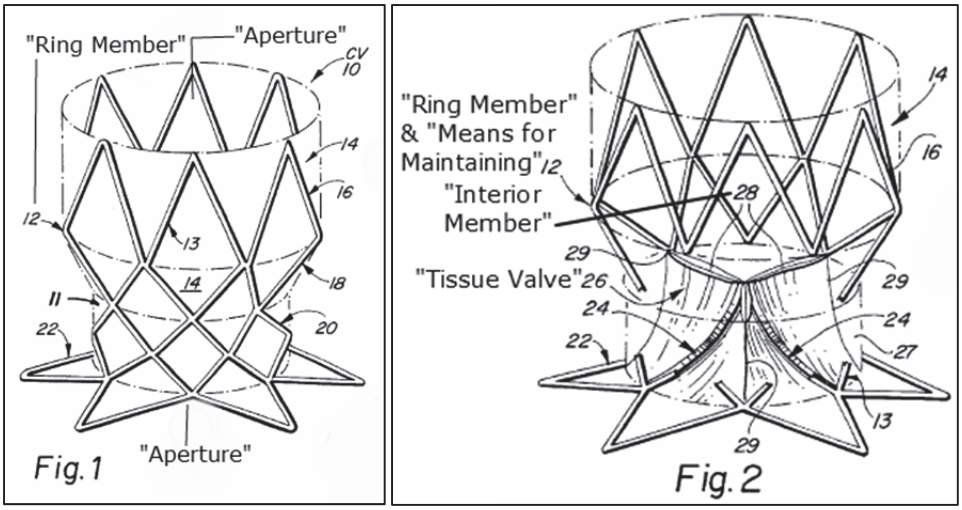
With regard to the function and purpose of the valve prosthesis, Andersen explains that the valve prosthesis ensures that the blood flows in one direction only and that it can be used to treat aorta insufficiency (i.e., leaking of the aortic valve

that causes blood to flow in the reverse direction during ventricular diastole, from the aorta into the left ventricle). *Andersen*, 3: 17-19, 53-57.

As explained in the accompanying Vassiliades Declaration (Exh. 1018), it is readily apparent and inherent that the biological valve disclosed by Andersen moves between a closed position and an open position in response to pressure changes in the aorta. Natural heart valves utilize the pressure gradient created during systole and diastole to open and close the valve. A prosthetic heart valve, whether of a mechanical design or a tissue design as disclosed in Andersen, must necessarily function in the same manner as the natural heart valve it replaces. Thus, prosthetic valves, including the one disclosed in Andersen, must necessarily utilize the pressure gradient created during systole and diastole to open and close the prosthetic valve such that the blood flow controlling function of the natural valve is replaced.

C. Claims 16 and 19-24 are Anticipated Under 35 U.S.C. §102(e) by US 6,458,153 to Bailey (Exh. 1006)

U.S. Patent No. 6,458,153 to Bailey et al. ("Bailey") was filed on December 31, 1999 and thus qualifies as prior art under § 102(e). Bailey was not cited during prosecution of the '228 Patent although it teaches a replacement aortic valve utilizing a biological xenograft valve within a stent. The claim chart attached as Appendix A-3 details how each element recited in claims 16 and 19-24 is anticipated by Bailey.



Referring to annotated Figures 1 and 2 above, Bailey discloses a prosthetic cardiac valve comprising a stent support member 12, a graft member 11 which covers at least a portion the stent 12, and biological xenograft valve flaps/leaflets 28. *Bailey*, Abstract; 1:6-21; 1:28-38; 5:61-6:9; 7:58-8:19. Bailey further discloses that blood flow regulation is provided by the combination of the prosthetic valve flaps 28 and the valve arms 24 moving between an open and closed position in response to blood pressure differentials acting upon the valve leaflets 26. *Bailey,* 6:10-14; 9:25-47; 10:31-44. Graft member 11 can also be made of biologically-derived membranes and is coupled to lumenal surface of the stent 12 and is exverted such that the free ends or valve flap portions 28 of the inner graft member are oriented toward the distal end of the stent 12. *Bailey*, 1:28-38; 7:58-8:4; 8:37-40; 9:11-35; Fig. 4. Bailey also discloses that stent 12 anchors to the aortic wall and engages the tissue of the aortic wall to retain the valve secured within the stent in position. 1:28-38; 5:61-6:9; 7:58-8:19.

Finally, Bailey discloses the operation of the prosthetic valve once implanted in the aorta. With reference to Figures 6A and 6B, Bailey explains that Figure 6A illustrates the heart during systole in which a positive pressure is applied to the prosthetic aortic valve by contraction of the left ventricle. The systolic pressure overcomes the bias exerted by the valve arms 24 and causes the valve leaflets 26 to open and release blood into the aorta. Figure 6B illustrates that the presence of a negative pressure head across the stent valve 10, i.e. such as that during diastole, causes the biased valve leaflets 26 which are already closed, to further close, and prevent regurgitation from the aorta into the left ventricle. *Bailey*, 10:33-39.

As explained in the accompanying Vassiliades Declaration (Exh. 1018), it is readily apparent and inherent that the biological valve disclosed by Bailey moves between a closed position and an open position in response to pressure changes in the aorta created during systole and diastole. Natural heart valves utilize the pressure gradient created during systole and diastole to open and close the valve. A prosthetic heart valve, whether of a mechanical design or a tissue design as disclosed in Bailey, must necessarily function in the same manner as the natural heart valve it replaces. Thus, prosthetic valves, including the one disclosed in Bailey, must necessarily utilize the pressure gradient created during systole and diastole to open and close the prosthetic valve such that the blood flow controlling function of the natural valve is replaced.

D. Claims 16 and 19 are Anticipated Under 35 U.S.C. §102(b) by DE Patent Application No. 195 46 692 to Figulla (Exhs. 1007 & 1008)

As explained in the accompanying Declaration of German Patent Attorney Felix Harbsmeier (Exh. 1012), German Patent Application No. 195 46 692 A1 to Figulla (Exhs. 1014 and 1015, "Figulla '692 Published Application") was published on June 19, 1997, but was published with figures that do not match the specification or the application as it was originally filed on December 14, 1995 (Exhs. 1007 and 1008, "Figulla '692 Filed Application"). The Figulla '692 Published Application describes four figures numbered 1 through 4; however, it includes only two figures, neither one of which corresponds to any of the described figures. Any person reading Figulla '692 Published Application would notice that the two figures included with the published application did not correspond to the four figures described in the specification of the published application. As such, Under Section 31 of the German Patent Act, any person noticing the incorrect published figures would have been able to inspect the file wrapper for the application that included Figulla '692 Filed Application and the four figures described in the specification of Figulla '692 Published Application. Thus, as of June 19, 1997, the Figulla '692 Filed Application was readily available to any and all persons with an interest in heart valve prostheses. *A fortiori*, the Figulla '692 Filed Application constitutes a "printed publication" as of June 19. 1997 and, therefore, qualifies as prior art under § 102(b). *See Kyocera Wireless Corp. v. Int'l Trade Comm'n*, 545 F.3d 1340, 1350

(Fed. Cir. 2008) (a reference is publicly available if it was "disseminated or otherwise made available to the extent that persons interested and ordinarily skilled in the subject matter or art exercising reasonable diligence, can locate it.").

Figulla '692 Filed Application was not cited during prosecution of the '228 Patent although it describes an aortic heart valve prosthesis made of a tissue valve, such as porcine tissue valve, for use within a stent. The claim chart attached as Appendix A-4 details how each element recited in claims 16 and 19 is met by Figulla '692 Filed Application. As shown below, Figure 2 of Figulla '692 Filed Application shows a "swine-heart valve" attached via sutures to "the proximal portion of the multi-component, self-expanding stent." *Figulla '692 Filed Application, p. 2, and Fig. 2 caption*. Figure 4 of Figulla '692 Filed Application shows the stent engaged with the wall of the aorta to hold the prosthetic valve in position.

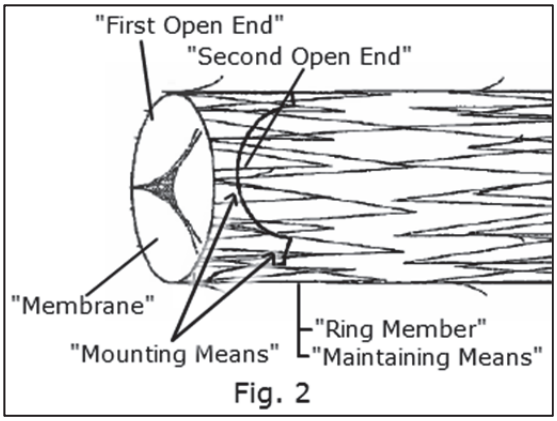
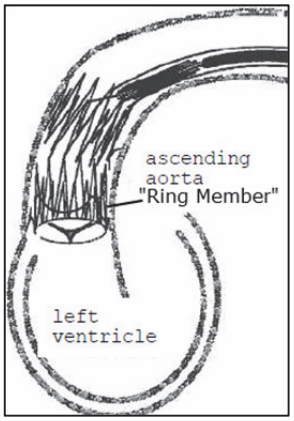


Fig. 2



As explained in the accompanying Vassiliades Declaration (Exh. 1018), it is readily apparent and inherent that the swine prosthetic heart valve disclosed by the Figulla '692 Filed Application moves between a closed position and an open posi-

tion in response to pressure changes in the aorta. Natural heart valves utilize the pressure gradient created during systole and diastole to open and close the valve. A prosthetic heart valve, whether of a mechanical design or a tissue design as disclosed in the Figulla '692 Filed Application, must necessarily function in the same manner as the natural heart valve it replaces. Thus, prosthetic valves, including the one disclosed in the Figulla '692 Filed Application, must necessarily utilize the pressure gradient created during systole and diastole to open and close the prosthetic valve such that the blood flow controlling function of the natural valve is replaced.

E. Claims 16 and 19 are Anticipated Under 35 U.S.C. §102(b) by US 5,855,597 to Jayaraman (Exh. 1009)

U.S. Patent No. 5,855,596 to Jayaraman ("Jayaraman") issued on January 5, 1999 and thus qualifies as prior art under § 102(b). Jayaraman was not cited during prosecution of the '228 Patent although it teaches a replacement aortic valve utilizing a bio-compatible material formed into a tri-cuspid valve within a stent. The claim chart attached as Appendix A-5 details how each element recited in claims 16 and 19 is anticipated by Jayaraman.

Referring to annotated Figure 10 below, Jayaraman discloses a star-shaped stent and replacement valve for us in repairing a damaged cardiac valve. *Jayaraman*, Abstract; 1:22-24; 3:36-40. Jayaraman discloses that the replacement valve is made from a sheet of flexible bio-compatible material (e.g., silk, DACRON, NY-

LON, etc.) and is sewn within the stent. *Jayaraman*, 3:41-48. As shown in Figure 16, Jayaraman discloses that the stent is placed in the aortic channel in contact with the aortic wall. *Jayaraman*, 3:53-59.

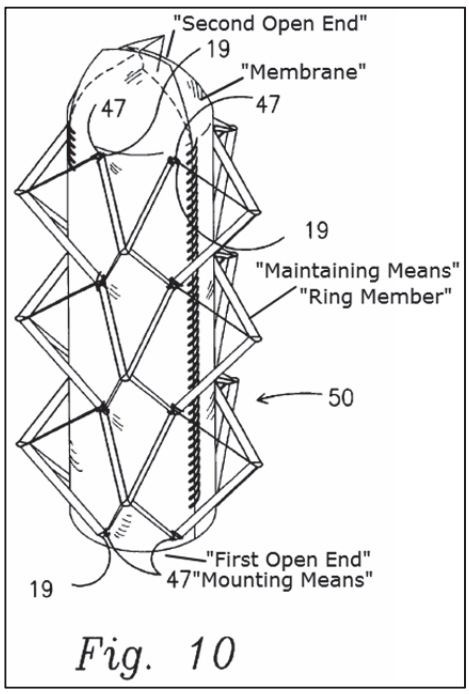


Fig. 10

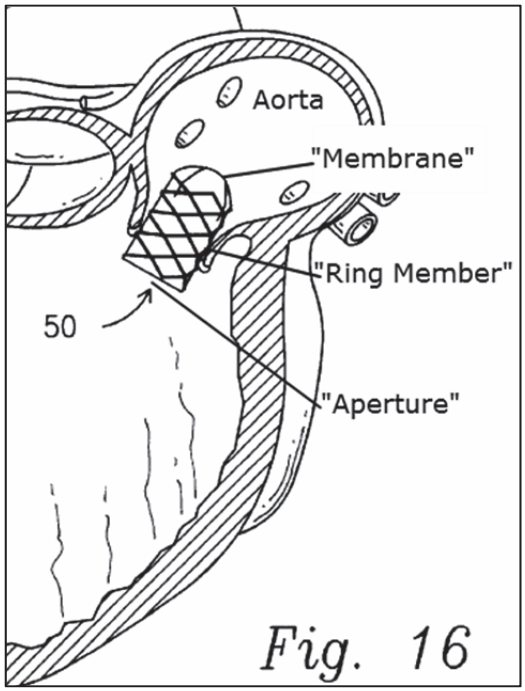


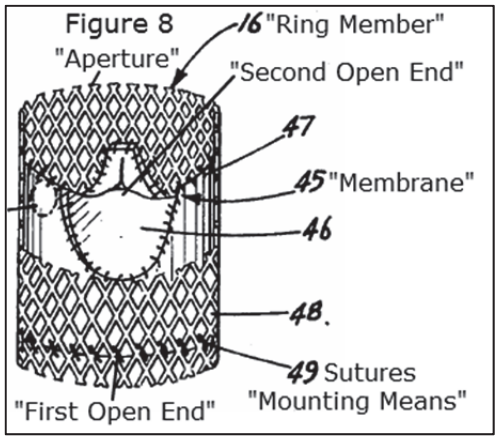
Fig. 16

As explained in the accompanying Vassiliades Declaration (Exh. 1018), it is readily apparent and inherent that the tri-cuspid flaps of the prosthetic heart valve disclosed by Jayaraman move between a closed position and an open position in response to pressure changes in the aorta. Natural heart valves utilize the pressure gradient created during systole and diastole to open and close the valve. A prosthetic heart valve, whether of a tissue design or a mechanical design as disclosed in Jayaraman, must necessarily function in the same manner as the natural heart valve it replaces. Thus, prosthetic valves, including the one disclosed in Jayaraman, must necessarily utilize the pressure gradient created during systole and diastole to open

and close the prosthetic valve such that the blood flow controlling function of the natural valve is replaced.

F. Claims 16 and 19 are Anticipated Under 35 U.S.C. §102(b) by US 3,657,744 to Ersek (Exh. 1010)

U.S. Patent No. 3,657,744 to Ersek ("Ersek") issued on April 25, 1972 and thus qualifies as prior art under § 102(b). Ersek was not cited during prosecution of the '228 Patent although it discloses an aortic heart valve prosthesis made of a donor aorta secured within a wire mesh fixation sleeve. The claim chart attached as Appendix A-6 details how each element recited in claims 16 and 19 is anticipated by Ersek.



Referring to annotated Figure 8 above, Ersek discloses a transplant aortic heart valve (or donor aorta) that is inserted in fixation sleeve 16 and attached circumferentially with sutures at points 47 and 49. *Ersek,* Abstract; 3:1-6, 28-35; 4:25-35. Ersek further discloses that fixation sleeve 16 is expanded radially into intimate engagement with the surrounding tissue, such as the aortic wall, to main-

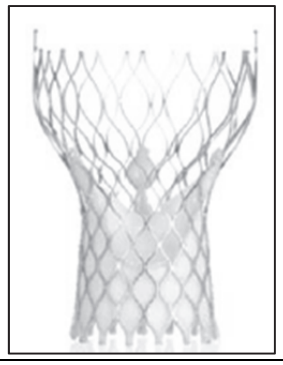
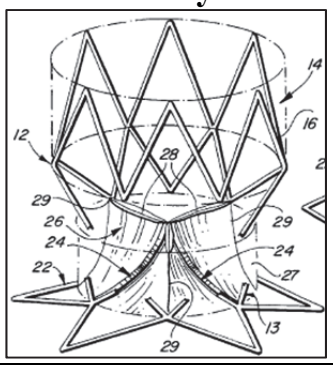
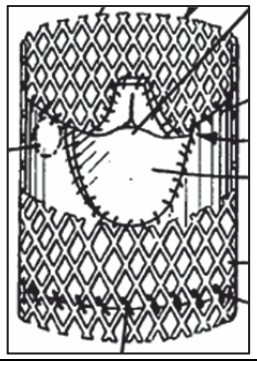
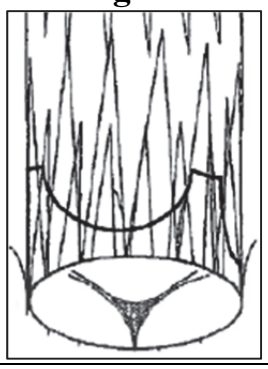
tain the fixation sleeve in place. *Ersek,* 1:12-16; 2:56-62; 3:1-6, 28-35, 41-55; 4:36-38.

As explained in the accompanying Vassiliades Declaration (Exh. 1018), it is readily apparent and inherent that the tissue leaflets of the prosthetic heart valve disclosed by Ersek move between a closed position and an open position in response to pressure changes in the aorta. Natural heart valves utilize the pressure gradient created during systole and diastole to open and close the valve. A prosthetic heart valve, whether of a mechanical design or a tissue design as disclosed in Ersek, must necessarily function in the same manner as the natural heart valve it replaces. Thus, prosthetic valves, including the one disclosed in Ersek, must necessarily utilize the pressure gradient created during systole and diastole to open and close the prosthetic valve such that the blood flow controlling function of the natural valve is replaced.

VI. CONCLUSION

Based on the foregoing, it is clear that claims 16 and 19-24 of the '228 Patent define subject matter that is anticipated by the prior are relied upon herein. If the claim constructions advanced by Patent Owner had been applied by the original Examiner, claims 16 and 19-24 of the '228 Patent would not have issued. As illustrated below, if a manufactured tissue valve sutured within a stent, such as Petitioner's accused products (*e.g.*, CoreValve), meets all the limitations of claims 16

and 19-24 of the '228 Patent, then the cited art (*e.g.*, Bailey, Ersek, Figulla, etc.) anticipates those same claims.

CoreValve	Bailey	Ersek	Figulla
			

The art cited above establishes a reasonable likelihood that Petitioner will prevail on at least one claim. Thus, the Petitioner requests institution of an *inter partes* review to cancel those claims.

Respectfully submitted,

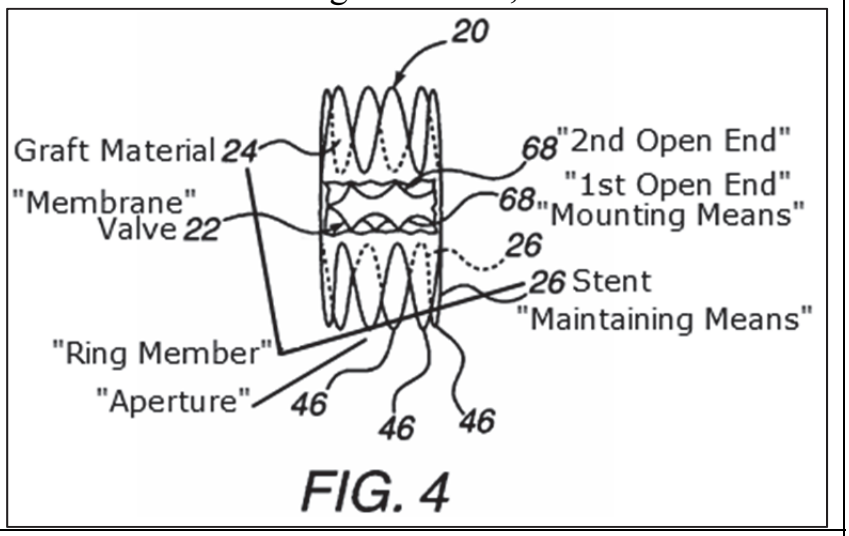
PILLSBURY WINTHROP SHAW PITTMAN LLP

/Jack S. Barufka/

Jack S. Barufka
Reg. No. 37,087
Tel. No. 703.770.7712
Fax No. 703.905.2500

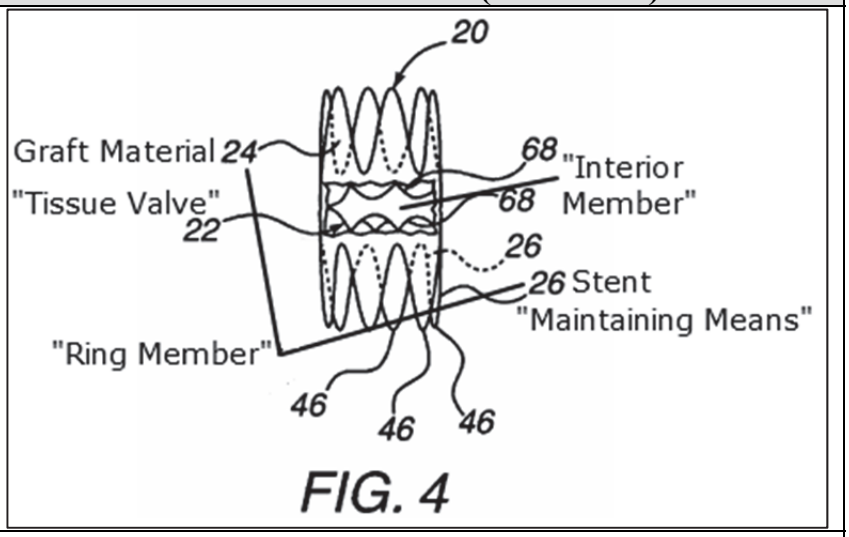
P.O. Box 10500
McLean, VA 22102
(703) 770-7900

Attachments: Appendices A-1 – A-6 (Claim Charts)
Exhibits 1001-1020

The '228 Patent	Appendix A-1: Anticipation by U.S. Pat. 5,957,949 to Leonhardt et al. (Exh. 1004)
16. An aortic valve for regulating a blood flow through an aortic channel surrounded by an aortic wall upon placement therein, said valve comprising:	Leonhardt discloses an aortic valve 20 for regulating a blood flow through an aortic channel surrounded by an aortic wall upon placement therein. Abstract; 1:11-14; 3:32-45; 5:51-59; 9:64-67; 12:28.
a ring member having a circumference adapted to seat about an aortic wall surrounding an aortic channel, said ring including an aperture for blood flow therethrough;	**[1]** Leonhardt discloses a "ring member" formed by the combination of tubular graft material 24 sutured to stent 26. 5:53-59. **[2]** Leonhardt further discloses that stent 26 coerces graft material 24 to substantially conform to the surface of a living tissue, such as the interior surface of the aortic wall. Abstract; 3:32-45; 4:14-16; 4:53-65. **[3]** As shown in annotated Fig. 4, Leonhardt discloses that the ring 24, 26 has an aperture for blood flow therethrough. *See also*, 5:51-59.  FIG. 4
a membrane having first and second spaced-apart open ends, said membrane made of a material resistant to a fluid flow therethrough; and	**[1]** As noted above in Section IV.E.1, the Patent Owner's construction of the claimed "membrane" includes not only synthetic materials (e.g., fabric or fibrous polymer), but also includes biological tissue. **[2]** Leonhardt discloses a "membrane" in the form of a biological valve 22, such as a porcine valve for use in a human. 6:23-32. **[3]** As shown in annotated Fig. 4 above, Leonhardt discloses that the biological valve 22 ("membrane") has first and second spaced-apart open

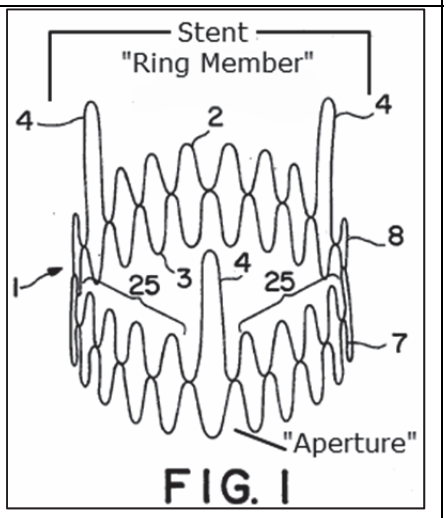
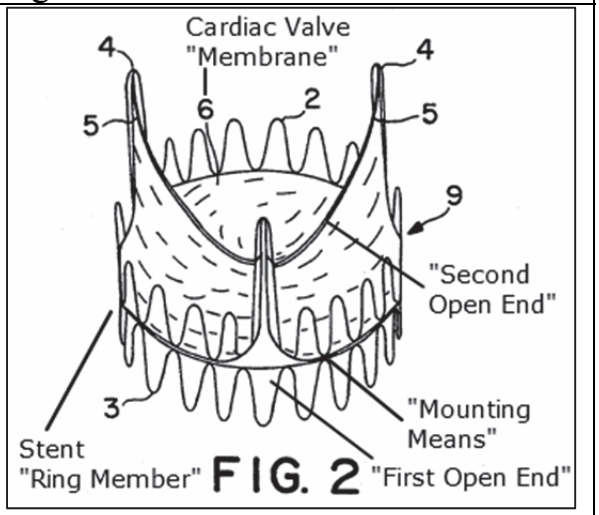
The '228 Patent	Appendix A-1: Anticipation by U.S. Pat. 5,957,949 to Leonhardt et al. (Exh. 1004)
	ends in that the valve 22 is positioned within the cylindrical passageway formed by the ring member 24, 26 and attached along the valve's commissural points 68 and around its base. 6:30-32. **[4]** Leonhardt further discloses that the valve is resistant to fluid flow in that the valve creates one-way flow and is capable of blocking flow in one direction. Abstract; 3:32-45; 5:51-59; 12:28.
means for mounting said first open end of said membrane about said ring aperture with said second open end displaced therefrom, said means moving said membrane second end between a first open position to allow a blood flow therethrough and a second closed position to preclude a blood flow therethrough.	**[1]** As noted above in Section IV.E.2, the Patent Owner's construction of the claimed "means for mounting" includes sutures. **[2]** Leonhardt discloses a "means for mounting" in that biological valve 22 is attached at its first open end 68 to stent 26, graft material 24, or both with sutures and/or biocompatible adhesive. 3:39-41; 6:23-32. Attachment is along biological valve's 22 commissural points 68 and around its base at the first open end of the valve. 3:39-41; 6:23-32. **[3]** As shown above in annotated Fig. 4, valve 22 ("membrane") is mounted within the cylindrical passageway formed by the combination of stent 26 and graft material 24 ("ring member"). **[4]** The "means for mounting" (sutures) enables the membrane second end to move between a first open position and a second closed position with pressure and/or flow changes. 1:11-14. *See* Note 1 below and Exhibit 1018. **Note 1:** As described in Section V above and the Declaration of Thomas Vassiliades, Jr., M.D. (Exh. 1018), prosthetic tissue heart valves (including prosthetic tissue heart valves that use pig heart valves), as disclosed in the '228 Patent and as well known in the art, are resistant to fluid flow and operate by moving between an open and closed position in response to blood flow of the heart. The prosthetic valve disclosed by Leonhardt (and the prosthetic valves of the other references relied on in this petition) moves between a closed position and an open position in response to pressure changes in the aorta. Specifically, the prosthetic valve disclosed

The '228 Patent	Appendix A-1: Anticipation by U.S. Pat. 5,957,949 to Leonhardt et al. (Exh. 1004)
	by Leonhardt (and the prosthetic valves of the other references relied on in this petition) moves to an open position in response to systolic ejection of blood from the left ventricle and moves to a closed position in response to diastolic filling of the left ventricle. *See* Declaration of Thomas Vassiliades, Jr., M.D. (Exh. 1018). Rather than repeat this Note below in other claim charts, Petitioner will instead refer back to this Note with the notation, "*See* Note 1 above."
19. The aortic valve as claimed in claim 16 further comprising means for maintaining said ring member in said seat about the aortic wall.	**[1]** As explained in claim 16, Leonhardt discloses an aortic valve. **[2]** As noted above in Section IV.E.4, the Patent Owner's construction of the claimed "means for maintaining" includes a stent that anchors to the aortic wall. **[3]** Leonhardt discloses a "means for maintaining" in the form of stent 26 which coerces graft material 24 to substantially conform to the surface of a living tissue, such as the interior surface of the aortic wall. Abstract; 3:32-45; 4:14-16, 53-65; 5:5-10; Figs. 1A-1C.
20. An aortic valve for controlling a blood flow through an aortic channel upon placement therein, said valve comprising:	Leonhardt discloses an aortic valve for controlling a blood flow through an aortic channel upon placement therein. Abstract; 1:11-14; 3:32-45; 5:51-59; 9:64-67; 12:28.
a tissue valve having an interior member made of a tissue material and presenting an opening movable between open and closed positions;	**[1]** Leonhardt discloses a "tissue valve" in the form of a biological valve 22, such as a porcine valve for use in a human. 6:23-32. **[2]** Specifically, as shown in annotated Fig. 4 below, Leonhardt discloses that the valve has an "interior member" in the form of a biological valve 22 with commissural points 68 and a base attached within the stent. 6:30-32. **[3]** Leonhardt further discloses that biological valve 22 ("tissue valve") opens and closes with pressure and/or flow changes. 1:11-14. *See* Note 1 above and Exhibit 1018.

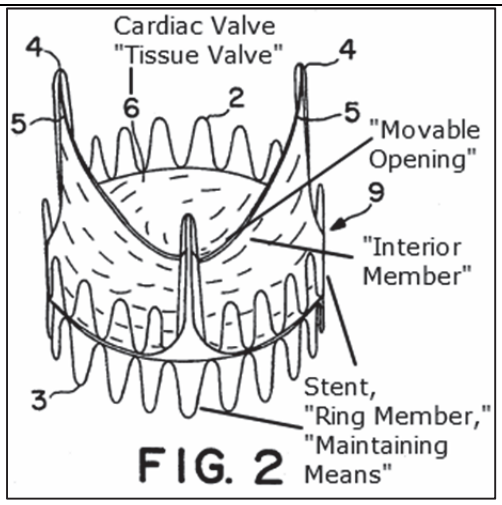
The '228 Patent	Appendix A-1: Anticipation by U.S. Pat. 5,957,949 to Leonhardt et al. (Exh. 1004)
	 FIG. 4
a ring member surrounding said tissue valve, said ring member having an outer circumference adapted to seat said ring member about an aortic wall surrounding an aortic channel;	**[1]** Leonhardt discloses a "ring member" formed by the combination of tubular graft material 24 sutured to stent 26. 5:53-59; Fig. 4. **[2]** Leonhardt discloses that the "ring member" (i.e., graft material 24 and to stent 26) surrounds biological valve 22 ("tissue valve"). 3:39-41; 6:23-32; Fig. 4. **[3]** Leonhardt further discloses that the "ring member" has an outer circumference adapted to seat the "ring member" about the aortic wall. Specifically, stent 26 coerces graft material 24 to substantially conform to the surface of a living tissue, such as the interior surface of the aortic wall. Abstract; 3:32-45; 4:14-16; 4:53-65.
means for maintaining said ring member in said seated position about the aortic wall,	**[1]** As noted above in Section IV.E.4, the Patent Owner's construction of the claimed "means for maintaining" includes a stent that anchors to the aortic wall. **[2]** Leonhardt discloses a "means for maintaining" in the form of stent 26 which coerces graft material 24 to substantially conform to the surface of a living tissue, such as the interior surface of the aortic wall, and retain the cylindrical passageway ("ring member") in place. Abstract; 3:32-45; 4:14-16; 4:53-65; 5:5-10; Figs. 1A-1C.
said tissue valve interior member responsive to changes of conditions	**[1]** Leonhardt discloses a "tissue valve interior member" in the form of a biological valve 22 with commissural points 68 and a base attached within the stent.

The '228 Patent	Appendix A-1: Anticipation by U.S. Pat. 5,957,949 to Leonhardt et al. (Exh. 1004)
within the aorta for movement of said opening between a first closed position and a second open position.	6:23-32; Fig. 4. **[2]** Leonhardt further discloses that biological valve 22 ("tissue valve") opens and closes with pressure and/or flow changes. 1:11-14. *See* Note 1 above and Exhibit 1018.
21. The aortic valve as claimed in claim 20 wherein said tissue valve interior member is responsive to changes in blood pressure in the aorta whereby to move said tissue valve between said first and second positions.	**[1]** As explained in claim 20, Leonhardt discloses a "tissue valve interior member" in the form of a biological valve 22 with commissural points 68 and a base attached within the stent. 6:23-32; Fig. 4. **[2]** Leonhardt further discloses that biological valve 22 ("tissue valve") opens and closes with pressure and/or flow changes. 1:11-14. *See* Note 1 above and Exhibit 1018.
22. The aortic valve as claimed in claim 21 wherein said tissue valve interior member moves to said second position in response to systolic ejection of blood from the left ventricle in which the blood pressure in the left ventricle is greater than the blood pressure in the aortic channel.	**[1]** As explained in claim 21, Leonhardt discloses a "tissue valve interior member" in the form of a biological valve 22 with commissural points 68 and a base attached within the stent. 6:23-32; Fig. 4. **[2]** Leonhardt further discloses that biological valve 22 ("tissue valve") opens with pressure and/or flow changes. 1:11-14. **[3]** Thus, Leonhardt discloses that biological valve 22 ("tissue valve") opens in response to systolic ejection of blood from the left ventricle in which the blood pressure in the left ventricle is greater than the blood pressure in the aortic channel. *See* Note 1 above and Exhibit 1018.
23. The aortic valve as claimed in claim 21 wherein said tissue valve interior member moves to said first position in response to diastolic filling of the left ventricle whereby the blood pressure in the aortic channel is greater than the blood pressure in the left ventricle.	**[1]** As explained in claim 21, Leonhardt discloses a "tissue valve interior member" in the form of a biological valve 22 with commissural points 68 and a base attached within the stent. 6:23-32; Fig. 4. **[2]** Leonhardt further discloses that biological valve 22 ("tissue valve") closes with pressure and/or flow changes. 1:11-14. **[3]** Thus, Leonhardt discloses that biological valve 22 ("tissue valve") closes in response to diastolic filling of the left ventricle whereby the blood pressure in the aortic channel is greater than the blood pressure in the left ventricle. *See* Note 1 above and Exhibit 1018.

The '228 Patent	Appendix A-1: Anticipation by U.S. Pat. 5,957,949 to Leonhardt et al. (Exh. 1004)
24. The aortic valve as claimed in claim 20 wherein said ring member contacts the wall of the aortic channel and seals said ring against the aortic channel wall to reduce blood flow therearound.	**[1]** As explained in claim 20, Leonhardt discloses a "ring member" formed by the combination of tubular graft material 24 sutured to stent 26. 5:53-59. **[2]** Leonhardt further discloses that stent 26 coerces graft material 24 to substantially conform to the surface of a living tissue, such as the interior surface of the aortic wall. Abstract; 3:32-45; 4:14-16; 4:53-65. **[3]** Leonhardt also discloses that the cylindrical passageway ("ring member") may be completely sealed to the living tissue by light activated biocompatible tissue adhesive between the outside of the tubular graft and the living tissue and that such seal would be substantially fluid-tight. Abstract; 3:42-45; 4:63-65; 12:54-57.

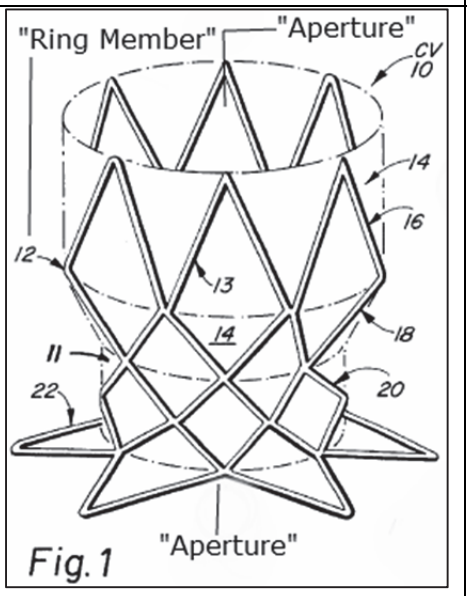
The '228 Patent	Appendix A-2: Anticipation by U.S. Pat. 5,411,552 to Andersen et al. (Exh. 1005)
16. An aortic valve for regulating a blood flow through an aortic channel surrounded by an aortic wall upon placement therein, said valve comprising:	Andersen discloses an aortic valve for regulating a blood flow through an aortic channel surrounded by an aortic wall upon placement therein. Abstract; 1:20-22; 3:37-42.
a ring member having a circumference adapted to seat about an aortic wall surrounding an aortic channel, said ring including an aperture for blood flow therethrough;	**[1]** Andersen discloses a "ring member" in the form of a stent 1 made from an expandable cylinder-shaped thread structure. Abstract; 4:3-11; 7:3-12. **[2]** Andersen further discloses that the stent 1 ("ring member") has a circumference that is expanded to wedge it against the wall of the aorta to surround the aortic channel. Abstract; 4:3-11; 5:47-49; 6:30-36. **[3]** As shown in annotated Fig. 1, stent 1 ("ring member") has an aperture for blood flow therethrough.  FIG. 1
a membrane having first and second spaced-apart open ends, said membrane made of a material resistant to a fluid flow therethrough; and	**[1]** As noted above in Section IV.E.1, the Patent Owner's construction of the claimed "membrane" includes not only synthetic materials (e.g., fabric or fibrous polymer), but also includes biological tissue. **[2]** Andersen discloses a "membrane" in the form of a biological cardiac valve 6 removed from a pig. 5:11-14, 29-30. **[3]** As shown in annotated Fig. 2, biological cardiac valve 6 ("membrane") has first and second  FIG. 2

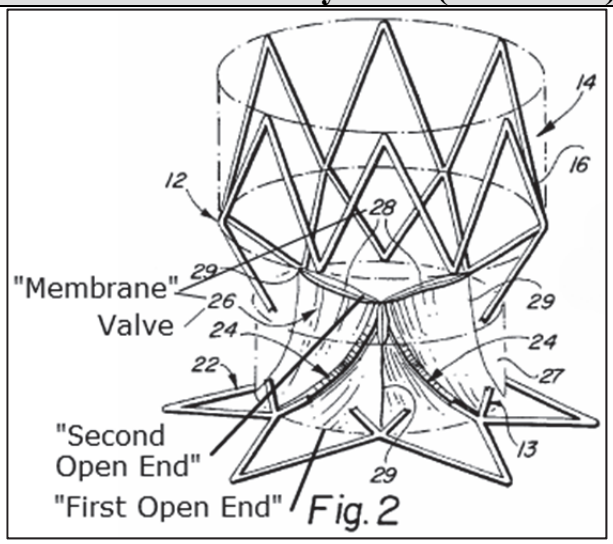
The '228 Patent	Appendix A-2: Anticipation by U.S. Pat. 5,411,552 to Andersen et al. (Exh. 1005)
	spaced apart open ends. **[4]** Andersen discloses that the function of the valve prosthesis is to ensure that the blood flows in one direction only. 3:17-19. Thus, Andersen discloses that biological cardiac valve 6 ("membrane") is resistant to fluid flow therethrough. *See* Note 1 above and Exhibit 1018.
means for mounting said first open end of said membrane about said ring aperture with said second open end displaced therefrom, said means moving said membrane second end between a first open position to allow a blood flow therethrough and a second closed position to preclude a blood flow therethrough.	**[1]** As noted above in Section IV.E.2, the Patent Owner's construction of the claimed "means for mounting" includes sutures. **[2]** Andersen discloses a "means for mounting" in the form of gluing, welding, or suturing valve 6 about the stent 1. Abstract; 2:35-37; 5:33-35. As shown above in annotated Fig. 2, Andersen discloses that the "first open end" of valve 6 is mounted within stent 1 with sutures, glue, or welds so that the first open end is about the stent aperture with the second open end displaced therefrom. Abstract; 2:35-37; 5:33-35. **[3]** Andersen discloses that the function of the valve prosthesis is to ensure that the blood flows in one direction only. 3:17-19. Andersen also discloses that the cardiac valve prosthesis can be used to treat aorta insufficiency (i.e., leaking of the aortic valve of the heart that causes blood to flow in the reverse direction during ventricular diastole, from the aorta into the left ventricle). 3:53-57. Andersen discloses that the sutures ("means for mounting") enable the membrane's 6 second end to move between a first open position and a second closed position to control blood flow in response to systolic and diastolic pressure differentials. *See* Note 1 above and Exhibit 1018.
19. The aortic valve as claimed in claim 16 further comprising means for maintaining said ring member in said seat about the aortic wall.	**[1]** As explained in claim 16, Andersen discloses an aortic valve. **[2]** As noted above in Section IV.E.4, the Patent Owner's construction of the claimed "means for maintaining" includes a stent that anchors to the aortic wall. **[3]** Andersen discloses a "means for maintaining" in the form of a stent 1 ("means for maintaining" and "ring member") that abuts the inner wall of the aorta to seat the valve prosthesis about the aortic wall. Abstract; 4:3-11; 5:9-28; 6:30-36; 7:3-12; Figs. 5-10.

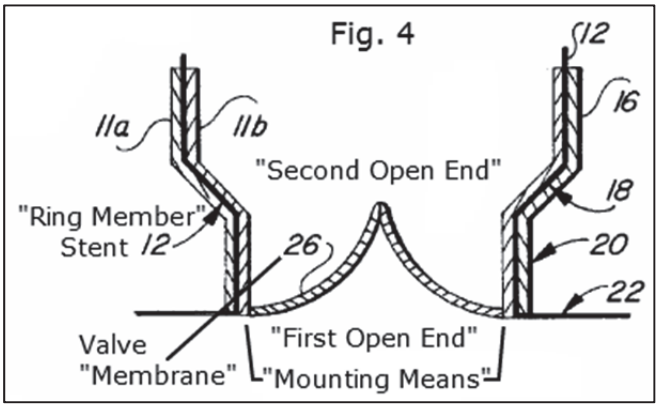
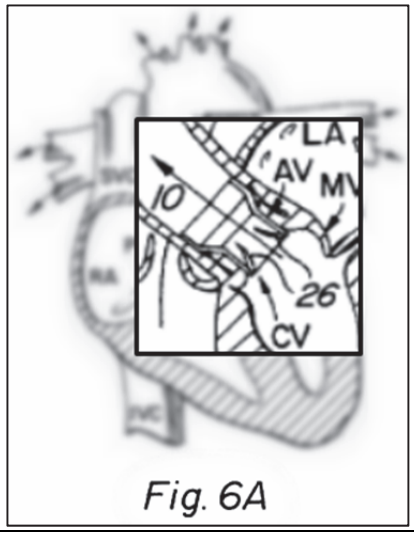
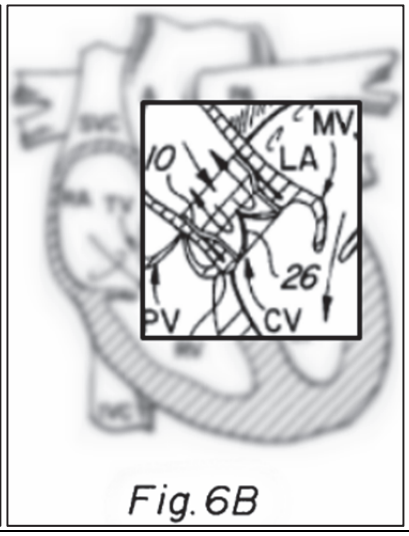
The '228 Patent	Appendix A-2: Anticipation by U.S. Pat. 5,411,552 to Andersen et al. (Exh. 1005)
20. An aortic valve for controlling a blood flow through an aortic channel upon placement therein, said valve comprising:	Andersen discloses an aortic valve for controlling a blood flow through an aortic channel upon placement therein. Abstract; 1:20-22; 3:37-42.
a tissue valve having an interior member made of a tissue material and presenting an opening movable between open and closed positions;	**[1]** Andersen discloses a "tissue valve" in the form of a biological cardiac valve 6 removed from a pig. 5:11-14, 29-30. **[2]** As shown in annotated Fig. 2, biological cardiac valve 6 ("tissue valve") has an interior member made of tissue material. **[3]** Andersen discloses that the function of the valve prosthesis is to ensure that the blood flows in one direction only. 3:17-19. Andersen also discloses that the cardiac valve prosthesis can be used to treat aorta insufficiency. 3:53-57. Thus, Andersen discloses a biological cardiac valve 6 ("tissue valve") with an opening movable between open and closed positions. *See* Note 1 above and Exhibit 1018.  FIG. 2
a ring member surrounding said tissue valve, said ring member having an outer circumference adapted to seat said ring member about an aortic wall surrounding an aortic channel;	**[1]** Andersen discloses a "ring member" in the form of a stent 1 made from an expandable cylinder-shaped thread structure. Abstract; 4:3-11; 7:3-12. **[2]** Andersen further discloses that the stent 1 ("ring member") has an outer circumference adapted to seat the "ring member" about an aortic wall surrounding an aortic channel. Specifically, stent 1 is expanded to wedge it against the wall of the aorta. Abstract; 4:3-11; 5:47-49; 6:30-36; Figs. 5-10.
means for maintaining said ring member in said seated position about the aortic wall,	**[1]** As noted above in Section IV.E.4, the Patent Owner's construction of the claimed "means for maintaining" includes a stent that anchors to the aortic wall. **[2]** Andersen discloses a "means for maintaining" in the form of the

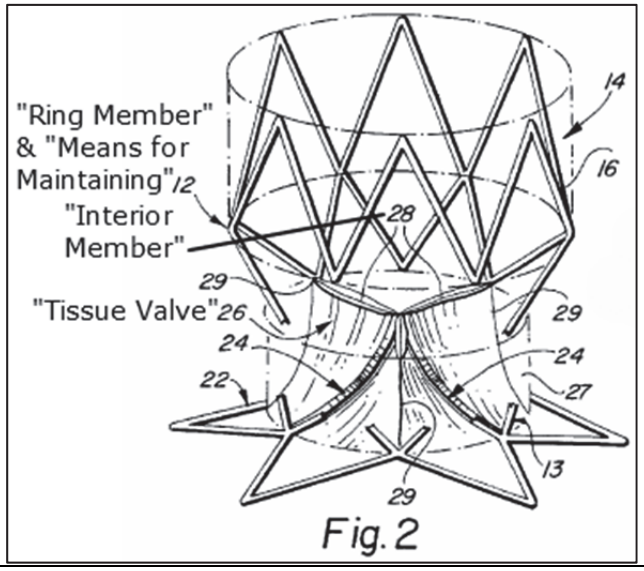
The '228 Patent	Appendix A-2: Anticipation by U.S. Pat. 5,411,552 to Andersen et al. (Exh. 1005)
	stent 1 ("means for maintaining" and "ring member") that abuts the inner wall of the aorta to ensure the securing of the valve prosthesis in the aorta in a seated position about the aortic wall. Abstract; 4:3-11; 5:9-28; 6:30-36; 7:3-12; Figs. 5-10.
said tissue valve interior member responsive to changes of conditions within the aorta for movement of said opening between a first closed position and a second open position.	**[1]** Andersen discloses a "tissue valve interior member" in the form of cardiac valve 6 that is responsive to changes of conditions (e.g., blood pressure) within the aorta. Specifically, Andersen discloses that the function of the valve prosthesis is to ensure that the blood flows in one direction only. 3:17-19. **[2]** Andersen also discloses that the cardiac valve prosthesis can be used to treat aorta insufficiency. 3:53-57. **[3]** Thus, Andersen discloses that the valve 6 ("tissue valve") has an interior member that moves between a first closed position and a second open position in response to systolic and diastolic pressure. *See* Note 1 above and Exhibit 1018.
21. The aortic valve as claimed in claim 20 wherein said tissue valve interior member is responsive to changes in blood pressure in the aorta whereby to move said tissue valve between said first and second positions.	**[1]** As explained in claim 20, Andersen discloses a "tissue valve interior member" in the form of cardiac valve 6. Specifically, Andersen discloses that the function of the valve prosthesis is to ensure that the blood flows in one direction only. 3:17-19. **[2]** Andersen also discloses that the valve prosthesis can be used to treat aorta insufficiency (i.e., leaking of the aortic valve of the heart that causes blood to flow in the reverse direction during ventricular diastole, from the aorta into the left ventricle). 3:53-57. **[3]** Thus, Andersen discloses that valve 6 ("tissue valve") has an interior member that moves between a first closed position and a second open position to control blood flow in response to systolic and diastolic pressure differentials. *See* Note 1 above and Exhibit 1018.
22. The aortic valve as claimed in claim 21 wherein said tissue valve interior member moves to said second position in response to systolic ejection of	**[1]** As explained in claim 21, Andersen discloses a "tissue valve interior member" in the form of cardiac valve 6 that is responsive to changes of conditions (e.g., blood pressure) within the aorta. **[2]** Andersen discloses that the function of the valve prosthesis is to ensure that the blood flows in one direction only. 3:17-19. **[3]** Andersen also discloses that the valve prosthesis can be used to treat aor-

The '228 Patent	Appendix A-2: Anticipation by U.S. Pat. 5,411,552 to Andersen et al. (Exh. 1005)
blood from the left ventricle in which the blood pressure in the left ventricle is greater than the blood pressure in the aortic channel.	ta insufficiency (i.e., leaking of the aortic valve of the heart that causes blood to flow in the reverse direction during ventricular diastole, from the aorta into the left ventricle). 3:53-57. **[4]** Thus, Andersen discloses that valve 6 ("tissue valve") has an interior member that moves to a second open position in response to systolic ejection of blood from the left ventricle in which the blood pressure in the left ventricle is greater than the blood pressure in the aortic channel. *See* Note 1 above and Exhibit 1018.
23. The aortic valve as claimed in claim 21 wherein said tissue valve interior member moves to said first position in response to diastolic filling of the left ventricle whereby the blood pressure in the aortic channel is greater than the blood pressure in the left ventricle.	**[1]** As explained in claim 21, Andersen discloses a "tissue valve interior member" in the form of cardiac valve 6. **[2]** Andersen discloses that the function of the valve prosthesis is to ensure that the blood flows in one direction only. 3:17-19. **[3]** Andersen also discloses that the valve prosthesis can be used to treat aorta insufficiency (i.e., leaking of the aortic valve of the heart that causes blood to flow in the reverse direction during ventricular diastole, from the aorta into the left ventricle). 3:53-57. **[4]** Thus, Andersen discloses that valve 6 ("tissue valve") has an interior member that moves to the first closed position in response to diastolic filling of the left ventricle whereby the blood pressure in the aortic channel is greater than the blood pressure in the left ventricle. *See* Note 1 above and Exhibit 1018.
24. The aortic valve as claimed in claim 20 wherein said ring member contacts the wall of the aortic channel and seals said ring against the aortic channel wall to reduce blood flow thereabout.	**[1]** As explained in claim 20, Andersen discloses a "ring member" in the form of a stent 1 made from an expandable cylinder-shaped thread structure. Abstract; 4:3-11; 7:3-12. **[2]** Andersen further discloses that the stent 1 is expanded to wedge it against the wall of the aorta and that it is sealed "tight against the inner wall of the aorta with a pressure which is sufficiently large to counteract a detachment due to the flow of the blood." Abstract; 4:3-11; 5:47-49; 6:30-36; Figs. 7-10.

The '228 Patent	Appendix A-3: Anticipation by U.S. Pat. 6,458,153 to Bailey et al. (Exh. 1006)
16. An aortic valve for regulating a blood flow through an aortic channel surrounded by an aortic wall upon placement therein, said valve comprising:	Bailey discloses an aortic valve for regulating a blood flow through an aortic channel surrounded by an aortic wall upon placement therein. Abstract; 1:6-21; 7:58-8:19.
a ring member having a circumference adapted to seat about an aortic wall surrounding an aortic channel, said ring including an aperture for blood flow therethrough;	**[1]** As shown in annotated Fig. 1, Bailey discloses a "ring member" in the form of stent 12 which has a circumference that is adapted to seat about the aortic wall surrounding the aortic channel. 1:28-38; 5:61-6:9; 7:58-8:19. **[2]** Bailey further discloses that the stent 12 ("ring member") has an aperture for blood flow therethrough. 7:58-8:19.  Fig.1
a membrane having first and second spaced-apart open ends, said membrane made of a material resistant to a fluid flow therethrough; and	**[1]** As noted above in Section IV.E.1, the Patent Owner's construction of the claimed "membrane" includes not only synthetic materials (e.g., fabric or fibrous polymer), but also includes biological tissue. **[2]** Bailey discloses a "membrane" in the form of a valve 26 including leaflets 28 that can be made of biologically-derived membranes or biocompatible synthetic materials. 1:28-38; 5:33-50; 8:37-40. **[3]** As shown in annotated Fig. 2 below, Bailey discloses that the valve made of a biologically-derived membrane ("membrane") has first and second spaced-apart open ends. 9:11-20. **[4]** Bailey further discloses that the valve leaflets 28 prevent blood flow from the aorta into the left ventricle when closed. 10:31-44. *See* Note 1 above and Exhibit 1018.

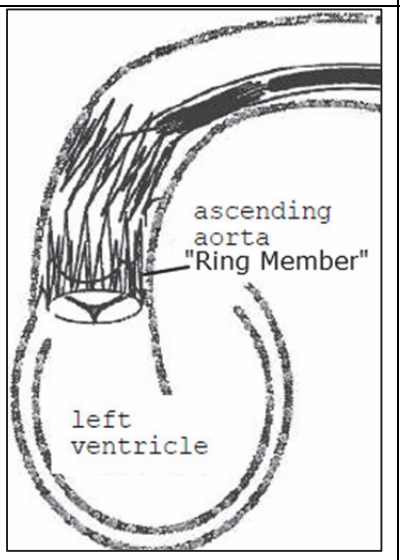
The '228 Patent	Appendix A-3: Anticipation by U.S. Pat. 6,458,153 to Bailey et al. (Exh. 1006)
	 Fig. 2 Petitioner notes that in the Bailey specification and figures, the valve leaflet portion of the valve are sometimes referred to by reference numeral 28 (e.g., Figure 2) and other times referred to by reference numeral 26 (e.g., Figures 4, 6A, 6B).
means for mounting said first open end of said membrane about said ring aperture with said second open end displaced therefrom, said means moving said membrane second end between a first open position to allow a blood flow therethrough and a second closed position to preclude a blood flow therethrough.	**[1]** As noted above in Section IV.E.2, the Patent Owner's construction of the claimed "means for mounting" includes sutures. **[2]** As shown in annotated Fig. 4 below, Bailey discloses a "means for mounting" the "first open end" of valve 26 in the form of sutures or encapsulation. 5:43-50. Specifically, Bailey discloses that graft member 11 (11a and 11b) is attached to stent 12 via sutures or encapsulation and that inner graft member 11b is exverted such that the free ends or valve flap portions (leaflets) of inner graft member 11b are oriented toward the distal end of stent 12. 1:28-38; 5:43-50; 7:58-8:4; 9:11-35; Fig. 4. **[3]** As shown in annotated Figs. 6A and 6B below, Bailey discloses that sutures ("means for mounting") enable the valve leaflets 26 at the second open end to move between first open (Fig. 6A) and second closed (Fig. 6B) positions to control the flow of blood between the aorta and left ventricle in response to blood pressure differentials acting upon the valve leaflets 26. 9:25-47; 10:31-44. *See* Note 1 above and Exhibit

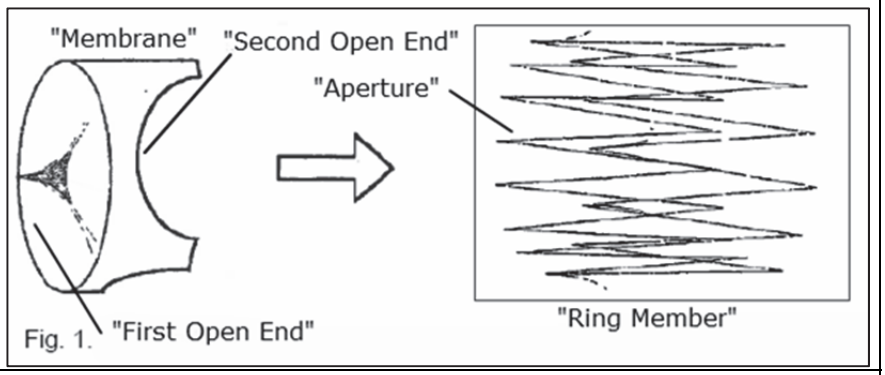
The '228 Patent	Appendix A-3: Anticipation by U.S. Pat. 6,458,153 to Bailey et al. (Exh. 1006)
	1018.   Fig. 6A  Fig. 6B
19. The aortic valve as claimed in claim 16 further comprising means for maintaining said ring member in said seat about the aortic wall.	**[1]** As explained in claim 16, Bailey discloses an aortic valve. **[2]** As noted above in Section IV.E.4, the Patent Owner's construction of the claimed "means for maintaining" includes a stent that anchors to the aortic wall. **[3]** Bailey discloses a "means for maintaining" in the form of stent 12 that anchors to the aortic wall. 1:28-38; 5:61-6:9; 7:58-8:19. As shown above in annotated Figs. 6A and 6B, the stent ("means for maintaining" and "ring member") engages the tissue of the aortic wall to retain the valve secured within the stent in position. 5:61-6:9.
20. An aortic valve for controlling a blood flow through an aortic channel upon placement	Bailey discloses an aortic valve for controlling a blood flow through an aortic channel upon placement therein. Abstract; 1:6-21; 7:58-8:19.

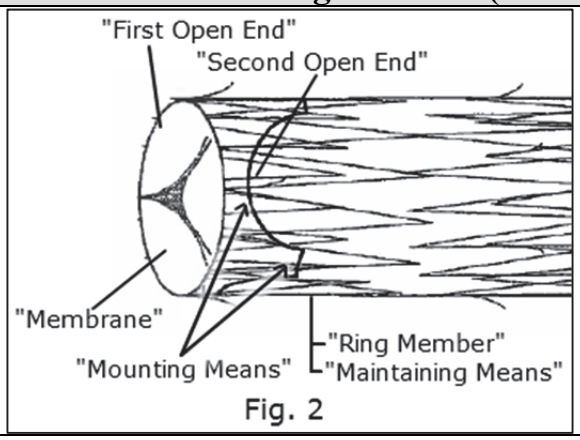
The '228 Patent	Appendix A-3: Anticipation by U.S. Pat. 6,458,153 to Bailey et al. (Exh. 1006)
therein, said valve comprising:	
a tissue valve having an interior member made of a tissue material and presenting an opening movable between open and closed positions;	**[1]** Bailey discloses a "tissue valve" in the form of valve 26 which can be made of biologically-derived membranes ("tissue material") or biocompatible synthetic materials. 1:28-38; 5:33-50; 8:37-40. **[2]** Bailey further discloses that the valve 26 includes "interior members" in the form of valve leaflets 28. 1:28-38; 5:33-50; 8:37-40; 9:11-24. **[3]** As shown above in annotated Figs. 6A and 6B, the valve leaflets 26 ("interior member") move between open (Fig. 6A) and closed (Fig. 6B) positions to control the flow of blood between the aorta and left ventricle in response to blood pressure differentials acting upon the valve leaflets 26 ("interior member"). 9:25-47; 10:31-44. *See* Note 1 above and Exhibit 1018.  Fig. 2
a ring member surrounding said tissue valve, said ring member having an outer circumference adapted to seat said ring member about an aortic wall surrounding an aortic channel;	**[1]** As shown above in annotated Fig. 1, Bailey discloses a "ring member" in the form of stent 12 which has an outer circumference that is adapted to seat the ring member about an aortic wall and surrounds the tissue valve. 1:28-38; 5:61-6:9; 7:58-8:19. **[2]** Bailey discloses that the stent 12 ("ring member") engages the tissue of the aortic wall to seat the "ring member" in position about the aortic channel. 1:28-38; 5:61-6:9; 7:58-8:19; Figs. 6A and 6B.

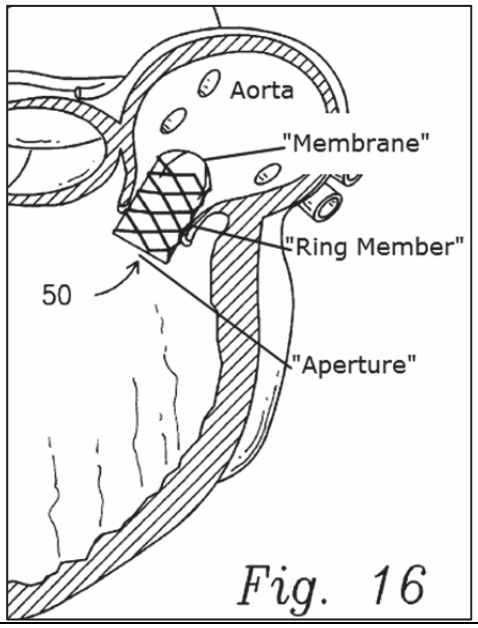
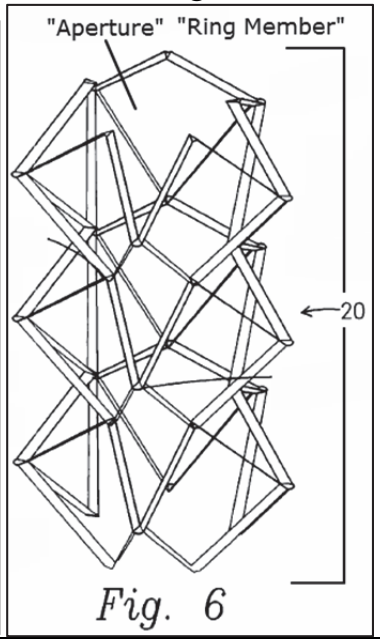
The '228 Patent	Appendix A-3: Anticipation by U.S. Pat. 6,458,153 to Bailey et al. (Exh. 1006)
means for maintaining said ring member in said seated position about the aortic wall,	**[1]** As noted above in Section IV.E.4, the Patent Owner's construction of the claimed "means for maintaining" includes a stent that anchors to the aortic wall. **[2]** Bailey discloses a "means for maintaining" in the form of stent 12 that engages the tissue of the aortic wall to retain the valve in position. 1:28-38; 5:61-6:9; 7:58-8:19; Figs. 6A and 6B.
said tissue valve interior member responsive to changes of conditions within the aorta for movement of said opening between a first closed position and a second open position.	**[1]** Bailey discloses a "tissue valve interior member" in the form of a valve leaflet that is responsive to changes of conditions (e.g., blood pressure) within the aorta. 1:28-38; 5:33-50; 8:37-40; 9:11-24. Specifically, as shown above in annotated Figs. 6A and 6B, the valve leaflets 26 ("interior members") move between first closed (Fig. 6B) and second open (Fig. 6A) positions in response to blood pressure differentials acting upon the valve leaflets 26 ("interior members"). 9:25-47; 10:31-44. **[2]** During diastole the valve leaflets 26 ("interior members") close. 10:39-44. **[3]** During systole the valve leaflets 26 ("interior members") open. 10:33-39. *See* Note 1 above and Exhibit 1018.
21. The aortic valve as claimed in claim 20 wherein said tissue valve interior member is responsive to changes in blood pressure in the aorta whereby to move said tissue valve between said first and second positions.	**[1]** As explained in claim 20, Bailey discloses a "tissue valve interior member" in the form of a valve leaflet. **[2]** As shown above in annotated Figs. 6A and 6B, Bailey discloses that the valve leaflets 26 ("interior members") move between first closed (Fig. 6B) and second open (Fig. 6A) positions to control the flow of blood between the aorta and left ventricle in response to blood pressure differentials acting upon the valve leaflets 26 ("interior members"). 9:25-47; 10:31-44. **[3]** During diastole the valve leaflets 26 ("interior members") close. 10:39-44. **[4]** During systole the valve leaflets 26 ("interior members") open. 10:33-39. *See* Note 1 above and Exhibit 1018.
22. The aortic valve as claimed in claim 21 wherein said tissue valve interior member moves to said second	**[1]** As explained in claim 21, Bailey discloses a "tissue valve interior member" in the form of a valve leaflet. **[2]** As shown above in annotated Fig. 6A, Bailey discloses that the valve leaflets 26 ("interior members") move to the second open position to allow blood flow from the

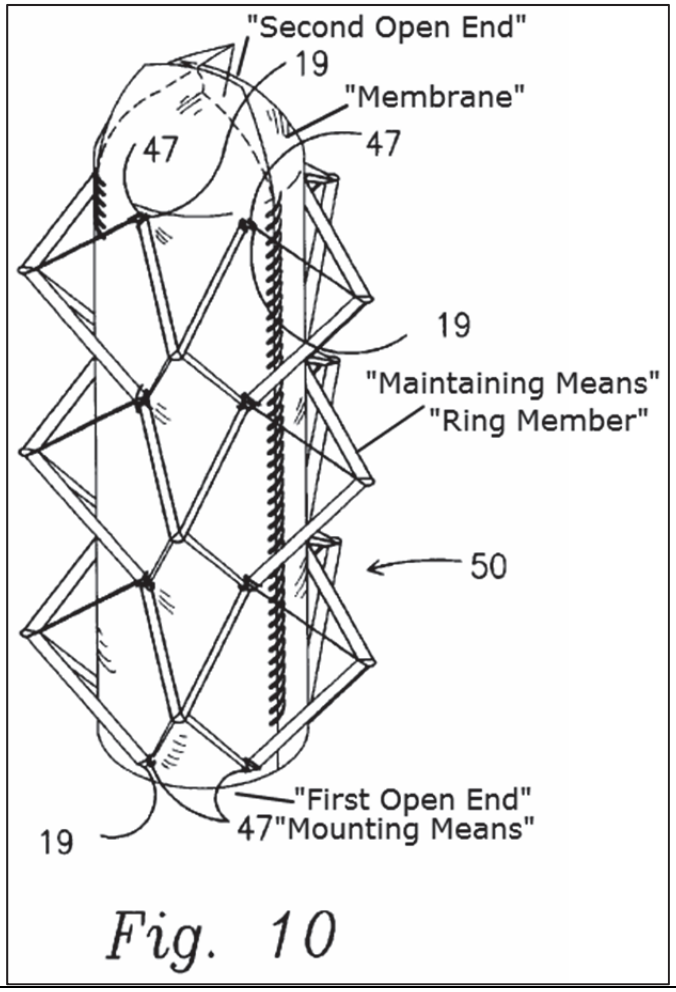
The '228 Patent	Appendix A-3: Anticipation by U.S. Pat. 6,458,153 to Bailey et al. (Exh. 1006)
position in response to systolic ejection of blood from the left ventricle in which the blood pressure in the left ventricle is greater than the blood pressure in the aortic channel.	left ventricle into the aorta in response to blood pressure differentials acting upon the valve leaflets 26 ("interior members") created during systole. 9:25-47; 10:31-44. **[3]** Thus, Bailey discloses that valve leaflets 26 move to an open position in response to systolic ejection of blood from the left ventricle in which the blood pressure in the left ventricle is greater than the blood pressure in the aortic channel. *See* Note 1 above and Exhibit 1018.
23. The aortic valve as claimed in claim 21 wherein said tissue valve interior member moves to said first position in response to diastolic filling of the left ventricle whereby the blood pressure in the aortic channel is greater than the blood pressure in the left ventricle.	**[1]** As explained in claim 21, Bailey discloses a "tissue valve interior member" in the form of a valve leaflet. **[2]** As shown above in annotated Fig. 6B, Bailey discloses that the valve leaflets 26 ("interior members") move to the first closed position to prevent blood flow from the aorta back into the left ventricle in response to blood pressure differentials acting upon the valve leaflets 26 ("interior members") created during diastole. 9:25-47; 10:31-44. [3] Thus, Bailey discloses that valve leaflets 26 move to a closed position in response to diastolic filling of the left ventricle whereby the blood pressure in the aortic channel is greater than the blood pressure in the left ventricle. *See* Note 1 above and Exhibit 1018.
24. The aortic valve as claimed in claim 20 wherein said ring member contacts the wall of the aortic channel and seals said ring against the aortic channel wall to reduce blood flow therearound.	**[1]** As explained in claim 20, Bailey discloses a "ring member" in the form of stent 12 which anchors to the aortic wall and surrounds the tissue valve. 1:28-38; 5:61-6:9; 7:58-8:19. **[2]** As shown above in annotated Figs. 6A and 6B, the stent 12 ("ring member") contacts the tissue of the aortic wall to retain the valve in position and seals against the aortic channel wall to reduce blood flow therearound. 1:28-38; 5:61-6:9; 7:58-8:19; Figs. 6A and 6B.

The '228 Patent	Appendix A-4: Anticipation by DE Patent App. No. 195 46 692 to Figulla et al. (Exhs. 1007 & 1008)
16. An aortic valve for regulating a blood flow through an aortic channel surrounded by an aortic wall upon placement therein, said valve comprising:	Figulla discloses a heart-valve prosthesis that uses a pig-heart valve for regulating a blood flow through an aortic channel surrounded by an aortic wall upon placement therein. Pages1and 2.
a ring member having a circumference adapted to seat about an aortic wall surrounding an aortic channel, said ring including an aperture for blood flow therethrough;	**[1]** As shown below in annotated Fig. 1, Figulla discloses a "ring member" in the form of a proximal portion of the self-expanding stent. **[2]** Figulla discloses that the proximal portion of the self-expanding stent ("ring member") has an outer circumference adapted to seat it about an aortic wall in that it uses the aortic wall for support and that a constant, tight fit with the aorta wall is sought. Page 2. Fig. 4 to the right shows the proximal portion of the self-expanding stent ("ring member") in contact with the wall of the ascending aorta. **[3]** Annotated Fig. 1 also shows that the self-expanding stent ("ring member") has an aperture for blood flow therethrough. 
a membrane having first and second spaced-apart open ends, said membrane made of a material resistant to a fluid flow therethrough; and	**[1]** As noted above in Section IV.E.1, the Patent Owner's construction of the claimed "membrane" includes not only synthetic materials (e.g., fabric or fibrous polymer), but also includes biological tissue. **[2]** Figulla discloses a "membrane" in the form of a pig-heart valve. Page 2. **[3]** As shown in Fig 1 below, the "membrane" is inserted into portion of a proximal stent. **[4]** Fig. 1 also shows the pig heart valve ("membrane") has first and second spaced-art open ends with an opening movable between open and closed positions. **[5]** Figulla discloses that the valve prosthesis is designed to replace a diseased heart valve. Thus, the pig heart valve ("membrane") controls

The '228 Patent	Appendix A-4: Anticipation by DE Patent App. No. 195 46 692 to Figulla et al. (Exhs. 1007 & 1008)
	the flow of blood and is resistant to reverse fluid flow. *See* Note 1 above and Exhibit 1018. 
means for mounting said first open end of said membrane about said ring aperture with said second open end displaced therefrom, said means moving said membrane second end between a first open position to allow a blood flow therethrough and a second closed position to preclude a blood flow therethrough.	**[1]** As noted above in Section IV.E.2, the Patent Owner's construction of the claimed "means for mounting" includes sutures. **[2]** Referring to Fig. 2 below, Figulla discloses a "means for mounting" the "first open end" of the pig heart valve ("membrane") in the form of sutures. Page 2, Figs. 1 and 2. Specifically, Figulla discloses that the pig heart valve ("membrane") is sewed into the proximal portion of the self-expanding stent ("ring member") so that the "first open end" of the pig heart valve ("membrane") is about the stent aperture with the "second open end" displaced therefrom. Page 2, Figs. 1 and 2. **[3]** Figulla discloses a pig heart valve ("membrane") that assumes the function of the natural heart. **[4]** Thus, sutures ("means for mounting") enables the second end of the pig heart valve ("membrane") to move between a first open and second closed position and an open position in response to pressure changes in the aorta. The first open position allows blood to flow therethrough and the second closed position precludes blood flow therethrough. *See* Note 1 above and Exhibit 1018.

The '228 Patent	Appendix A-4: Anticipation by DE Patent App. No. 195 46 692 to Figulla et al. (Exhs. 1007 & 1008)
	 Fig. 2
19. The aortic valve as claimed in claim 16 further comprising means for maintaining said ring member in said seat about the aortic wall.	**[1]** As explained in claim 16, Figulla discloses an aortic valve. **[2]** As noted above in Section IV.E.4, the Patent Owner's construction of the claimed "means for maintaining" includes a stent that anchors to the aortic wall. **[3]** Figulla discloses a "means for maintaining" in the form of a self-expanding stent with an outer circumference adapted to use the aortic wall for support. Page 2. Figulla further explains that a constant, tight fit with the aorta wall is sought. Page 2. Fig. 4 above shows the self-expanding stent (both the proximal and distal portions) in contact with the wall of the ascending aorta.

The '228 Patent	Appendix A-5: Anticipation by U.S. Patent 5,855,597 to Jayaraman (Exh. 1009)
16. An aortic valve for regulating a blood flow through an aortic channel surrounded by an aortic wall upon placement therein, said valve comprising:	Jayaraman discloses an aortic valve for regulating a blood flow through an aortic channel surrounded by an aortic wall upon placement therein. Abstract; 1:22-24; 3:36-40.
a ring member having a circumference adapted to seat about an aortic wall surrounding an aortic channel, said ring including an aperture for blood flow therethrough;	**[1]** Jayaraman discloses a "ring member" in the form of stent created by a chain of interconnected star-shaped members with a central opening. 1:34-41; Fig. 6. **[2]** As shown in annotated Fig. 16, Jayaraman discloses that the stent ("ring member") is placed in the aortic channel in seated contact with the aortic wall. **[3]** Jayaraman further discloses an "aperture" for blood flow in the form of a central opening within the stent. 1:34-41; Fig. 6.  Fig. 16  Fig. 6
a membrane having first and second spaced-apart open ends, said membrane made of a material resistant to a fluid flow therethrough; and	**[1]** As noted above in Section IV.E.1, the Patent Owner's construction of the claimed "membrane" includes synthetic materials (e.g., fabric or fibrous polymer) and biological tissue. **[2]** Jayaraman discloses a "membrane" in the form of a flexible bio-compatible material that is used to form a replacement aortic valve tri-cuspid device. 1:34-41; 2:29-48. **[3]** As shown in annotated Fig. 10, replacement aortic valve tri-cuspid device has first and

The '228 Patent	Appendix A-5: Anticipation by U.S. Patent 5,855,597 to Jayaraman (Exh. 1009)
	second open ends that are spaced-apart. **[4]** As shown in annotated Fig. 10, replacement aortic valve tri-cuspid device ("membrane") has an opening with three flaps that move between an open and closed position. The purpose of the invention described in Jayaraman is to replace a cardiac valve; thus, the three flaps at the opening can move to a closed position to preclude blood from flowing through. 1:22-24; 3:37-40. *See Note 1 above and Exhibit 1018.*  *Fig. 10*
means for mounting said first open end of said membrane about said ring aperture with said second open end displaced therefrom,	**[1]** As noted above in Section IV.E.2, the Patent Owner's construction of the claimed "means for mounting" includes sutures. **[2]** Jayaraman discloses a "means for mounting" in the form of sutures. Specifically, Jayaraman discloses sewing the "first open end" of replacement aortic valve tri-cuspid device 45 within stent at points 47

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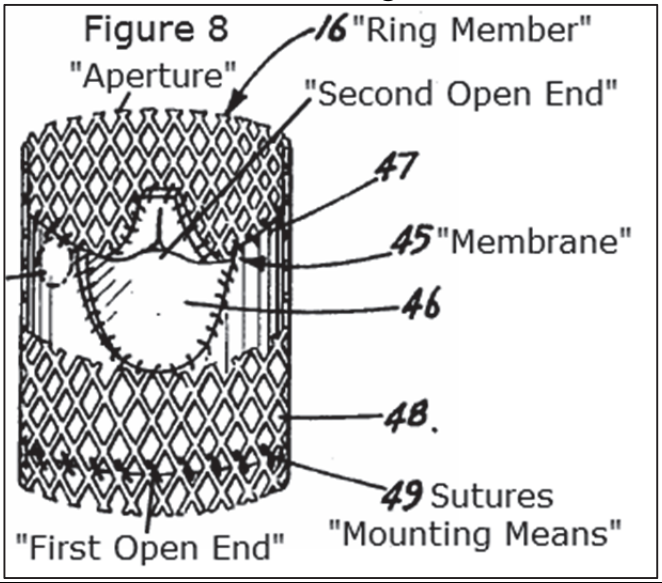
said means moving said membrane second end between a first open position to allow a blood flow therethrough and a second closed position to preclude a blood flow therethrough.	as shown in annotated Fig. 10 above. 3:41-48. **[3]** As shown in annotated Fig. 10, replacement aortic valve tri-cuspid device ("membrane") has an opening with three flaps ("second open end") that move between an open and closed position. The sutures ("means for mounting") enable the three flaps at the "second open end" of the replacement aortic valve tri-cuspid device ("membrane") to move between a first open position to allow blood flow through and a second closed position to preclude blood from flowing through. 1:22-24; 3:37-40. *See* Note 1 above and Exhibit 1018.
19. The aortic valve as claimed in claim 16 further comprising means for maintaining said ring member in said seat about the aortic wall.	**[1]** As explained in claim 16, Jayaraman discloses an aortic valve. **[2]** As noted above in Section IV.E.4, the Patent Owner's construction of the claimed "means for maintaining" includes a stent that directly anchors to the aortic wall. **[3]** Jayaraman discloses a "means for maintaining" in the form of stent created by a chain of interconnected star-shaped members and maintain the device in an expanded state at the implant site of the aorta as shown in Fig. 16. 1:34-41. **[4]** As shown in annotated Fig. 16 above, Jayaraman discloses that the stent is placed in the aortic channel in contact with the aortic wall. 3:53-59.

The '228 Patent	Appendix A-6: Anticipation by US 3,657,744 to Ersek (Exh. 1010)
16. An aortic valve for regulating a blood flow through an aortic channel surrounded by an aortic wall upon placement therein, said valve comprising:	Ersek discloses an aortic valve for regulating a blood flow through an aortic channel surrounded by an aortic wall upon placement therein. 2:47:-55, 3:41-55, 4:25-31, 36-38, and 45-52.
a ring member having a circumference adapted to seat about an aortic wall surrounding an aortic channel, said ring including an aperture for blood flow therethrough;	**[1]** As shown in annotated Fig. 8 below, Ersek discloses a "ring member" in the form of a deformable fixation sleeve 16. 1:12-16; 2:56-62; 4:25-31; Fig. 8. **[2]** Ersek further discloses that fixation sleeve 16 ("ring member") is expanded radially into intimate engagement with the surrounding tissue, such as the aortic wall. 1:12-16; 2:56-62; 3:1-6, 28-35, 41-55; 4:36-38. **[3]** Annotated Fig. 8 also shows that fixation sleeve 16 includes an aperture for blood flow therethrough. 
a membrane having first and second spaced-apart open ends, said membrane made of a material resistant to a fluid flow therethrough; and	**[1]** As noted above in Section IV.E.1, the Patent Owner's construction of the claimed "membrane" includes not only synthetic materials (e.g., fabric or fibrous polymer), but also includes biological tissue. **[2]** Ersek discloses a "membrane" in the form of a donor aorta or a transplant aortic heart valve. Abstract, 3:1-6 and 28-35 and 4:25-35. **[3]** As shown in annotated Fig. 8 above, Ersek discloses that the aortic valve 45 ("membrane") has a "first open

The '228 Patent	Appendix A-6: Anticipation by US 3,657,744 to Ersek (Exh. 1010)
	end" that is attached to the fixation sleeve 16 ("ring member") by sutures 49 and a "second open end" attached by sutures 47. 4:25-31. **[4]** The three-pronged commissure donor aorta valve 45 ("membrane") allows fluid to flow in only one direction and resists fluid flow in the reverse direction. *See* Note 1 above and Exhibit 1018.
means for mounting said first open end of said membrane about said ring aperture with said second open end displaced therefrom, said means moving said membrane second end between a first open position to allow a blood flow therethrough and a second closed position to preclude a blood flow therethrough.	**[1]** As noted above in Section IV.E.2, the Patent Owner's construction of the claimed "means for mounting" includes sutures. **[2]** Ersek discloses a "means for mounting" in the form of suturing donor aorta 45 ("membrane") to the interior of the fixation sleeve 16 ("ring member"). 4:25-31. Specifically, Ersek discloses that the "first end" of donor aorta is mounted via sutures at 49. 4:25-31; Fig. 8. **[3]** As shown in annotated Fig. 8, Ersek discloses the use of a donor aorta 45 ("membrane") with a three-pronged commissure structure at the "second end." 4:25-31. Aortic valves, such as the donor aorta 45 disclosed in Ersek, have an opening that moves between a closed position and an open position to control blood flow in response to changes in blood pressure in the aorta; thus, Ersek discloses that the sutures enable the membrane "second end" to move between a first open position to allow a blood flow therethrough and a second closed position to preclude a blood flow therethrough. *See* Note 1 above and Exhibit 1018.
19. The aortic valve as claimed in claim 16 further comprising means for maintaining said ring member in said seat about the aortic wall.	**[1]** As discussed above in claim 16, Ersek discloses an aortic valve. **[2]** As noted above in Section IV.E.4, the Patent Owner's construction of the claimed "means for maintaining" includes a stent that directly anchors to the aortic wall. **[3]** Ersek discloses a "means for maintaining" in the form of a fixation sleeve 16 which is expanded radially into intimate engagement with the surrounding tissue, such as the aortic wall, to maintain fixation sleeve 16 in a seated position about the aortic wall. 1:12-16; 2:56-62; 3:1-6, 28-35, 41-55; 4:36-38.

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 Exhibits 1001-1020 and Appendices A-1 – A-6 was served by EXPRESS MAIL this 31st day of January, 2014 on the attorney of record of Troy R. Norred, owner of the subject patent, at the USPTO correspondence address of record listed below:

James Kernell
Erickson, Kernell, Derusseau & Kleypas, LLC
8900 State Line Road, Suite 500
Leawood, KS 66206

Courtesy copies were also delivered to Troy R. Norred's litigation counsel:

David Marcus
Bartle & Marcus LLC
1100 Main Street, Suite 2730
Kansas City, MO 64105

Respectfully submitted,

PILLSBURY WINTHROP SHAW PITTMAN LLP

/Jack S. Barufka/

Jack S. Barufka
Reg. No. 37,087
Tel. No. 703.770.7712
Fax No. 703.905.2500

P.O. Box 10500
McLean, VA 22102
(703) 770-7900