IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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

U.S. Patent No. 6,482,228

Filed: November 14, 2000

Issued: March 25, 2003 Attorney Docket No.: 058888-0000014

Inventor(s): Norred, Troy R.

Assignee: Norred, Troy R.

Title: PERCUTANEOUS AORTIC VALVE REPLACEMENT Panel: To Be Assigned

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P.O. Box 1450
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PETITION FOR INTER PARTES REVIEW UNDER 37 C.F.R. § 42.100

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Inter partes review is respectfully requested for claims 16-19 of U.S. Patent No. 6,482,228 ("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[1] (collectively "Petitioner") are the real parties-in-interest.

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 (Feb. 6, 2013). In addition, the '228 Patent is the subject of IPR2014-00111, which is concurrently filed with this petition.

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	Evan Finkel (Reg. No. 49,059) PILLSBURY WINTHROP SHAW PITTMAN LLP Postal and Hand Delivery Address 725 S. Figueroa Street, Suite 2700

[1] 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.

Lead Counsel	Back-Up Counsel
McLean, Virginia 22102 Telephone: 703.770.7712 Facsimile: 703.906.2500 Email: jack.barufka@pillsburylaw.com	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

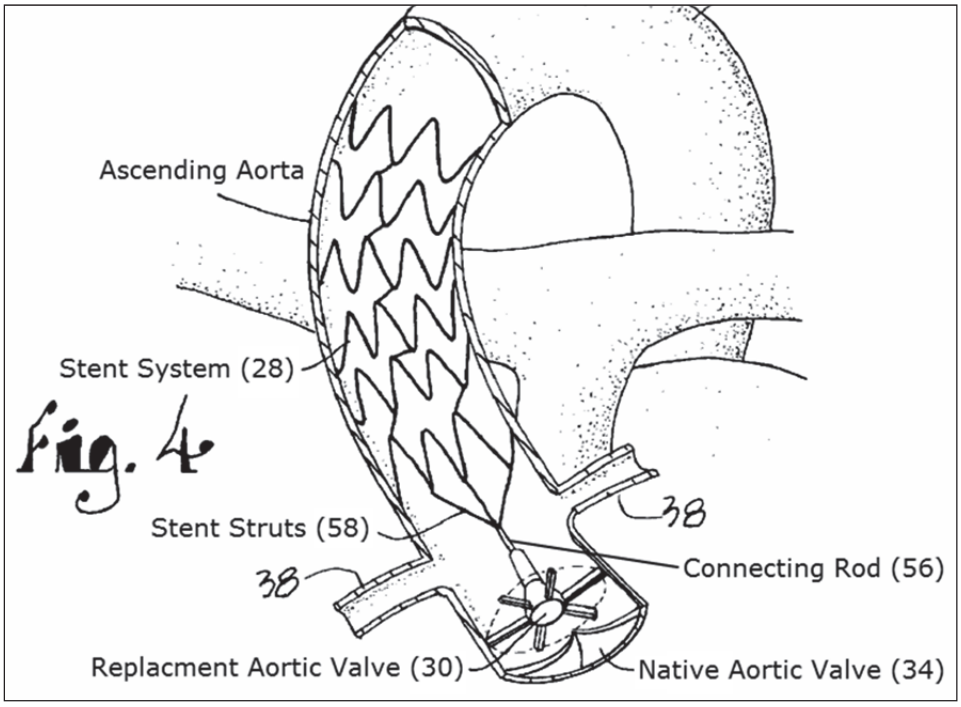
The undersigned authorizes the Office to charge Deposit Account No. 033975 for the fee set forth in 37 C.F.R. § 42.15(a), or any other applicable fees, for this Petition for *inter partes* review. The undersigned further authorizes payment for any additional fees that might be due in connection with 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 held in place with a stent system. *'228 Patent, 1: 6-9*. Shown below is an

annotated version of Figure 4 showing the placement of Replacement Aortic Valve 30 and Stent System 28 in the ascending aorta.



The ‘228 Patent discloses four replacement valve designs that can be secured in a stent system: an umbrella valve 30 (Figs. 1-9); a conical valve 66 (Figs. 10-13); a trihedral valve 82 (Figs. 14-17); and biological tissue, such as cadaver or porcine, valves 100 (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 discloses that each of these replacement valve de-

signs, when anchored in a stent system, would be disposed against the aorta wall to reduce or eliminate peri-valvular leaks.

With respect to independent claim 16 and its dependent claims 17-19, 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*.

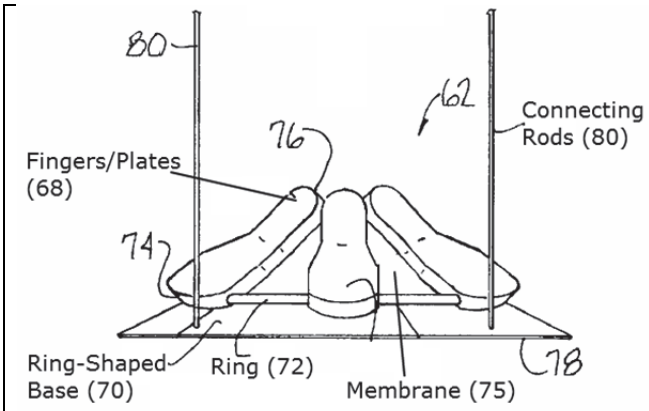


Fig. 10: Conical Valve in Closed Position

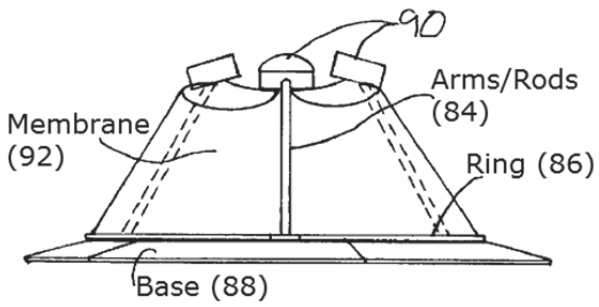


Fig. 16: Trihedral Valve in Open Position

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 to Ring-Shaped Base 70 by Ring 72. *'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 aor-

tic 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 Base 88 by Ring 86 and interconnected to each other by Membrane 92. *'228 Patent, 5:33-62*. 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*.

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 Nov. 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 Aug. 9, 2001 (*id.*, paper 3, "August 2001 Office Action"), the Examiner stated in a Jan. 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 Feb. 26, 2002 (*id.*, paper 5) that, among other things, ostensibly made non-substantive grammatical amendments to improve the language of claims 16-24. The Examiner subsequently issued a Notice of Allowability on Apr. 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 the 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* review; and (5) this Petition is filed after the later of (a) the date that is nine months after the date of the grant of the '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 16-19 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 16-19 of the '228 Patent is requested.

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

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

No.	Grounds
1	Claims 16-19 are anticipated by US 6,440,164 ("DiMatteo")
2	Claims 16-18 are anticipated by US 3,548,417 ("Kischer")
3	Claims 16-19 are anticipated by US 6,299,637 ("Shaolian")
4	Claims 16-18 are anticipated by US 4,030,142 ("Wolfe")

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

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

Petitioner notes that a claim is given the "broadest reasonable construction in light of the specification" in *inter partes* review. *See 37 C.F.R. § 42.100(b)*. As described in Section III.A above, the '228 Patent is directed to artificial aortic heart valve replacements that can be anchored in place with a stent system and discloses four such replacement valve embodiments.

1. "membrane"

The term "membrane" is used in claims 16 and 17. It is expected that the Patent Owner will stretch the meaning of this term to not only refer to materials such as fabrics or polymers, but also to include "tissue." That is therefore the way this term is applied for the purposes of *inter partes* review. However, it should be noted that the '228 Patent draws a distinction between the terms "material" 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 biological tissue incorporated valves, such as cadaver/porcine valves." *'228 Patent, 5:64-65*. Thus, Petitioner submits that the term "membrane" will more appropriately be construed in litigation to include fabrics or polymers, but not tissue.

2. "Means for mounting"

Claim 16 recites a "means for mounting said first open end of said membrane about said ring aperture with said second open end displaced therefrom." This limitation is a "means plus function" limitation to be construed under 35 U.S.C. § 112, ¶6. The '228 Patent describes the "means" for performing the claimed function as follows:

> "The fingers 68 are generally wedge or bowling pin-shaped and are hingedly secured together by ring 72 extending through the base 74 of each finger 68 and interconnected by a biocompatible, durable, flexible generally conically-shaped fabric 75 membrane secured to the inside surfaces 69 of the fingers." (*'228 Patent, 4:56-61*).
>
> "Arms 84 are hingedly attached to ring 86 of base 88 and extend upwardly and radially inwardly from base 88 to generally form a trihedron or cone…A cone-shaped membrane 92 of fibrous polymer is secured to each arm 84 and base 88 (not shown in FIG. 14)." (*'228 Patent, 5:36-42*).

Therefore, the '228 Patent's specification supports an interpretation of the "means" for performing the claimed function as "fingers or arms hingedly attached to a ring" or an equivalent structure. That construction is also consistent with the structure of the "means" recited in dependent claim 17 as "at least one arm having a first end hingedly secured to said ring member"

3. "Means for maintaining"

Claim 19 recites a "means for maintaining said ring member in said seat about the aortic wall." This limitation is to be construed as a "means plus function" limitation under 35 U.S.C. § 112, ¶6. Regarding the embodiment corresponding to claim 19, the '228 Patent describes the "means" for performing the claimed functions as follows: "Valve 66 is anchored along the root of the aortic valve with connecting rods 80" and "Valve 82 is anchored along the aortic valve root wall with connecting rods (not shown; see connecting rods 80, Fig. 10)." *'228 Patent, 5:21-22 & 48-49*. Therefore, the '228 Patent's specification supports an interpretation of the "means" for performing the claimed function as "connecting rods" or an equivalent structure.

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

An explanation of how construed claims 16-19 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 in Section V and in claim charts A-1 to A-4.

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-4.

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 16-19 are Anticipated Under 35 U.S.C. §102(e) by U.S. Patent No. 6,440,164 to DiMatteo (Exh. 1003)

U.S. Patent No. 6,440,164 to DiMatteo et al. ("DiMatteo") was filed on October 21, 1999 and thus qualifies as prior art under § 102(e). DiMatteo was not cited during prosecution of the '228 Patent although it describes a prosthetic aortic valve with hinged leaflets that control blood flow through the valve. *DiMatteo, 1:4-6*, 3:18-27. The claim chart attached as Appendix A-1 details how each element recited in claims 16-19 is anticipated by DiMatteo. Figure 1 below shows one embodiment of the valve in a closed position where Leaf Valve Portion 14 is connected to Tubular Body Portion 12 at a Hinge Line 22. Figure 3 below shows the same embodiment, but with the valve in an open position and Valve Leafs 40 spread to allow blood to flow through Tubular Body Portion 12. Figure 16 below

shows another embodiment where Valve Leafs 40 are interconnected with Webbing 84. *DiMatteo, 11:10-15*.

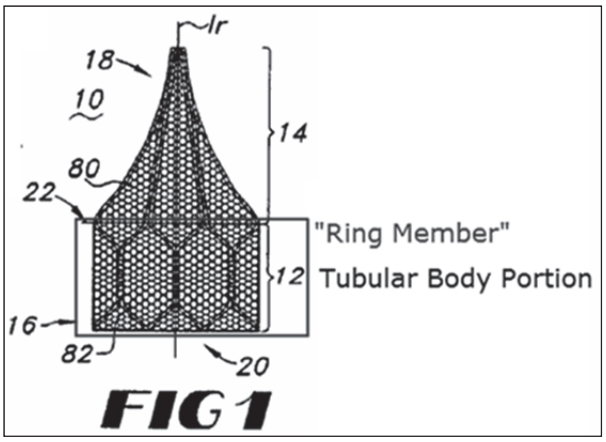


FIG 1

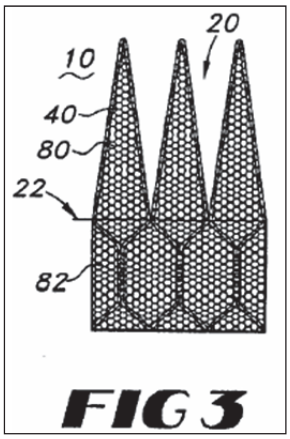


FIG 3

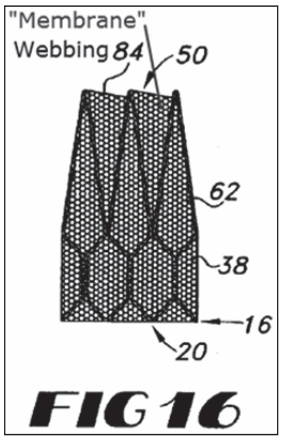
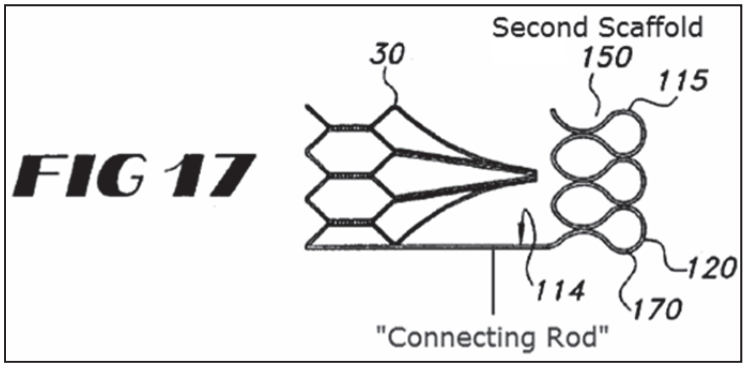


FIG 16

As shown below in Figure 17, DiMatteo further teaches that the valve can be secured in place by mechanically joining the valve to a Second Scaffold 150 (*e.g.*, stent) via a wire 114. *DiMatteo, 13:43-51*.

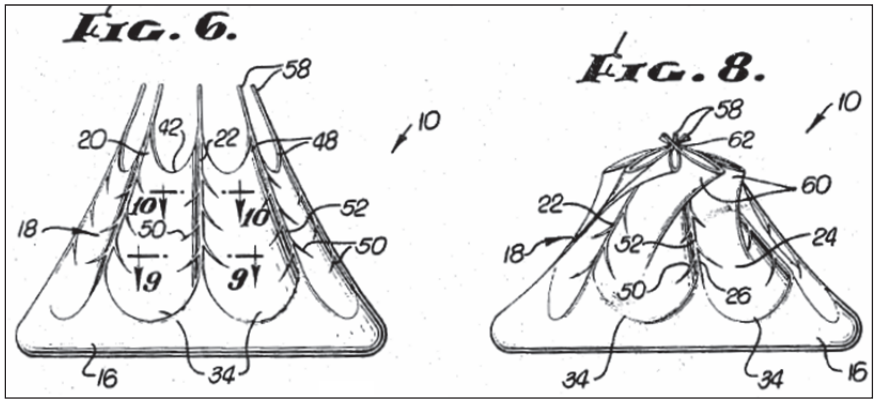
FIG 17



B. Claims 16-18 are Anticipated Under 35 U.S.C. §102(b) by U.S. Patent No. 3,548,417 to Kischer (Exh. 1004)

U.S. Patent No. 3,548,417 to Kischer ("Kischer") issued on December 22, 1970 and thus qualifies as prior art under § 102(b). Kischer was not cited during prosecution of the '228 Patent although it describes a prosthetic aortic valve with a

frusto-conical sheet material connected to ribs that rotate radially about a base ring. *Kischer, 1:67-69 and 2:1-30*. The claim chart attached as Appendix A-2 details how each element recited in claims 16-18 is anticipated by Kischer. Figures 6 and 8 below show the valve in open and closed positions, respectively. As shown in the figures, Ribs 22 are attached to Wall 18, which is attached to annular Base 16 through which blood flows. The stiffening support for the sheet material (*e.g.*, Ribs 22) induces "the material [Wall 18] to rotate in its movement between its first and second position." *Kischer, 2:14*-20. The pressure differential caused by the heart as it pumps blood forces the valve to open and close with Wall 18 rotating relative to Base 16 and at least partially about the axis of the wall. *Kischer, 4:37-63*.



C. Claims 16-19 are Anticipated Under 35 U.S.C. §102(e) by U.S. Patent No. 6,299,637 to Shaolian (Exh. 1005)

U.S. Patent No. 6,299,637 to Shaolian et al. ("Shaolian") was filed on August 20, 1999 and thus qualifies as prior art under § 102(e). Shaolian was not cited during prosecution of the '228 Patent although it describes a valve with hinged valve leaflets within a tubular support structure that may be utilized as a venous

valve or elsewhere in the body. *Shaolian, 4:35-41 and 9:40-67*. The claim chart attached as Appendix A-3 details how each element recited in claims 16-19 is anticipated by Shaolian. Figure 6 below shows a valve embodiment that is referred to as the "two leaflet 'duck bill'" which comprises Leaflets 76 and 78 that comprise "flexible wire struts, covered by a blood flow blocking membrane such as PTFE or Dacron." *Shaolian 9:44-46*. Figure 4 below shows a tubular wireframe for supporting the prosthetic valve. "Each of the leaflets 76 and 78 are rotatably connected to the inside wall of a tubular wire frame 44." *Shaolian 9:47-49*. Leaflets 76 and 78 control blood flow through tubular wireframe 44 by pivoting towards each other to close the valve and away from each other to open the valve. *Shaolian, 9:50-59*.

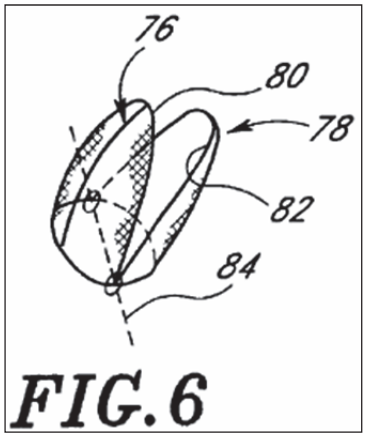


FIG. 6

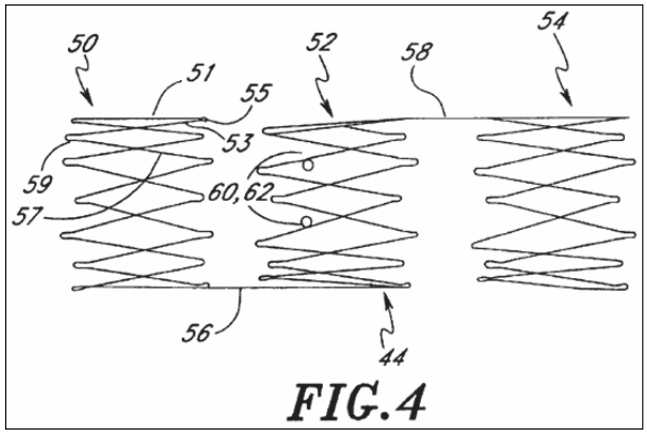


FIG. 4

Shaolian further teaches that the center section 52 of the tubular wireframe 44, which is connected to the valve leaflets 76 and 78, can be connected to additional sections 50 and 54 by connectors 56 and 58 respectively. *Shaolian, 6:60-62*.

D. Claims 16-18 are Anticipated Under 35 U.S.C. §102(b) by U.S. Patent No. 4,030,142 to Wolfe (Exh. 1006)

U.S. Patent No. 4,030,142 to Wolfe ("Wolfe") issued on June 21, 1977 and thus qualifies as prior art under § 102(b). Wolfe was not cited during prosecution of the '228 Patent although it describes a prosthetic heart valve that can be adapted to replace an aortic valve. The claim chart attached as Appendix A-4 details how each element recited in claims 16-18 is anticipated by Wolfe. Shown below in Figures 2B (closed position) and 2C (open position) is one embodiment of the heart valve taught in Wolfe. Cuspids 38, which are formed of a plastic material such as polypropylene, move radially to control the flow of blood through the valve. *Wolfe, 1:60-2:4*. Each Cuspid 38 is connected to an Upstream Annular Section 40 through an Armature Construction 54 that is hingedly connected to Annular Ring 56. *Wolfe, 5:27-45*. The valve is held in place by Valve Seat Assembly 14, which includes a Fixation Cover 20 that is sutured to the heart tissue. *Wolfe, 3:51-64*.

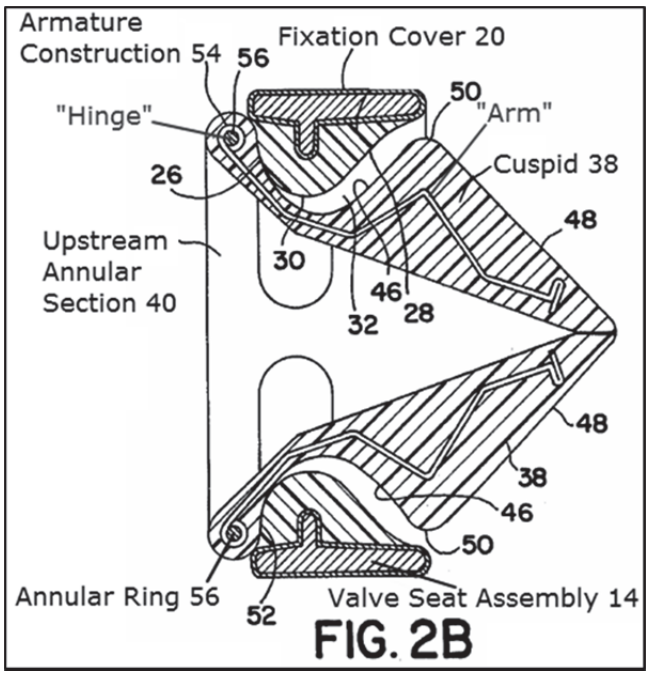


FIG. 2B

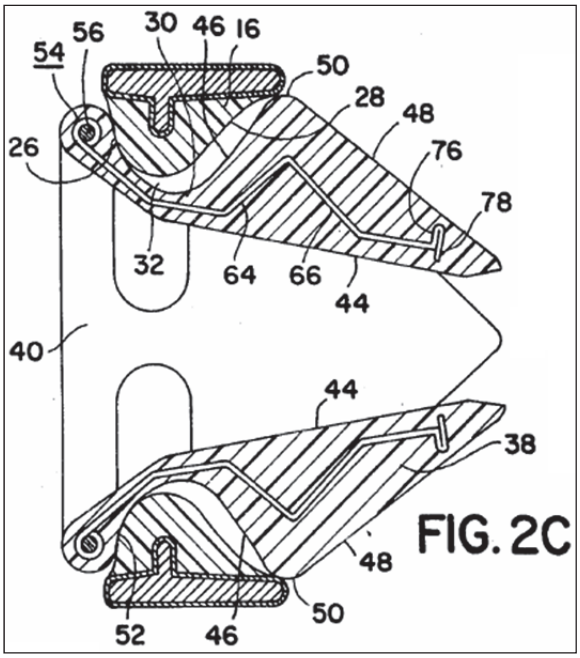


FIG. 2C

VI. CONCLUSION

Based on the foregoing, it is clear that claims 16-19 of the '228 Patent define subject matter that is anticipated. The art cited above was never considered by the original Examiner, and if it had been claims 16-19 of the '228 Patent would not have issued. 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,

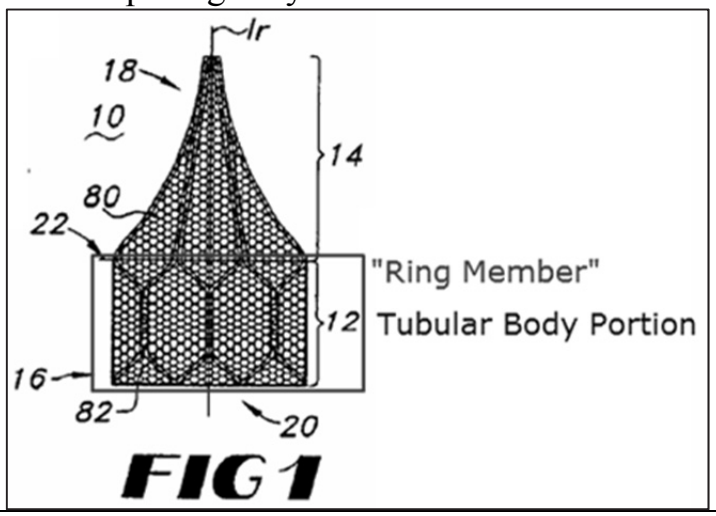
PILLSBURY WINTHROP SHAW PITTMAN LLP

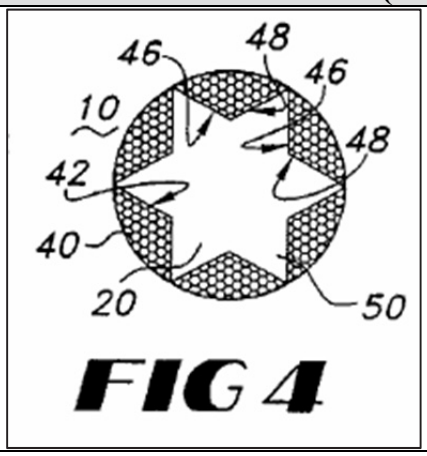
/Jack Barufka/

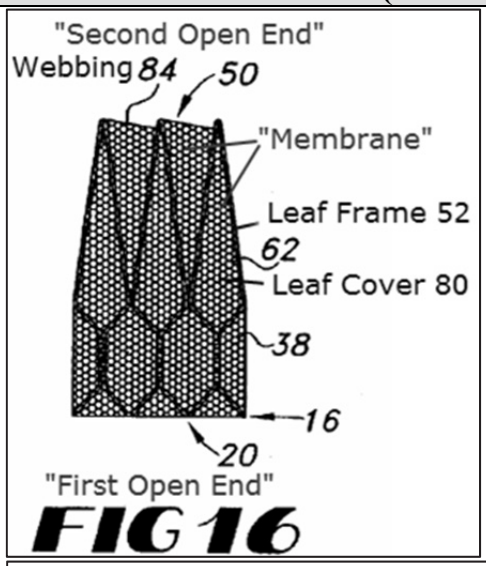
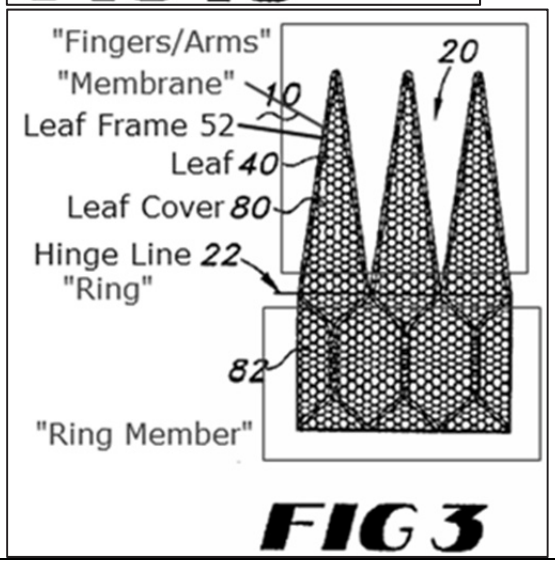
Jack S. Barufka
Reg. No. 37,087
Tel. No. 703.770.7712
Fax No. 703.905.2500

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

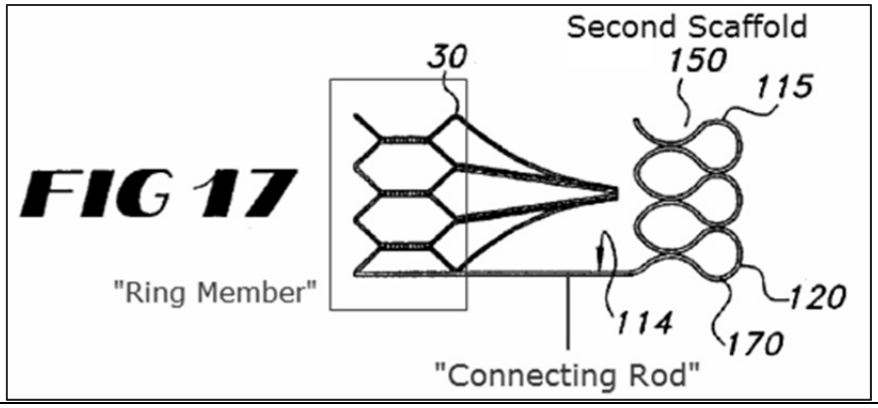
Attachments: Appendices A-1 – A-4 (Claim Charts)
Exhibits 1001-1006

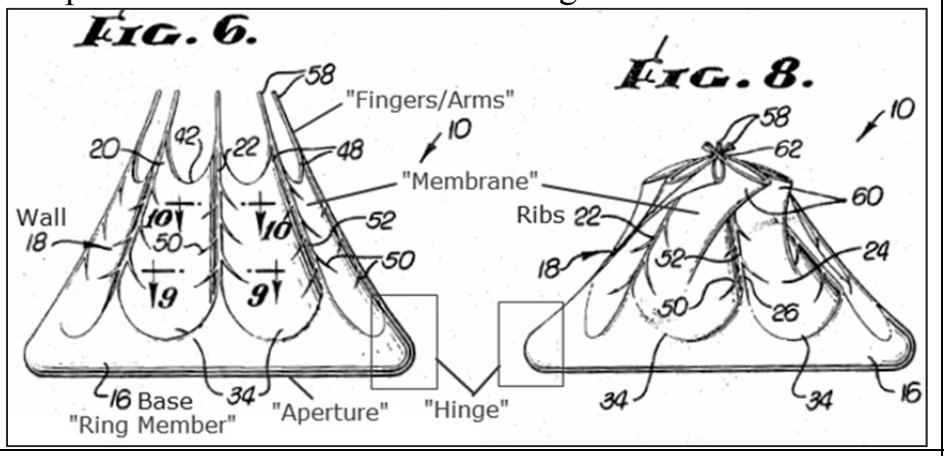
The '228 Patent	Appendix A-1: Anticipation By US 6,440,164 to DiMatteo (Exh. 1003)
16. An aortic valve for regulating a blood flow through an aortic channel surrounded by an aortic wall upon placement therein, said valve comprising:	To the extent that the preamble is limitation, DiMatteo discloses a prosthetic aortic valve for regulating blood flow upon placement in the aorta. 1:4-6 and 2:26-31.
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]** DiMatteo discloses a ring member in the form of a "tubular body portion 12." **[2]** The tubular body portion 12 ("ring member") has a circumference adapted to seat about an aortic wall surrounding an aortic channel in that it provides "fluid-tight engagement with the body lumen" such as an aortic channel **[3]** to regulate the flow of blood flowing through the tubular body portion 12 ("ring member"). 3:29-33 and 7:38-49. Fig. 1 below shows tubular body portion 12 ("ring member"). Fig. 4 below is a top view of the valve in an open position showing an "aperture for blood flow therethrough" in the form of passageway 20.  FIG 1

The '228 Patent	Appendix A-1: Anticipation By US 6,440,164 to DiMatteo (Exh. 1003)
	 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]** DiMatteo discloses a membrane in the form of "valve leaf covers" and "webbing" attached to leaf frame 52 ("arm"). **[2]** As shown in Fig. 16, the valve leaf cover 80 and webbing 84 (together the "membrane") have a first open end at passageway 20 ("ring aperture") of tubular body portion 12 ("ring member") and **[3]** a second open end at downstream opening 50, with such ends being spaced apart as shown. **[4]** The valve leaf covers (which form part of the "membrane") are a "fluid-impermeable biocompatible non-thrombogenic" material. 2:48-50 and 10:26-41. The webbing (which forms the other part of the "membrane") is made of the same material as inner liner 82 (not shown), which can be "polymeric" or "tissue," and is resistant to fluid flow as it is intended to "provide a larger surface area for the body fluid to act upon when urging the valve leafs 40 between the open and closed configuration." 11:10-15 and 36-55.

The '228 Patent	Appendix A-1: Anticipation By US 6,440,164 to DiMatteo (Exh. 1003)
	 FIG 16  FIG 3
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	**[1]** As noted above in Section IV.E.3, the claimed "means for mounting" disclosed in the '228 Patent comprises fingers or arms hingedly attached to a ring. As shown above in Fig. 3, DiMatteo discloses a leaf frame or "arm" 52 hingedly attached to tubular body portion 12 ("ring member"). The leaf frame 52 ("arm") is covered with leaf cover 80 and webbing 84 ("membrane") which is hingedly attached to hinge line 22 about passageway 20 ("ring aperture") of tubular body portion 12 ("ring member"). 7:24-55 and 11:9-15. **[2]** DiMatteo discloses that leaf frame 52 ("arms") deflects leaf cover 80 and webbing 84 ("membrane") between open and closed positions. 3:18-27 and 7:33-36. As shown in Figs. 3 and 4, valve

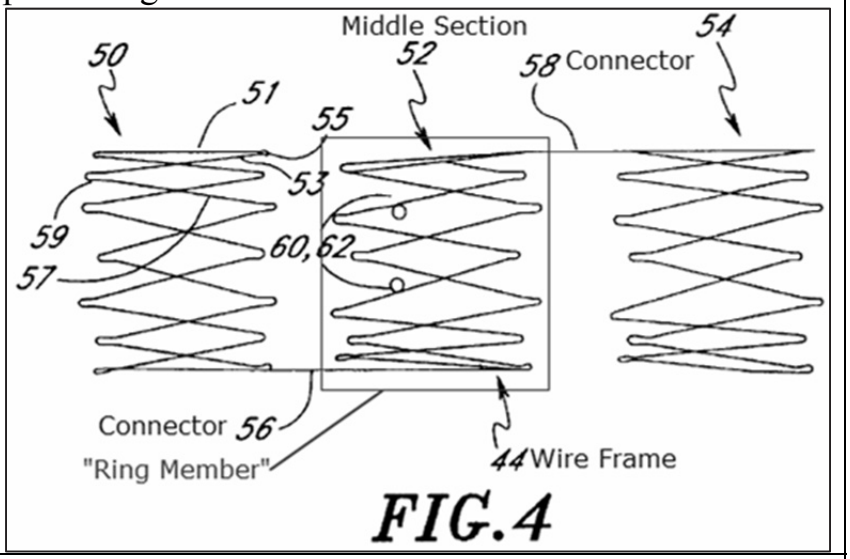
The '228 Patent	Appendix A-1: Anticipation By US 6,440,164 to DiMatteo (Exh. 1003)
position to allow a blood flow therethrough and a second closed position to preclude a blood flow therethrough.	leafs 40 containing leaf frames 52 ("arms") have moved apart and extend generally along a path blood flow to in a first open position. **[3]** DiMatteo further discloses that these arms generally traverse a blood flow path when at a second closed position. Fig. 1 show valve leafs 40 containing leaf frames 52 ("arms") generally traversing a blood flow path in a closed position. *See also* 2:34-38, 6:63-37, 7:7-12.
17. The aortic valve as claimed in claim 16 wherein said mounting means comprises at least one arm having a first end hingedly secured to said ring member and a free end spaced therefrom, said first end of said at least one arm secured to said first end of said membrane, said free end of said at least one arm secured to said second end of said membrane, said at least one arm responsive to a blood flow within the channel for movement with said membrane between said first open and second closed positions.	**[1]** As explained above in claim 16, DiMatteo discloses a mounting means including "at least one arm" in the form of leaf frame 52. **[2]** As shown in Figs. 3 and 16 above, the leaf frame 52 ("arms") in DiMatteo is hingedly connected at hinge line 22 to tubular body portion 12 ("ring member") with a free downstream end that moves radially between an open and closed position. 7:24-55 and 11:9-15. **[3]** Figs. 3 and 16 further show that leaf cover 80 and webbing 84 ("membrane") are attached to the leaf frame 52 ("arm") at both the hinge line 22 and second end 55. *See also* 2:34-38, 3:18-27, 6:63-37, and 7:7-12, 24-55, and 11:9-15. **[4]** DiMatteo further discloses that leaf frame 52 ("arms") move between open and closed positions in response to fluid pressure differentials: "the fluid pressure differential acts to open the valve when the fluid pressure upstream of the valve leaf portion is greater than the fluid pressure downstream of the valve leaf portion" and "[w]hen the pressure differential is too low, the valve closes to prevent back flow." 3:18-27, 6:53-67, and 7:4-12, 33-36.

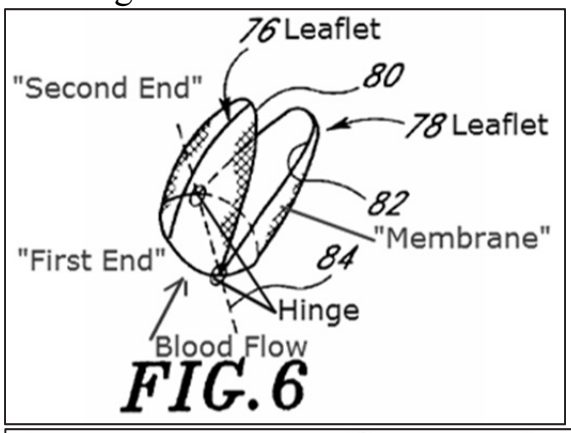
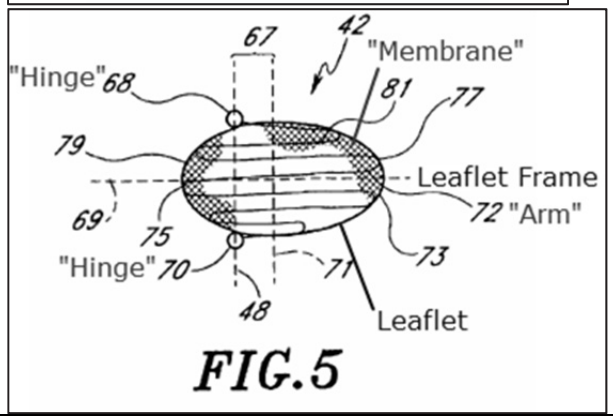
The '228 Patent	Appendix A-1: Anticipation By US 6,440,164 to DiMatteo (Exh. 1003)
18. The aortic valve as claimed in claim 17 wherein said at least one arm extends generally along a path of said blood flow at said first open position, and generally traverses a blood flow path when at said second closed position.	**[1]** As explained in claim 17 above, DiMatteo discloses "at least one arm" in the form of leaf frame 52. **[2]** DiMatteo further discloses that these arms extend generally along a path of said blood flow at a first open position. Fig. 3 shows leaf frame 52 ("arms") generally along the blood flow path in an open position. *See also* 2:34-38, 3:18-27, 6:53-67, and 7:4-12, 33-36. **[3]** DiMatteo further discloses that these arms generally traverse a blood flow path when at a second closed position. Fig. 1 shows leaf frame 52 ("arms") generally traversing a blood flow path in a closed position. *See also* 2:34-38, 3:18-27, 6:53-67, and 7:4-12, 33-36.
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 above, DiMatteo discloses "ring member" in the form of tubular body portion 12. **[2]** As noted above in Section IV.E.4, the claimed "means for maintaining" disclosed in the '228 Patent comprises connecting rods. DiMatteo discloses a connecting rod in the form of a wire 114 that connects the valve's tubular body portion 12 ("ring member") to a collapsible scaffold 150. *See* Fig. 17 below and 13:43-51. **[3]** The position of the tubular body portion 12 ("ring member") is maintained in its seat about the aortic wall by being mechanically joined via wire 114 ("connecting rod") to a second scaffold 150 which is designed to engage the tissue of the aorta and provide additional support to the valve. *See also* 3:29-33. 

The '228 Patent	Appendix A-2: Anticipation By US 3,548,417 to Kischer (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:	To the extent that the preamble is a limitation, Kischer discloses a "prosthetic heart valve suitable for the replacement of any of the natural heart valves" including an aortic valve. 1:13-20 and 67-69.
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]** Kischer discloses a ring member in the form of annular base 16. **[2]** Base 16 ("ring member') has a circumference adapted to seat about the wall of the aorta in that "the valve is sutured at the base 16 to the artery wall 28 by thread extending about or through the base." 3:11-13 and Figs. 1 and 2. **[3]** Annotated Figs. 6 and 8 show base 16 ("ring member") with an aperture for blood flow therethrough. 2:4-13 and 4:5-16. 
a membrane having first and second spaced-apart open ends, said membrane made of a material resistant to a fluid flow therethrough; and	**[1]** Kischer discloses a membrane in the form of frusto-conical wall 18 formed a thin sheet material. 2:1:13 and 21-24. **[2]** As shown above in Fig. 6, the wall 18 ("membrane") has a first open end at base 16 ("ring member") and a second downstream open end at edge 42, with such ends being spaced apart as shown. **[3]** Kischer further disclose that the frusto-conical wall 18 ("membrane") is "impervious to blood and resistant to body fluids" therethrough. 2:1-13.
means for mounting said first open	**[1]** As noted above in Section IV.E.3, the claimed "means for mounting" disclosed in the '228 Patent comprises fingers or

The '228 Patent	Appendix A-2: Anticipation By US 3,548,417 to Kischer (Exh. 1004)
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.	arms hingedly attached to a ring. Kischer discloses the same or equivalent structure attached to a ring. Specifically, Kischer discloses ribs 22 ("arms") hinged about the aperture of base 16 ("ring member"). **[2]** As shown in Figs. 6 and 8, wall 18 ("membrane") is attached to ribs 22 ("arms") and moves between open and closed positions. **[3]** Kischer further discloses that ribs 22 ("arms") induces the wall 18 ("membrane") "to rotate in its movement between its first and second position" with a first position that has an "open passage to pass blood" and a second position where "the material ["membrane"] closes the passage and blocks reverse flow of blood therethrough." 2:5-20.
17. The aortic valve as claimed in claim 16 wherein said mounting means comprises at least one arm having a first end hingedly secured to said ring member and a free end spaced therefrom, said first end of said at least one arm secured to said first end of said membrane, said free end of said at least one arm secured to said second end of said membrane, said at least one arm re-	**[1]** As explained above in claim 16, Kischer discloses a mounting means including "at least one arm" in the form of ribs 22. **[2]** As shown in Figs. 6 and 8 above, the ribs 22 ("arms") are hingedly secured about base 16 ("ring member") in such a way that the downstream ends can rotate between an open and closed position. 4:41-63. **[3]** As shown above in Figs. 6 and 8, ribs 22 ("arms") have a first end hingedly connected to base 16 ("ring member") via the wall 18 ("membrane") and also have first end of wall 18 ("membrane") secured to ribs 22 ("arms") at that point. Wall 18 ("membrane") is also attached at the spaced apart free ends of ribs 22 ("arms") at cusp peaks 48, shown in Fig. 6 above. **[4]** Kischer also discloses that ribs 22 ("arms") are responsive to blood flow. Ribs 22 ("arms") move to an open position to allow blood flow therethrough when "the result of a pressure differential between the interior and exterior of the valve 10 in favor of the valve interior as is the case for example for an aortic valve during a pumping contraction of the left ventricle" and ribs 22 ("arms') move to a closed position when the pressure differential reverses in favor of the valve exterior. 4:41-63.

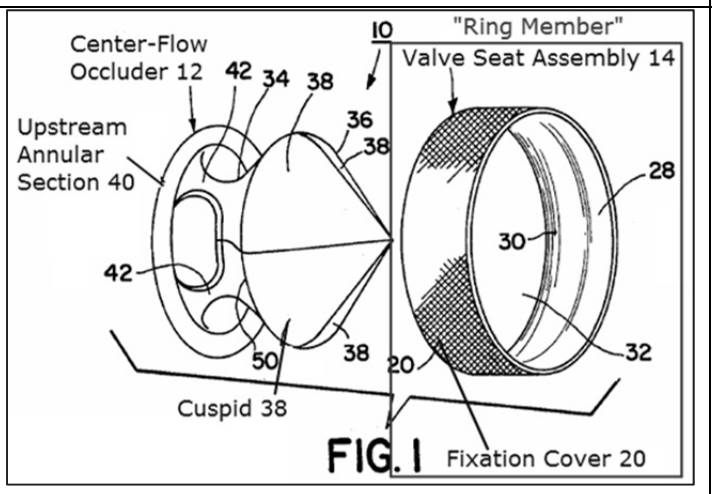
The '228 Patent	Appendix A-2: Anticipation By US 3,548,417 to Kischer (Exh. 1004)
sponsive to a blood flow within the channel for movement with said membrane between said first open and second closed positions.	
18. The aortic valve as claimed in claim 17 wherein said at least one arm extends generally along a path of said blood flow at said first open position, and generally traverses a blood flow path when at said second closed position.	**[1]** As explained above in claim 17, Kischer discloses "at least one arm" in the form of ribs 22. **[2]** Kischer further discloses that these ribs 22 ("arms") extend generally along a path of said blood flow at a first open position. Fig. 6 above shows ribs 22 ("arms") generally along the path of blood flow in an open position. *See also* 2:5:13 and 4:41-63. **[3]** Kischer further discloses that these ribs 22 ("arms") generally traverse a blood flow path when at a second closed position. Fig. 8 shows ribs 22 ("arms") generally traversing a blood flow path in a closed position. *See also* 2:5:13 and 4:41-63.

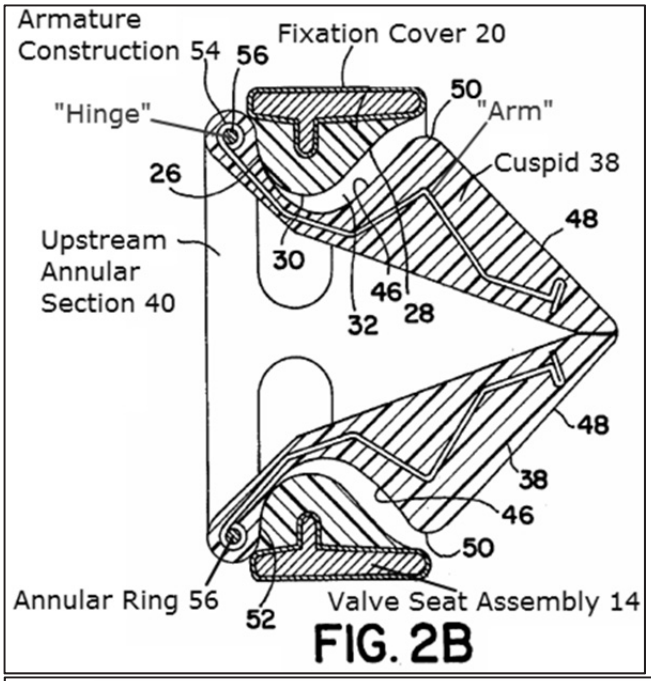
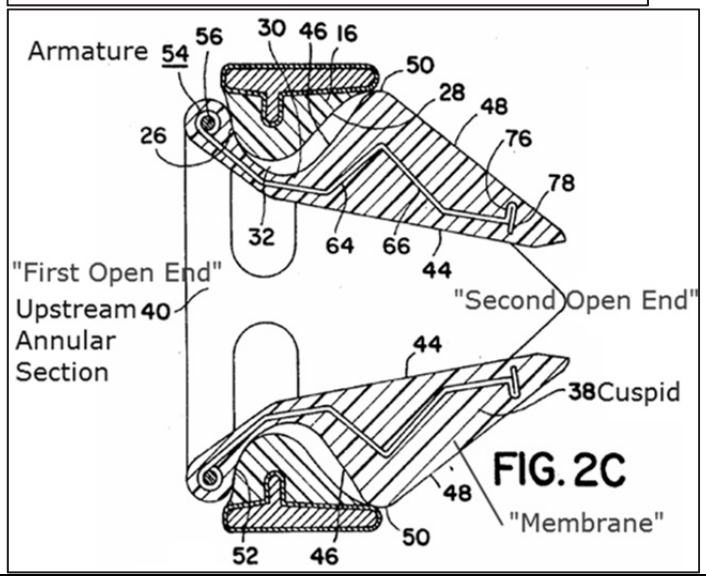
The '228 Patent	Appendix A-3: Anticipation By US 6,299,637 to Shaolian (Exh. 1005)
16. An aortic valve for regulating a blood flow through an aortic channel surrounded by an aortic wall upon placement therein, said valve comprising:	To the extent that the preamble is a limitation, Shaolian discloses a prosthetic venous valve design that "may be utilized elsewhere in the body" to regulate blood flow. 4:36-42.
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]** Shaolian discloses a ring member in the form of middle section 52 of tubular wire frame 44. **[2]** Section 52 ("ring member") has a circumference adapted to seat about an aortic wall surrounding an aortic channel in that it is designed to "exert a radially outwardly directed force on the vessel wall to assist in the retention" of the valve through contact with a vessel wall, such as an artery wall. 5:63-67. **[3]** Annotated Fig. 4 below shows section 52 ("ring member") with an aperture creating "a flow path extending therethrough, for permitting venous blood flow." 3:13-14.  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]** Shaolian discloses a membrane in the form of a "leaflet cover 74 such as a layer of PTFE or Dacron secured to one or both sides of the leaflet frame 72." 8:24-27. **[2]** As shown below in Fig. 6, which depicts the "duck bill valve" apart from wire frame's 44 middle section 52 ("ring member") in which it resides, the leaflets 76/78 and their attached leaflet covers ("mem-

The '228 Patent	Appendix A-3: Anticipation By US 6,299,637 to Shaolian (Exh. 1005)
	brane") have a first open end on the hinge side and a second downstream open end, with such ends being space apart as shown. **[3]** Shaolian further discloses that the material on the leaflets is resistant to fluid flow therethrough in that the material has a "blood flow blocking function." 8:33-35.  FIG. 6  FIG. 5
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	**[1]** As noted above in Section IV.E.3, the claimed "means for mounting" disclosed in the '228 Patent comprises fingers or arms hingedly attached to a ring. Shaolian similarly discloses a leaflet frame 72 ("arms") formed by "flexible wire struts" hingedly connected to the inside wall of tubular wire frame's 44 middle section 52 ("ring member"). **[2]** Shaolian discloses that the flexible wire struts of leaflet frame 72 ("arms") are "covered by a blood flow blocking membrane such as PTFE or Dacron" ("membrane") to form leaflets 78 that are "moveable between a first position in which blood is permitted to flow in a forward direc-

The '228 Patent	Appendix A-3: Anticipation By US 6,299,637 to Shaolian (Exh. 1005)
therethrough.	tion, and a second position which inhibits blood flow in a reverse direction." 5:2-6 and 9:44-46.
17. The aortic valve as claimed in claim 16 wherein said mounting means comprises at least one arm having a first end hingedly secured to said ring member and a free end spaced therefrom, said first end of said at least one arm secured to said first end of said membrane, said free end of said at least one arm secured to said second end of said membrane, said at least one arm responsive to a blood flow within the channel for movement with said membrane between said first open and second closed positions.	**[1]** As explained above in claim 16, Shaolian discloses mounting means including "at least one arm" in the form of the leaflet's "flexible wire struts." **[2]** As shown in Figs. 5 and 6 above, the flexible wire struts ("arms") form a leaflet frame 72 which is hingedly attached to the inside wall of a tubular wire frame's 44 middle section 52 ("ring member") through "the use of interconnecting loops or other pivotable connection." 9:40-67. **[3]** Shaolian discloses that the leaflet's flexible wire struts 72 ("arms") are covered by a blood flow blocking membrane that extends from a first hinged end to the second free end. **[4]** Shaolian further discloses that the edges of the membrane covered leaflet "are pivotable towards each other to close the valve and away from each other to open the valve with little or no spring bias, and in response to blood flow." 9:40-67.
18. The aortic valve as claimed in claim 17 wherein said at least one arm extends generally along a path of said blood flow at said first open position, and generally traverses a blood flow path when at said second closed position.	**[1]** As explained in claim 17 above, Shaolian discloses "at least one arm" in the form of the leaflet's "flexible wire struts." **[2]** Shaolian further discloses that these flexible wire struts ("arms") extend generally along the path of said blood flow at a first open position. Fig. 6 above shows leaflet 78 with internal flexible wire struts ("arms") generally along the path of blood flow in an open position. Shaolian further discloses that "forward blood flow from the rotational axis 84 in the direction of the first and second leaflet edges 80 and 82 will tend to open the valve." 9:53-59. **[3]** Shaolian discloses that these flexible wire struts ("arms") generally traverse a blood flow path when at a second closed position in that it discloses leaflets 78 "are pivotable to-

The '228 Patent	Appendix A-3: Anticipation By US 6,299,637 to Shaolian (Exh. 1005)
	wards each other to close the valve." 9:53-59.
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 above in claim 16, Shaolian discloses a "ring member" in the form of middle section 52 of tubular wire frame 44. **[2]** As noted above in Section IV.E.4, the claimed "means for maintaining" disclosed in the '228 Patent comprises connecting rods. As shown above in Fig. 4, Shaolian discloses a connecting rod in the form connectors 56 and 58 that connect middle section 52 ("ring member") to additional expandable wire frames. *See* 6:60-63. **[3]** These additional sections provide "relatively greater radial strength" that assist in retaining middle section 52 ("ring member") in its position with respect to the vessel wall. *See* 5:63-67 and 7:6-13.

The '228 Patent	Appendix A-4: Anticipation By US 4,030,142 to Wolfe (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:	To the extent that the preamble is a limitation, Wolfe discloses a prosthetic valve for regulating blood flow that "can be adapted to replace the tricuspid and/or aortic valves" by placement in the aorta. 1:7-9 and 45-51.
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]** Wolfe discloses a ring member comprised of the structure formed by ring-shaped "annular ring" 56 (see Figs. 2A and 2B below) of Upstream Annular Section 40 (see Fig. 1 to the right) seated within ring-shaped "valve seat assembly 14" (see Fig. 1 to the right). **[2]** The valve seat assembly 14 has a circumference adapted to seat about an aortic wall surrounding an aortic channel in that it includes "fixation cover 20" which is "initially secured to the heart tissue by suturing." 3:51-64. **[3]** Annotated Fig. 1 to the right shows valve seat assembly 14 with an aperture for blood flow therethrough in the form of passageway 32.  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]** Wolfe discloses a membrane in the form of an occluder 12 with cuspids 38 **[2]** "formed of a plastic material, such as polypropylene" which is resistant to fluid flow therethrough. 1:60-2:4. **[3]** As shown below in Fig. 2C, the cuspids 38 ("membrane") have a first open end at the upstream annular section 40 and a second open end at the downstream section, with such ends being spaced apart as shown. **[4]** When the cuspids 38 are closed, as shown in Fig.

The '228 Patent	Appendix A-4: Anticipation By US 4,030,142 to Wolfe (Exh. 1006)
	2B below, blood is prevented from flowing through the valve.  FIG. 2B  FIG. 2C
means for mounting said first open end of said membrane about said ring aperture with said second open end displaced there-	**[1]** As noted above in Section IV.E.3, the claimed "means for mounting" disclosed in the '228 Patent comprises fingers or arms hingedly attached to a ring. Wolfe discloses the same or equivalent structure hingedly attached to a ring in the form of armature 54, within plastic covered cuspids 38, which is hingedly connected to annular ring 56 at about passageway 32("ring aperture"). 5:27-45. **[2]** Wolfe discloses

The '228 Patent	Appendix A-4: Anticipation By US 4,030,142 to Wolfe (Exh. 1006)
from, 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.	that the plastic covered cuspids 38 of the occluder 12 ("membrane") "are movable radially with respect to each other between a closed condition in which they engage each other, and an opened condition in which they are radially spaced apart to provide a passage through the occluder for the flow of blood." 1:60- 2:4. As shown above in Fig. 2B, the arms in Wolfe are formed by armature 54 within plastic covered cuspid 38, which is hingedly connected to annular ring 56 at about passageway 32 ("ring aperture"). 5:27-45. **[3]** Wolfe further discloses that these arms extend generally along a path of said blood flow at a first open position, and generally traverses a blood flow path when at a second closed position. Fig. 2B above shows cuspids 38 with internal armature 54 ("arms") generally traversing a blood flow path in a closed position to preclude blood flow. Fig. 2C above shows cuspids 38 with internal armature 54 ("arms") generally along the path of blood flow in an open position. *See also* 1:60-2:4.
17. The aortic valve as claimed in claim 16 wherein said mounting means comprises at least one arm having a first end hingedly secured to said ring member and a free end spaced therefrom, said first end of said at least one arm secured to said first end of said membrane, said free end of said at least one arm secured to said second end of said membrane, said at	**[1]** As explained above in claim 16, Wolfe discloses a mounting means including "at least one arm" in the form of armature 54. **[2]** As shown in Fig. 2B above, the armature 54 ("arms") in Wolfe are hingedly connected at one end to annular ring 56 seated on valve seat assembly 14 ("ring member"). The armature 54 ("arms") are within plastic covered cuspid 38 ("membrane"). The armature 54 is secured at the hinged end to the plastic covered cuspid 38 ("membrane"). The armature 54 is secured at the spaced apart free end (see downstream end of armature 54 at overlapping bent sections 76 and 78) to the plastic covered cuspid 38 ("membrane"). 5:27-45, 6:14-19. **[3]** The plastic covered cuspids 38 of the occluder 12 ("membrane") are "connected to the upstream annular section through flexible stems, and are movable radially with respect to each other between a closed condition in which they engage each other, and an opened condition in which they are radially spaced apart to provide a passage through the occluder for the flow of blood." 1:60- 2:4. **[4]** Wolfe further discloses that the cuspids ("membrane") of the valve open and close in response to blood pressure changes

The '228 Patent	Appendix A-4: Anticipation By US 4,030,142 to Wolfe (Exh. 1006)
least one arm responsive to a blood flow within the channel for movement with said membrane between said first open and second closed positions.	associated with ventricle contractions caused by the heart as it pumps blood. 3:29-42.
18. The aortic valve as claimed in claim 17 wherein said at least one arm extends generally along a path of said blood flow at said first open position, and generally traverses a blood flow path when at said second closed position.	**[1]** As explained in claim 17 above, Wolfe discloses "at least one arm" in the form of an armature 54. **[2]** Wolfe further discloses that these armatures 54 ("arms") extend generally along a path of said blood flow at a first open position. Fig. 2C above shows cuspids 38 with internal armature 54 ("arms") generally along the path of blood flow in an open position. *See also* 1:60-2:4. **[3]** Wolfe further discloses that these armatures 54 ("arms") generally traverse a blood flow path when at a second closed position. Fig. 2B shows cuspids 38 with internal armature 54 ("arms") generally traversing a blood flow path in a closed position. *See also* 1:60-2:4.

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 and all exhibits/attachments thereto (Exhs. 1001-1006 and Appendices A1-A4) were served in their entirety by EXPRESS MAIL this 31st day of October, 2013 on the attorney of record of Troy R. Norred, owner of the subject patent, as indicated below:

Chase & Yakimo, L.C.
4400 College Boulevard, Suite 130
Overland Parks, KS 66211

and litigation counsel for the same:

David Marcus
Graves Bartle Marcus & Garrett, LLC
1100 Main Street, Suite 2700
Kansas City, MO 64105

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

Respectfully submitted,

PILLSBURY WINTHROP SHAW PITTMAN LLP

/Jack 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