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 IPR2014-00823
Patent 6,482,228

Attorney Docket No. 058888-0000023

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

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Declaration of Felix Harbsmeier with attached exhibits (1-5): • Exhibit 1: German Patent No. DE 195-46-692 C2 as granted on November 7, 2002 [also attached at Ex. 1007]. • Exhibit 2: The complete prosecution history for patent DE 195-46-692 C1 [also attached at Ex. 1008]. • Exhibit 3: German Patent App. No. DE 195-46-692 as filed on December 14, 1995 [also attached at Ex. 1003, with certified English translation at Ex. 1004]. • Exhibit 4: German Patent App. No. DE 195-46-692 A1 as published on June 19, 1997 [also attached at Ex. 1009, with certified English translation at Ex. 1010]. • Exhibit 5: Sections 31 and 32 of the German Patent Act in effect as of June 19, 1997 through November 14, 2000 [also attached at Ex. 1011, with certified English translation at Ex. 1012].	1006
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Exhibit Description	Exhibit No.
Declaration of Thomas Vassiliades, Jr., M.D. with attached Exhibit 1: Curriculum Vitae of Thomas Vassiliades, Jr., M.D.	1013
Patent Trial and Appeal Board Decision Instituting *Inter Partes* Review for Case No. IPR2013-00111	1014
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Inter partes review is respectfully requested for claims 20-24 of U.S. Patent No. 6,482,228 ("the '228 Patent") (Ex. 1001). Filed concurrently with this Petition is a motion for joinder with the instituted *inter partes* review *Medtronic, Inc., et al. v. Troy R. Norred*, Case No. IPR2014-00111, setting forth fully the reasons supporting the institution of this Petition and the reasons for joinder.

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 two instituted *inter partes* reviews, both styled as *Medtronic, Inc., et al. v. Troy R. Norred*, Case No. IPR2014-00110 ("IPR2014-00110) and Case No. IPR2014-00111 ("IPR2014-

[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.

00111"). *See* Ex. 1015 (IPR2014-00110 Decision) and 1014 (IPR2014-00111 Decision). Finally, the '228 Patent is the subject of IPR2014-00395, which is currently pending.

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

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

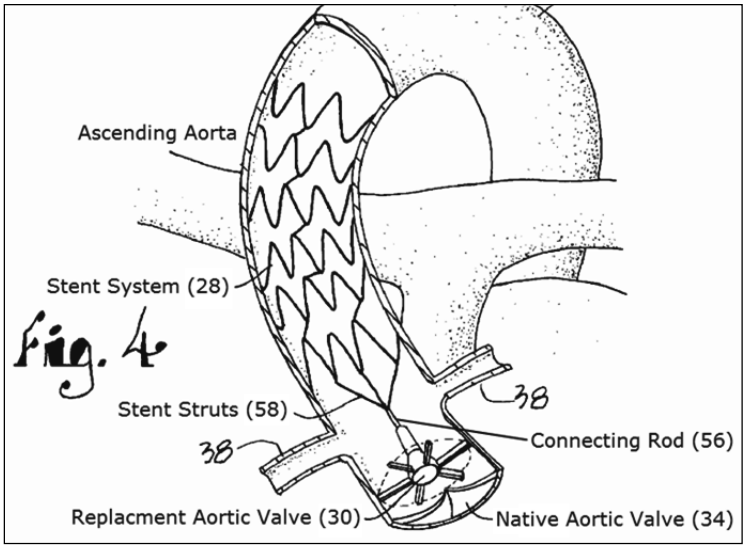
II. PAYMENT OF FEES UNDER 37 C.F.R. § 42.103

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. 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 (Ex. 1001) contains 24 claims, including four independent apparatus claims (claims 1, 12, 16, and 20). The '228 Patent relates to an aortic heart valve replacement that is placed in the ascending aorta and held in place by a stent and connecting rod. Ex. 1001, col. 1, ll. 6-9, col. 6, ll. 1-8, Fig. 4. 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.

With respect to independent claim 20 and its dependent claims 21-24, the ‘228 Patent’s alleged invention is an exogenous, aortic tissue valve secured in a stent system (see annotated Figure 18 below) for controlling blood flow through an aortic channel. Ex. 1001, col. 8, ll. 27-59. As shown in Figure 18 below, the tissue valve comprises a Cadaver/Porcine Valve 100 with an opening movable between open and closed positions, which is 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. Ex. 1001, col. 6, ll. 1-8. The tissue valve is anchored along the root of the aortic valve with Connecting Rods 104. *Id*.

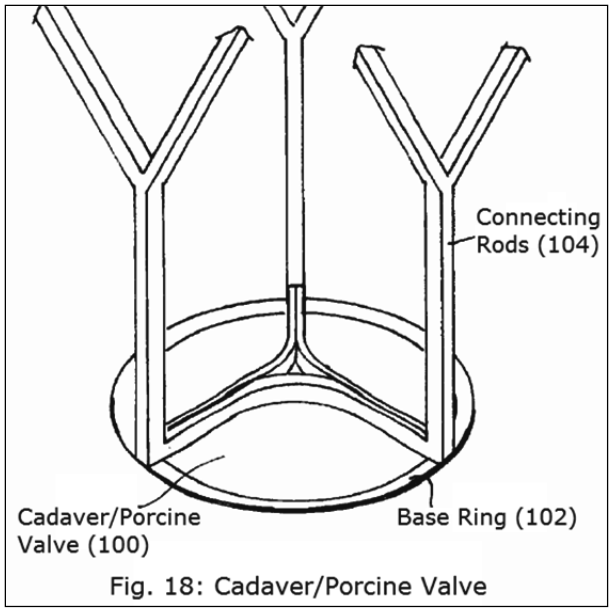


Fig. 18: Cadaver/Porcine Valve

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

Referring to the prosecution history of the '228 Patent (Ex. 1002), the '228 Patent was filed as U.S. App. Serial No. 09/712,121 on Nov. 14, 2000 (*see* Ex. 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 reply to the August 2001 Office Action, applicant filed a response on Feb. 6, 2002 (*id.*, paper 5) that, among other things, made substantive amendments to the language of claims 16-24. In spite of the fact that Patent Owner substantially amended claim 20 (originally claim 23) by removing the "means for moving" language with respect to the "tissue valve interior member," Patent Owner neverthe-

less made a representation to the Patent Office that the amendments were nonsubstantive and grammatical. 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. Although Petitioner was served more than one year ago with a complaint asserting infringement of the '228 Patent, the normal statutory one-year bar under 35 U.S.C. § 315(b) does not apply here because (1) the Board has already instituted an *inter partes* review trial on the '228 Patent on a timely first petition filed by Petitioner (Case No. IPR2014-00111), and (2) Petitioner accompanies this second petition with a motion for joinder under 35 U.S.C. § 315(c).

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

The precise relief requested by Petitioner is that claims 20-24 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 20-24 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 and 103: (1) claims 20-24 are anticipated by DE App. No. 195 46 692 to Figulla et al. ("Figulla"); and (2) claims 20-24 are obvious over Figulla in view of U.S. Patent No. 6,139,575 to Shu et al. ("Shu"). 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)

In a related instituted *inter partes* review, IPR2014-00111, the Board construed the following terms and phrases: the term "tissue" means "biological tissue;" the phrase "means for maintaining" means "rods 104 interacting with stent 28;" and the phrase "ring member" is not limited to a specific material and "does not require a particular sealing function." Ex. 1014 (IPR2014-00111 Decision), pp. 5-11. The Board also indicated that the functional phrase "seated position about the aortic wall," recited in claim 20, carries its ordinary meaning. *Id.* at p. 9. The Board

explained that this phrase "means that the ring is positioned against the aortic wall" and the Board "decline[d] to require the ring to seal with the aortic wall." *Id*.

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

An explanation of how construed claims 20-24 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 in Section V and in Claim Charts (or Appendices) A-1 to A-2.

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 (or Appendices) A-1 to A-2.

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 20-24 are Anticipated Under 35 U.S.C. §102(b) by DE Patent Application No. 195 46 692 to Figulla (Ex. 1003 & 1004)

As explained in the accompanying Declaration of German Patent Attorney Felix Harbsmeier (Ex. 1006), German Patent Application No. 195 46 692 A1 to Figulla (Ex. 1009 and 1010, "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 (Ex. 1003

and 1004, "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. Under Section 31 of the German Patent Act, any person interested in inspecting the file wrapper for the application that included Figulla '692 Filed Application would have been able to do so. Thus, any person noticing the incorrect figures and that was interested in the correct contents would have had full access to the same. 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 tissue, such as porcine tissue, for use with a stent system. The claim chart attached as Appendix A-1 details how each element recited in claims 20-24 is met by Figulla '692 Filed Application.

Annotated Figure 1 below shows that the "aortal bioprosthesis or artificial aortal valve" (e.g., "pig-heart valve") disclosed in the Figulla '692 Filed Application attached within the proximal member of the multi-component stent. Ex. 1004, p. 9, and Fig. 1 caption.

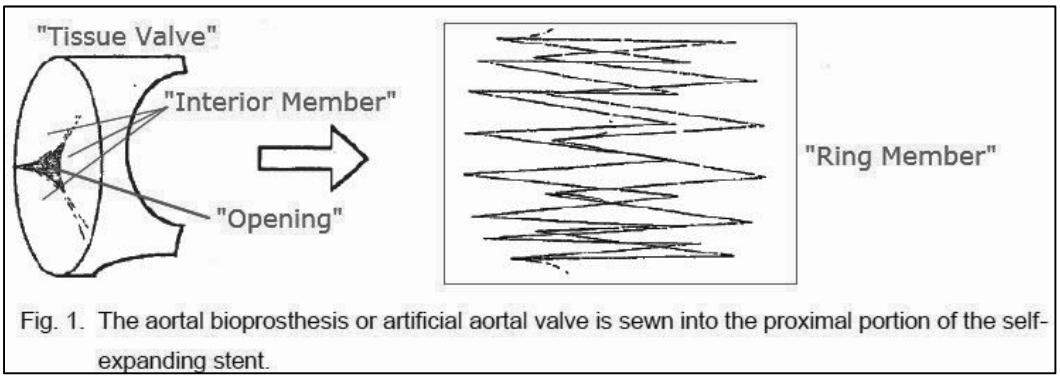


Fig. 1. The aortal bioprosthesis or artificial aortal valve is sewn into the proximal portion of the self-expanding stent.

Annotated Figure 2 below shows that the proximal member of the multi-component stent is connected to the distal members of the multi-component stent with rods. Ex. 1004, p. 9, and Fig. 2 caption.

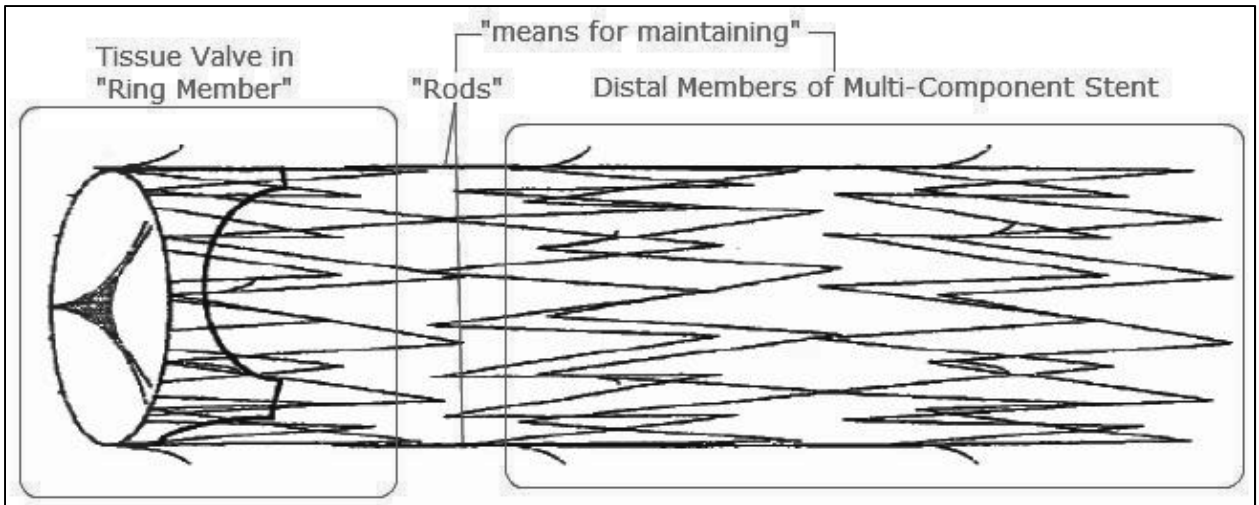
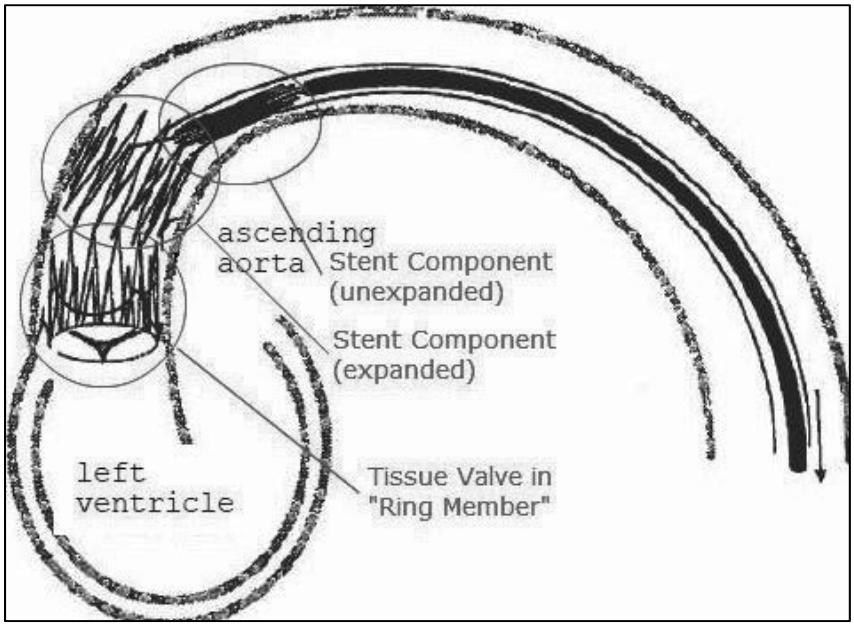


Fig. 2. The aortal bioprosthesis or artificial aortal valve in the proximal portion of the multi-component, self-expanding stent

Annotated Figure 4 below shows the heart valve prosthesis of Figulla ‘692 Filed Application partially deployed in the ascending aorta. Ex. 1004, Fig. 4 caption. Shown in the figure is a tissue valve within the proximal member of the multi-component stent. The ring in an expanded state that is connected to a second stent component in an expanded state and that is further connected to a third stent component in an unexpanded state. *Id*.



As explained in the accompanying Vassiliades Declaration (Ex. 1013), it is readily apparent and inherent that the prosthetic pig-heart valve disclosed by the Figulla ‘692 Filed Application 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 by moving the valve’s leaflets between an open and closed position. 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, the prosthetic valve 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. Furthermore, it is readily apparent and inherent that the "constant, tight fit" of the prosthetic pig-heart valve disclosed by the Figulla '692 Filed Application reduces the blood flow around the prosthetic valve (*i.e.*, flow between the prosthetic valve and the aortic wall) so that the blood flow can be controlled by the movable opening of the prosthetic valve. Ex. 1004, p. 9.

B. Claims 20-24 are Obvious Under 35 U.S.C. §103 Over Figulla In View of U.S. Patent No. 6,139,575 to Shu (Ex. 1003-1005)

With respect to the actual operation of the prosthetic tissue valve disclosed in Figulla, as noted in Section V.A above, and in Appendix A-1, it is readily apparent and inherent that the prosthetic valve disclosed in Figulla, like the native valve it replaces, must necessarily open and close in response to pressure differentials created by the systolic and diastolic phases of the cardiac cycle. Such operation also would have been obvious in view of Shu, which discloses how a native heart valve works and the fact that the prosthetic heart valve is designed to mimic the

operation of the native heart valve. Ex. 1005, col. 1, ll. 11-27; col. 2, ll. 4-15, 36-42 and 45-50.

In particular, Shu discloses that during each cardiac cycle, the natural heart valves alternatively open to allow blood to flow through them and then close to block blood flow. Ex. 1005, col. 1, ll. 11-13. During systole, the aortic and pulmonary valves open to allow blood flow into the aorta and pulmonary arteries. *Id*. at col. 1, ll. 13-17. Conversely, during diastole, the aortic and pulmonary valves close to prevent reverse blood flow from the aorta and pulmonary arteries into the ventricles. *Id*. at col. 1, ll. 17-20. The cardiac valves open and close passively in response to blood pressure changes operating against the valve leaflet structure. *Id*. at col. 1, ll. 21-23.

Section V.A and Appendix A-1 are relied upon for the relevant teachings of Figulla, while Appendix A-2 shows the relevant disclosures of Shu regarding the operation of a heart valve during the cardiac cycle. A person of ordinary skill in the art would have been motivated to combine Figulla and Shu because both are directed to prosthetic valves that are designed to replace the function of a natural valve. Thus, a person of ordinary skill in the art would understand Figulla in view of Shu to teach a prosthetic tissue valve as claimed in Claim 20 and that: is responsive (opens and closes) to conditions (pressure differentials) in the aorta as recited in Claims 20 and 21; opens during systole as recited in Claim 22; closes during di-

astole as recited in Claim 23; and seals against the aortic channel wall to reduce blood flow around the prosthetic tissue valve as recited in Claim 24.

VI. CONCLUSION

Based on the foregoing, it is clear that claims 20-24 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 20-24 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,

Date: May 27, 2014

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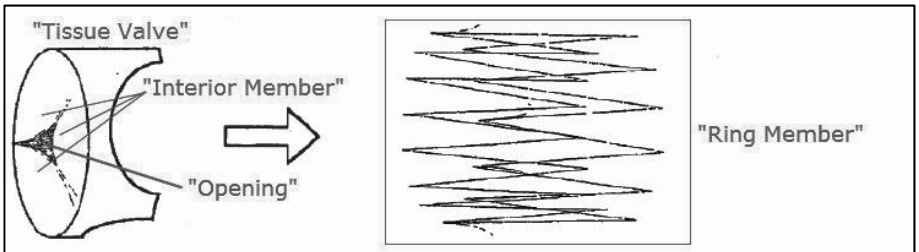
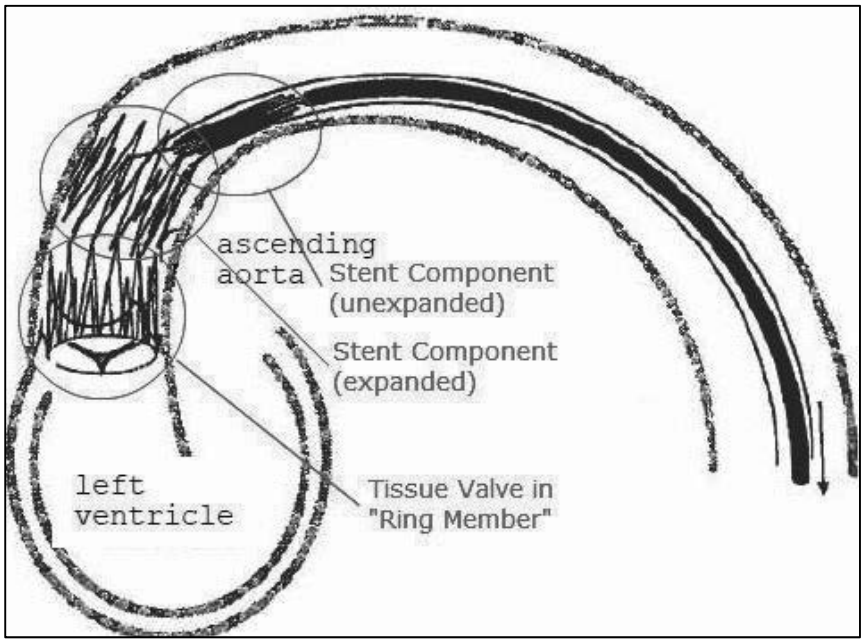
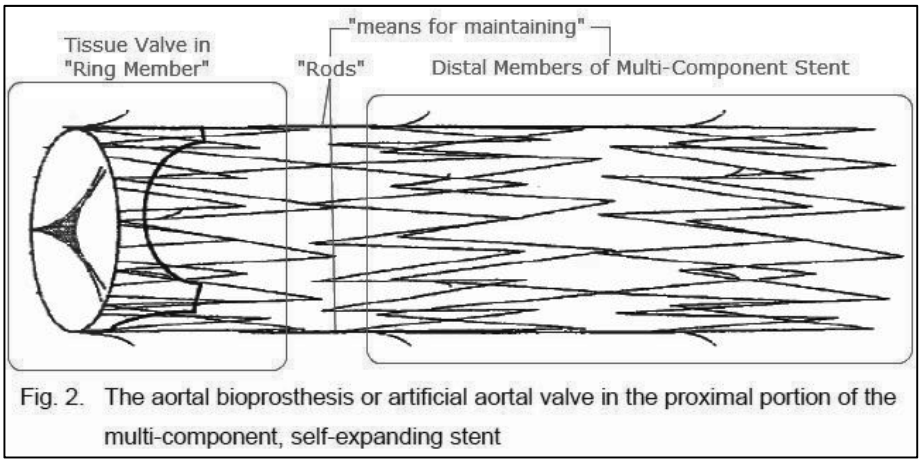
Attachments: Appendices A-1 – A-2 (Claim Charts)
Exhibits 1001-1015

The '228 Patent	Appendix A-1: DE 195 46 692 to Figulla (Ex. 1003 & 1004)
20. An aortic valve for controlling a blood flow through an aortic channel upon placement therein, said valve comprising:	Figulla discloses a heart-valve prosthesis that uses a pig-heart valve to replace the function of a native aortic valve. Ex. 1004, p. 8-9. The heart-valve prosthesis disclosed in Figulla is implanted in the aorta and anchored to the aorta wall. *Id*.
a tissue valve having an interior member made of a tissue material and presenting an opening movable between open and closed positions;	**[1]** Figulla discloses a tissue valve in the form of a "pig-heart valve." Ex. 1004, p. 2. **[2]** As shown in annotated Figure 1 below, the pig-heart valve ("tissue valve") is inserted into the proximal member of a multi-component ring-shaped stent ("ring member"). Figure 1 also shows the movable opening and the "interior member" of the pig-heart valve ("tissue valve"). The pig-heart valve ("tissue valve") has movable valve leaflets ("interior member") made of pig heart ("a tissue material") and presents an opening movable between open and closed positions. *See also* Note 1 below.  Fig. 1. The aortal bioprosthesis or artificial aortal valve is sewn into the proximal portion of the self-expanding stent. **Note 1:** As described in the Declaration of Thomas Vassiliades, Jr., M.D. (Ex. 1013), 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, operate by moving between an open and closed position in response to blood flow of the heart. The pig-heart prosthetic valve disclosed by Figulla (and the prosthetic valve of Shu) moves between a closed position and an open position in response to pressure changes in the aorta. *See* Ex. 1013. Rather than repeat this Note below, Petitioner will in-

The '228 Patent	Appendix A-1: DE 195 46 692 to Figulla (Ex. 1003 & 1004)
	stead refer back to this Note with the notation, "*See* Note 1 above."
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 Figure 1, Figulla discloses a ring member in the form of a proximal member of the multi-component stent. **[2]** Figulla further discloses that the pig-heart valve ("tissue valve") is sewn into the proximal member of the multi-component stent ("ring member"). Ex. 1004, p. 9. **[3]** Figulla discloses that the proximal member of the multi-component stent ("ring member") has an outer circumference adapted to seat it about an aortic wall in that it uses the aortic wall for support. *Id*. Annotated Figure 4 below shows the proximal member of the multi-component stent ("ring member") in contact with the wall of the ascending aorta. 
means for maintaining said ring member in said seated position about the aortic wall,	**[1]** As noted above in Section IV.E, the claimed "means for maintaining" disclosed in the '228 Patent comprises rods interacting with a stent. Figulla discloses the same or equivalent structure in the form of rods or wires that connect the members of the multi-component stent. As shown below in

The '228 Patent	Appendix A-1: DE 195 46 692 to Figulla (Ex. 1003 & 1004)
	annotated Figure 2, the proximal member of the stent ("ring member") housing the pig-heart valve ("tissue valve") is connected to the distal stent segments via connecting wires ("rods"). Ex. 1004, p. 9. **[2]** Figulla further discloses that the connecting wires ("rods") help maintain the proximal member of the stent's ("ring member") position in the aorta by connecting it to the distal member of the stent which is anchored to the aorta wall such that "a constant, tight fit of the heart-valve stent configuration is possible." *Id*.  Fig. 2. The aortal bioprosthesis or artificial aortal valve in the proximal portion of the multi-component, self-expanding stent
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]** Figulla discloses a tissue valve interior member in the form of movable valve leaflets of a pig-heart valve that "replaces the diseased heart valve" and assumes the function of the natural heart. Ex. 1004, p. 9. **[2]** As shown above in annotated Figure 1, the pig-heart valve has a movable opening formed by the valve leaflets ("interior member") of the pig-heart valve ("tissue valve"). **[3]** The pig-heart valve disclosed by Figulla moves between a closed position and an open position in response to pressure changes in the aorta. *See* Note 1 above.
21. The aortic valve as claimed in claim 20 wherein said tissue valve interior member is respon-	**[1]** As explained in claim 20, Figulla discloses a tissue valve interior member in the form of movable valve leaflets of a pig-heart valve that "replaces the diseased heart valve" and assumes the function of the natural heart. Ex. 1004, p. 9. **[2]** The valve leaflets of the pig-heart valve disclosed by Figulla

The '228 Patent	Appendix A-1: DE 195 46 692 to Figulla (Ex. 1003 & 1004)
sive to changes in blood pressure in the aorta whereby to move said tissue valve between said first and second positions.	move between a closed position and an open position in response to changes in blood pressure in the aorta acting upon the pig heart valve. *See* Note 1.
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, Figulla discloses a tissue valve interior member in the form of movable valve leaflets of a pig-heart valve that "replaces the diseased heart valve" and assumes the function of the natural heart. Ex. 1004, p. 9. **[2]** The valve leaflets of the pig-heart valve disclosed by Figulla 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.
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, Figulla discloses a tissue valve interior member in the form of movable valve leaflets of a pig-heart valve that "replaces the diseased heart valve" and assumes the function of the natural heart. Ex. 1004, p. 9. **[2]** The valve leaflets of the pig-heart valve disclosed by Figulla 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.

The '228 Patent	Appendix A-1: DE 195 46 692 to Figulla (Ex. 1003 & 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 above in claim 20, Figulla discloses a ring member in the form of the proximal member of a multi-component stent ("ring member"). Ex. 1004, p. 9, Figs. 1, 2, and 4. **[2]** Annotated Figure 4 above shows the proximal member of the stent ("ring member") engaging the aortic wall after being placed in the aorta. **[3]** Figulla further discloses the reduction of blood flow therearound in that it discloses the use of a stent anchored to the aorta to create a "constant, tight fit of the heart-valve stent configuration." Ex. 1004, p. 9.

The '228 Patent	Appendix A-2: Figulla In View of US 6,139,575 to Shu (Ex. 1003-1005)
20. An aortic valve for controlling a blood flow through an aortic channel upon placement therein, said valve comprising:	**[1]** Figulla discloses a heart-valve prosthesis that uses a pig-heart valve to replace the function of a native aortic valve. Ex. 1004, p. 8-9. The heart-valve prosthesis disclosed in Figulla is implanted in the aorta and anchored to the aorta wall. *Id*. **[2]** Shu discloses a multi-leaflet prosthetic heart valve. Ex. 1005, p. 1 (Abstract); col. 1, ll. 5-8. Within the "Background of the Invention" section, Shu teaches the operation of a native heart valve during the cardiac cycle, how pressure changes cause the opening and closing of the leaflets of the heart valve during systole and diastole, and efforts to create prosthetic heart valves that mimic the function of a native heart valve. Ex. 1005, col. 1, ll. 11-27; col. 2, ll. 4-15. Furthermore, Shu discloses prosthetic tri-leaflet valves that mimic the operation of a natural heart valve and incorporates by reference examples of such valves (i.e., U.S. Pat. Nos. 4,222,126; 4,364,127; 5,500,016; and 5,562,729). Ex. 1005, col. 2, ll. 4-15.
a tissue valve having an interior member made of a tissue material and presenting an opening movable between open and closed positions;	**[1]** Figulla discloses a tissue valve in the form of a "pig-heart valve." Ex. 1004, p. 2. **[2]** As shown in annotated Figure 1 above, the pig-heart valve ("tissue valve") is inserted into the proximal member of a multi-component stent ("ring member"). Figure 1 also shows the movable opening and the "interior member" of the pig-heart valve ("tissue valve"). The pig-heart valve ("tissue valve") has movable valve leaflets ("interior member") made of pig heart ("a tissue material") and presents an opening movable between open and closed positions. *See also* Note 1 above. **[3]** Shu discloses that aortic valves open and close in response to changes in conditions within the aorta in that it discloses that "cardiac valves open and close passively in response to blood pressure changes operating against the valve leaflet structure." Ex. 1005, col. 1, ll. 22-24. Shu explains that "valve leaflets close when forward pressure gradient reverses and urges blood flow backward and open when forward pressure gradient urges blood flow forward." Ex. 1005, col. 1, ll. 24-27. **[5]** Shu further discloses that prosthetic heart valves "mimic the operation of a natural tricuspid valve." Ex. 1005, col. 2,

The '228 Patent	Appendix A-2: Figulla In View of US 6,139,575 to Shu (Ex. 1003-1005)
	ll. 4-15, 36-42 and 45-50. Thus, Shu teaches that prosthetic heart valve of Figulla has an opening movable between open and closed positions.
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 Figure 1, Figulla discloses a ring member in the form of a proximal member of a multi-component stent. **[2]** Figulla further discloses that the pig-heart valve ("tissue valve") is sewn into the proximal member of the multi-component stent ("ring member"). Ex. 1004, p. 9. **[3]** Figulla discloses that the proximal member of the multi-component stent ("ring member") has an outer circumference adapted to seat it about an aortic wall in that it uses the aortic wall for support. *Id*. Annotated Figure 4 above shows the proximal member of the multi-component stent ("ring member") in contact with the wall of the ascending aorta.
means for maintaining said ring member in said seated position about the aortic wall,	**[1]** As noted above in Section IV.E, the claimed "means for maintaining" disclosed in the '228 Patent comprises rods interacting with a stent. Figulla discloses the same or equivalent structure in the form of wires that connect the members of a multi-component stent. As shown above in annotated Figure 2, the proximal member of the stent ("ring member") housing the pig-heart valve ("tissue valve") is connected to the distal stent segments via connecting wires ("rods"). Ex. 1004, p. 9. **[2]** Figulla further discloses that the connecting wires ("rods") help maintain the proximal member of the stent's ("ring member") position in the aorta by connecting it to the distal member of the stent which is anchored to the aorta wall such that "a constant, tight fit of the heart-valve stent configuration is possible." *Id*.
said tissue valve interior member responsive to changes of conditions within the aorta for movement of said open-	**[1]** Figulla discloses a tissue valve interior member in the form of movable valve leaflets of a pig-heart valve that "replaces the diseased heart valve" and assumes the function of the natural heart. Ex. 1004, p. 9. **[2]** As shown above in annotated Figure 1, the pig-heart valve has a movable opening formed by the valve leaflets ("interior member") of the pig-

The '228 Patent	Appendix A-2: Figulla In View of US 6,139,575 to Shu (Ex. 1003-1005)
ing between a first closed position and a second open position.	heart valve ("tissue valve"). **[3]** The pig-heart valve disclosed by Figulla moves between a closed position and an open position in response to pressure changes in the aorta. *See* Note 1 above. **[4]** Shu discloses that aortic valves open and close in response to changes in conditions within the aorta in that it discloses that "cardiac valves open and close passively in response to blood pressure changes operating against the valve leaflet structure." Ex. 1005, col. 1, ll. 22-24. Shu explains that "valve leaflets close when forward pressure gradient reverses and urges blood flow backward and open when forward pressure gradient urges blood flow forward." Ex. 1005, col. 1, ll. 24-27. **[5]** Shu further discloses that prosthetic heart valves "mimic the operation of a natural tricuspid valve." Ex. 1005, col. 2, ll. 4-15, 36-42 and 45-50. Thus, Shu teaches that prosthetic heart valve of Figulla opens and closes in response to changes of conditions within the aorta.
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, Figulla in view of Shu discloses a tissue valve interior member in the form of movable valve leaflets of a pig-heart valve that assumes the function of the natural heart. **[2]** The valve leaflets of the pig-heart valve disclosed by Figulla move between a closed position and an open position in response to changes in blood pressure in the aorta acting upon the pig heart valve. *See* Note 1. **[3]** Shu discloses that aortic valves open and close in response to blood pressure changes in that it discloses that "cardiac valves open and close passively in response to blood pressure changes operating against the valve leaflet structure." Ex. 1005, col. 1, ll. 22-24. Shu teaches that "valve leaflets close when forward pressure gradient reverses and urges blood flow backward and open when forward pressure gradient urges blood flow forward." Ex. 1005, col. 1, ll. 24-27. **[4]** Shu further discloses that prosthetic heart valves mimic the operation natural valves. Ex. 1005, col. 2, ll. 4-15 and 45-50. Thus, Shu teaches that prosthetic heart valve of Figulla opens and closes in response to blood pressure changes in the aorta.

The '228 Patent	Appendix A-2: Figulla In View of US 6,139,575 to Shu (Ex. 1003-1005)
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, Figulla in view of Shu discloses a tissue valve interior member in the form of movable valve leaflets of a pig-heart valve that assumes the function of the natural heart. **[2]** The valve leaflets of the pig-heart valve disclosed by Figulla 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. **[3]** Shu discloses that aortic valves open during systole to "allow blood flow into the aorta" when the forward pressure gradient acts against the valve leaflet structure. Ex. 1005, col. 1, ll. 13-27. **[4]** Shu further discloses that prosthetic heart valves mimic the operation of natural valves. Ex. 1005, col. 2, ll. 4-15. Thus, Shu teaches that prosthetic heart valve of Figulla 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.
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, Figulla in view of Shu discloses a tissue valve interior member in the form of movable valve leaflets of a pig-heart valve that assumes the function of the natural heart. **[2]** The valve leaflets of the pig-heart valve disclosed by Figulla 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. **[3]** Shu discloses that aortic valves close during diastole "to prevent reverse blood flow from the aorta…into the ventricles" when the forward pressure gradient reverses and urges blood flow backward against the valve leaflet structure. Ex. 1005, col. 1, ll.13-27. **[4]** Shu further discloses that prosthetic heart valves mimic the operation of natural valves. Ex. 1005, col. 2, ll. 4-15. Thus, Shu teaches that prosthetic heart valve of Figulla 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.

The '228 Patent	Appendix A-2: Figulla In View of US 6,139,575 to Shu (Ex. 1003-1005)
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 above in claim 20, Figulla discloses a ring member in the form of the proximal member of a multi-component stent ("ring member"). Ex. 1004, p. 9, Figs. 1, 2, and 4. **[2]** Annotated Figure 4 above shows the proximal member of the stent ("ring member") engaging the aortic wall after being placed in the aorta. **[3]** Figulla further discloses the reduction of blood flow therearound in that it discloses the use of a stent anchored to the aorta to create a "constant, tight fit of the heart-valve stent configuration." Ex. 1004, p. 9.

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. §§ 42.6 and 42.105, I hereby certify that a true copy of the SECOND PETITION FOR *INTER PARTES* REVIEW UNDER 37 C.F.R. § 42.100 with Appendices A-1 – A-2 and Exhibits 1001-1015 was served by EXPRESS MAIL (or by means at least as fast and reliable) this 27th day of May, 2014 on the attorney of record of U.S. Patent No. 6,482,228 shown in PAIR and the attorneys of record for related IPR2014-00111 and the concurrent litigation matter:

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