UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ST. JUDE MEDICAL, LLC
Petitioner

v.

SNYDERS HEART VALVE LLC
Patent Owner

Patent No. 6,821,297 to Robert V. Snyders
Issue Date: November 23, 2004
Title: ARTIFICIAL HEART VALVE

Inter Partes Review No. IPR2018-00109

PETITION FOR *INTER PARTES* REVIEW OF CLAIMS 18 AND 20 OF U.S. PATENT NO. 6,821,297

Mail Stop: Patent Board
Patent Trial and Appeal Board
U.S. Patent And Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes, Rules & Other Authorities

EXHIBIT LIST

Exhibit #	Reference
1001	U.S. Patent No. 6,821,297
1002	Complaint, *Snyders Heart Valve LLC v. St. Jude Med. S.C., Inc. et al.*, Civil Action No. 4:16-cv-00812 (E.D. Tex.Sherman Div. Oct. 25, 2016)
1003	Declaration of Lakshmi Prasad Dasi, Ph.D.
1004	*Curriculum Vitae* of Lakshmi Prasad Dasi, Ph.D.
1005	Lyle J. Olsen *et al.*, *Aortic Valve Stenosis: Etiology, Pathophysiology, Evaluation, and Management*, 12 Curr Probl Cardiol (August 1987), at 458-508 ("Anatomical Drawing Source")
1006	U.S. Patent No. 5,411,552 (issued May 2, 1995) ("Andersen")
1007	U.S. Patent No. 5,545,214 (issued Aug. 13, 1996) ("Stevens")
1008	U.S. Patent No. 5,855,601 (issued Jan. 5, 1999) ("Bessler")
1009	International Publication No. WO 98/29057 (published July 9, 1998) ("Letac")
1010	U.S. Patent No. 3,671,979 (issued June 27, 1972) ("Moulopoulos")
1011	Provisional Application No. 60/179,853 — Specification, Appendix A, Appendix B, Cover Sheet
1012	Rejection, U.S. Serial No. 09/775,360, Apr. 10, 2002
1013	U.S. Patent No. 5,332,402 (issued July 26, 1994) ("Teitelbaum")
1014	Response, U.S. Serial No. 09/775,360, July 10, 2002
1015	Amendment After Final, U.S. Serial No. 09/775,360, Dec. 16, 2002
1016	U.S. Patent No. 6,540,782 (issued Apr. 1, 2003) ("Parent Application")
1017	U.S. Patent No. 5,957,949 (issued Sept. 28, 1999) ("Leonhardt")
1018	Final Rejection, U.S. Serial No. 10/135,746, Feb. 11, 2004
1019	Supplemental Amendment, U.S. Serial No. 10/135,746, July 9, 2004
1020	U.S. Patent No. 5,413,599 (issued May 9, 1995) ("Imachi")
1021	U.S. Patent No. 4,339,831 (issued July 20, 1982) ("Johnson")
1022	U.S. Patent No. 5,397,351 (issued Mar. 14, 1995) ("Pavcnik")
1023	U.S. Patent No. 3,657,744 (issued Apr. 25, 1972) ("Ersek")
1024	U.S. Patent No. 6,458,153 (issued Oct. 1, 2002) ("Bailey")
1025	Jerald L. Cohen *et al.*, *Two-dimensional echocardiographic preoperative prediction of prosthetic aortic valve size*, 107(1) Am. Heart J. (Jan. 1984), at 108-112

Exhibit #	Reference
1026	John A. Ormiston *et al.*, *Size and Motion of the Mitral Valve Annulus in Man:I.A Two-dimensional Echocardiographic Method and Findings in Normal Subjects*, 64(1) Circulation (July 1981), at 113-120
1027	Thomas Sandgren *et al.*, *The diameter of the common femoral artery in healthy human: Influence of sex, age, and body size*, 29 J. Vasc. Surg. (Mar. 1999), at 503-510
1028	John O. Burris *et al.*, *Pathophysiological Considerations In Aortic Valve Disease*, 147(18) Annals New York Academy Scis. (Oct. 30, 1969), at 716-724
1029	Lieutenant Richard Gorlin (MC) USNR & Robert B. Case, M.D., *Clinical Diagnosis of Aortic-Valve Disease*, 255(8) New England J. Med. (Aug. 23, 1956), at 368-373
1030	Blase A. Carabello, *Mitral Valve Disease*, 18 Curr Probl Cardiol (July 1993), at 425-478
1031	Kenneth V. Iserson MD, FACEP, *J.-F.-B. Charrière: The Man Behind The "French" Gauge*, 5 J. Emerg. Med. (1987), at 545-548
1032	Kenneth V. Iserson MD, FACEP, *The Origins Of The Gauge System For Medical Equipment*, 5 J. Emerg. Med. (1987), at 45-48
1033	Robert V. Snyders, M.D.
1034	Marc Bessler, M.D.
1035	Prof. Alain Cribier, M.D.
1036	Howard J. Leonhardt, Honorary Ph.D.
1037	Kou Imachi, Ph.D.
1038	Spyridon D. Moulopoulos, Ph.D, M.D.
1039	Disclosure of Asserted Claims and Infringement Contentions ("Contentions"), *Snyders Heart Valve LLC v. St. Jude Med. S.C., Inc. et al.*, Civil Action No. 4:16-cv-00812 (E.D. Tex.Sherman Div. May 1, 2017)
1040	Disclosure of Asserted Claims and Infringement Contentions ("Contentions") Exhibit 2, *Snyders Heart Valve LLC v. St. Jude Med. S.C., Inc. et al.*, Civil Action No. 4:16-cv-00812 (E.D. Tex.Sherman Div. May 1, 2017)

Exhibit #	Reference
1041	Joint Claim Construction & Prehearing Statement, *Snyders Heart Valve LLC v. St. Jude Med. S.C., Inc. et al.*, Civil Action No. 4:16-cv-00812 (E.D. Tex.Sherman Div. July 24, 2017), ECF No. 153
1042	N. Zuhdi, M.D. *et al., Porcine Aortic Valves as Replacements for Human Heart Valves,* 17(5) Annals Thoracic Surg. (May 1974), at 479-491
1043	Edward B. Stinson *et al., Long-term experience with porcine aortic valve xenografts,* 73(1) J. Thoracic & Cardiovascular Surg. (Jan. 1977), at 54-63
1044	Aortic Valve© 1997-2017 Medical Legal Art.
1045	U.S. Patent No. 17,520 (issued June 9, 1857)
1046	U.S. Patent No. 3,543,674 (issued Dec. 1, 1970)
1047	U.S. Patent No. 4,783,662 (issued Nov. 8, 1988)
1048	U.S. Patent No. 6,267,776 (issued July 31, 2001)
1049	U.S. Patent No. 1,466,114 (issued Aug. 28, 1923)
1050	U.S. Patent No. 2,282,285 (issued May 5, 1942)
1051	U.S. Patent No. 3,253,326 (issued May 31, 1966)
1052	Notice of Allowance, U.S. Serial No. 10/135,746, July 27, 2004
1053	U.S. Patent No. 6,623,518 (issued Sep. 23, 2003) ("Thompson")
1054	International Publication No. WO 1997/016133 (published May 9, 1997) ("Taylor")
1055	Non-Final Rejection, U.S. Serial No. 10/135,746, Sep. 10, 2003
1056	Response to Non-Final, U.S. Serial No. 10/135,746, Nov. 24, 2003
1057	Response to Final, U.S. Serial No. 10/135,746, May 11, 2004
1058	U.S. Patent No. 5,421,955 (issued June 6, 1995) ("Lau")
1059	U.S. Patent No. 5,292,331 (issued Mar. 8, 1994)
1060	Ulrich Sigwart *et al., Intravascular Stents to Prevent Occlusion and Restenosis After Transluminal Angioplasty,* 316(12) New England J. Med. (Mar. 19, 1987), at 701-706
1061	H.R. Andersen *et al., Transluminal implantation of artificial heart valves. Description of a new expandable aortic valve and initial results with implantation by catheter technique in closed chest pigs,* 13 Euro. Heart J. (1992), at 704-708
1062	U.S. Patent Application No. 09/775,360 (as filed)

Exhibit #	Reference
1063	U.S. Patent No. 4,580,568 (issued Apr. 8, 1986)

Petitioner, St. Jude Medical, LLC, requests *inter partes* review of claims 18 and 20 ("challenged claims") of U.S. Patent No. 6,821,297 ("the '297 Patent") (Ex.1001).

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

A. Notice Of Each Real-Party-In-Interest

The Real-Parties-In-Interest for this Petition are St. Jude Medical S.C., Inc., and St. Jude Medical, Cardiology Division, Inc., which are both wholly owned subsidiaries of St. Jude Medical, LLC, which is itself a wholly owned subsidiary of Abbott Laboratories. All are Real-Parties-In-Interest and are collectively referred to herein as "St. Jude."

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

Patent Owner, Snyders Heart Valve LLC, filed suit against Petitioner on October 25, 2016, in the Eastern District of Texas, Sherman Division (Civil Action No. 4:16-cv-00812), alleging infringement of the challenged claims of the '297 Patent (Ex.1002) and its parent, U.S. Patent No. 6,540,782 (Ex.1016). While the present Petition is directed exclusively to method claims 18 and 20 of the '297 Patent, a second IPR Petition is filed concurrently seeking cancellation of device claims 1-3, 8, 9, 22, 23, 31-35, 37-39, and 45 of the '297 Patent bearing Attorney Docket No. STJUDE 7.1R-004. Two other IPRs are being filed

concurrently against select claims of Ex.1016 bearing Attorney Docket Nos. STJUDE 7.1R-002 and STJUDE 7.1R-003.

NOTICE OF LEAD AND BACKUP COUNSEL

Lead Counsel:	**Backup Counsel:**
Michael H. Teschner (Reg. 32,862) MTeschner.ipr@ldlkm.com Postal and Hand-Delivery Address 600 South Avenue West Westfield, NJ 07090 Telephone: 908.518.6313 Fax: 908.654.7866	Stephen M. Lund (Reg. No. 64,249) slund@lernerdavid.com Maegan A. Fuller (Reg. No. 71,596) MFuller.ipr@ldlkm.com Postal and Hand-Delivery Address 600 South Avenue West Westfield, NJ 07090 Telephone: 908.654.5000 Fax: 908.654.7866

C. Notice Of Service Information

Please address all correspondence to the lead and backup counsel at the address shown above. Petitioner also consents to electronic service by e-mail at: MTeschner.ipr@ldlkm.com, MFuller.ipr@ldlkm.com, and slund@lernerdavid.com.

D. Grounds For Standing

Petitioner certifies that: (1) the ’297 Patent is available for IPR; and (2) Petitioner is not barred or estopped from requesting IPR of the ’297 Patent on the grounds identified herein. The fee for this Petition has been paid. The Office is hereby authorized to charge any fee deficiencies to, or credit any overpayments to, deposit account no. 12-1095 in connection with this Petition.

II. STATEMENT OF PRECISE RELIEF REQUESTED (37 C.F.R. § 42.22(a))

For the reasons set forth herein, there is a reasonable likelihood that Petitioner will prevail with respect to at least one of the challenged claims in this Petition. Accordingly, Petitioner requests institution of an IPR and cancellation of method claims 18 and 20 of the '297 Patent.

III. IDENTIFICATION OF THE CHALLENGE (37 C.F.R. § 42.104(b))

Petitioner requests that the challenged claims be canceled as unpatentable based on the following grounds:

Ground 1. Claims 18 and 20 are anticipated by Leonhardt.

Ground 2. Claims 18 and 20 are obvious over Leonhardt.

Ground 3. Claims 18 and 20 are obvious over Leonhardt in view of Johnson.

Pursuant to 37 C.F.R. § 42.6(d), a copy of each reference is filed herewith. In support of the proposed grounds of unpatentability, this Petition is accompanied by the declaration of Dr. Lakshmi Prasad Dasi (Ex.1003), explaining what the art would have conveyed to a person of ordinary skill in the art ("POSA") at the time of the invention. Dr. Dasi's *curriculum vitae* is included as well (Ex.1004).

IV. INTRODUCTION AND SUMMARY OF ARGUMENT

Some artificial heart valves can be collapsed, inserted into the heart, and expanded in the annulus of a defective native valve to take over that valve's

function. These collapsible valves are implanted much like cardiac stents, through the patient's vasculature, avoiding invasive open chest surgery. The described invention relates to methods of implanting one specific collapsible implantable valve architecture. But, according to Patent Owner, who purchased this patent and its parent just prior to commencing litigation, the claims are not so limited. The method claims at issue here recite methods of implanting this specific valve device.

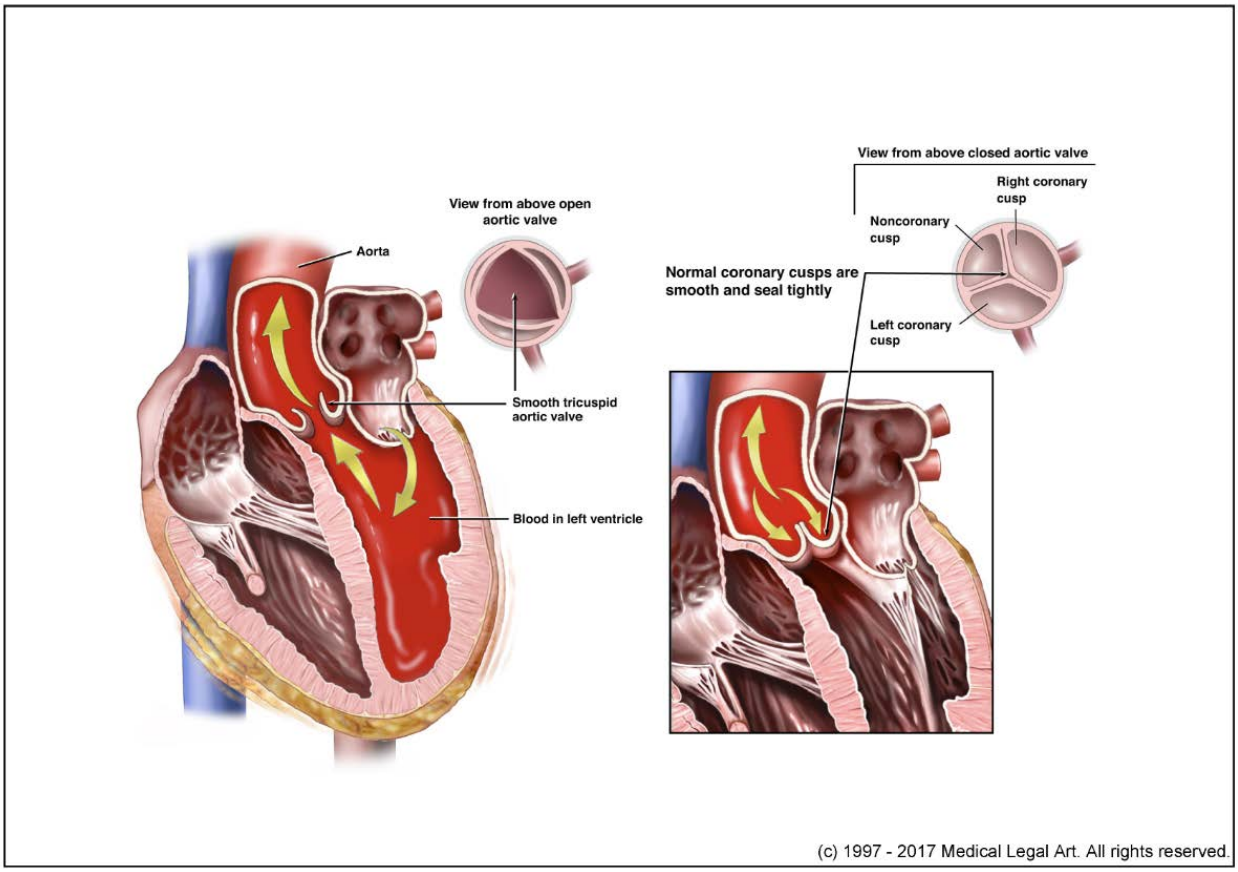
V. BACKGROUND

Surgical replacement valves date back more than a half century, as the references cited in the '297 Patent established. (Exs.1001 col.1:57-65; 1003 ¶24.) However, valve replacement surgery is extremely invasive. (Ex.1001 col.1:29-46.) Perhaps not surprisingly, the development of transcatheter devices and procedures had already begun in an effort to overcome the many disadvantages of open surgical intervention by the time this patent was filed. (*Id.* 1:66-2:24; Ex.1003 ¶24.)

A. Native And Replacement Valves

FIG.A is an anatomical drawing of a native human aortic valve.

FIG.A



(Ex.1044, with redactions.)

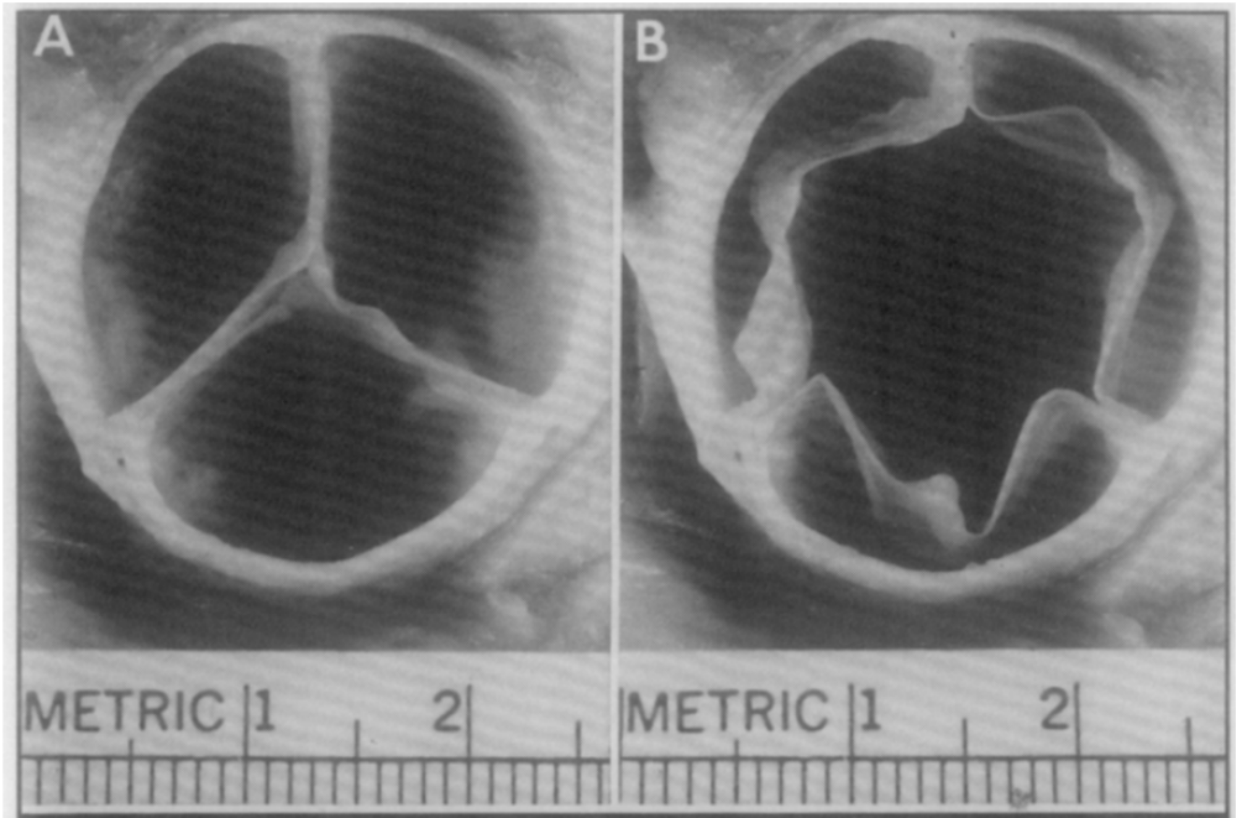
The aortic valve shown in FIG.A is referred to as a "tricuspid" valve because the valve element comprises three separate leaflets or "cusps" that cooperate to permit forward (downstream), and prevent reverse (upstream), blood flow. Other valves, such as the mitral valve, have only two leaflets. In the above example, when the left ventricle contracts, the resulting pressure differential forces blood from the heart into the aorta through the aortic valve. The three leaflets are forced apart, moving outwardly toward the annulus wall, thereby allowing blood to flow downstream between them. (Ex.1003 ¶22.) When the contraction stops, blood

attempts to flow upstream, back into the ventricle. Because of the arrangement and location of the leaflets, blood forces them to come back together in the center of the annulus (coaptation), stopping the flow of blood. This anatomy is shared with other mammals such as pigs. Indeed, porcine valves have long been used as replacements for human valves. (*Id.* ¶23.)

As shown in FIG.B, many of the designs for collapsible replacement valves, including those approved in the U.S. and those disclosed in prior art patents (*e.g.*, shown below the photos of the native valve), mimic this natural trileaflet architecture. (*Id.* ¶¶26-28.)

FIG.B

Native valve



(A) Native valve closed; (B) Native valve opened

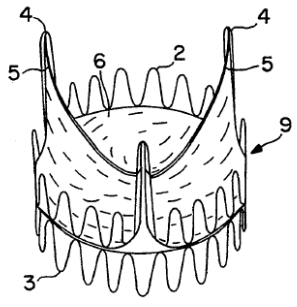


FIG. 2

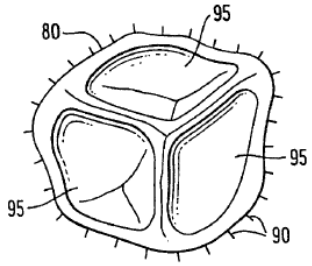


FIG. 12

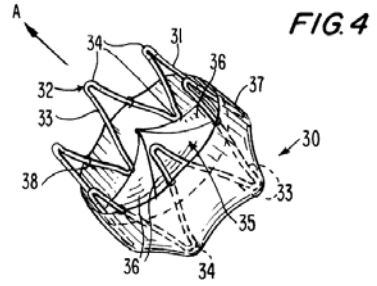
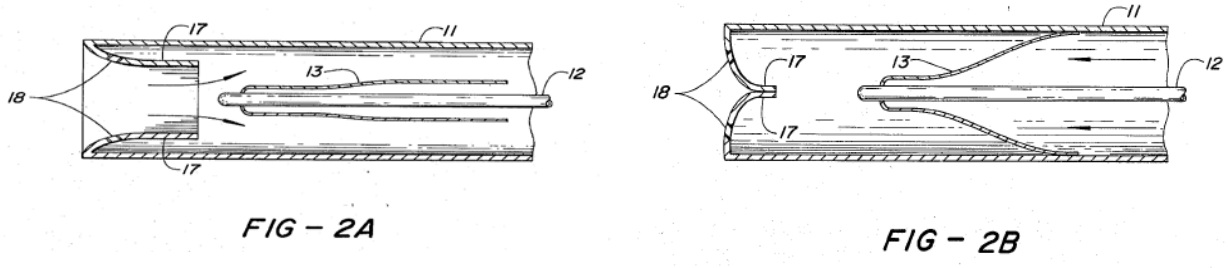


FIG. 4

(*See* Exs.1005 p.461, FIG.1; 1006 FIG.2; 1007 FIG.12; 1008 FIG.4.)

Others suggested a single flap or inverted funnel shaped valve element that opens and closes in a manner that is the opposite of a native valve.



(Ex.1010 FIGS.2A, 2B.) In FIG.2A, the native valve is in the open position with its leaflets 17 pushed toward the walls of the vessel to create a central opening. The funnel valve, to its right, is also open, but flap 13 is compacted into the center of the vessel with blood flowing around and not through it. In FIG.2B, both valves are closed to prevent backflow. In the leaflet valve on the left, the leaflets 17 are forced into the center where they meet and form a seal. In the funnel valve on the right, the flap 13 fills with blood and expands outwardly until the edges meet the vessel. (Ex.1003 ¶¶29-32.)

Johnson, U.S. Patent No. 4,339,831 (Ex.1021), also discloses an inverted funnel valve made from a unitary flap attached to U-shaped frame elements so as to form what Dr. Snyders referred to as “reversing” or “reversed” cusps. (Exs.1011 App.A p.A-3:17-26; App.B p.B-8:13-24; *see also* 1003 ¶33.)

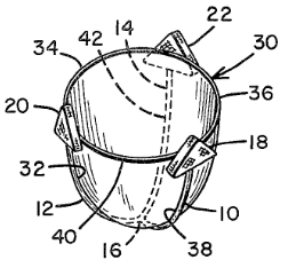


Fig. 2

B. Transcatheter Implantation

Before there were transcatheter or percutaneous heart valves, interventional cardiologists had been using transcatheter procedures to perform angioplasty and the placement of cardiac stents in blocked coronary arteries, whose entrances are immediately downstream of the aortic valve. (Ex.1003 ¶41.)

The procedure described in Lau *et al.* is typical of the implantation techniques used for placing cardiac stents. (Exs.1058; 1003 ¶42.) The stent is first mounted on the distal extremity of the delivery catheter — in this case, a balloon catheter. The catheter-stent assembly is introduced into the patient's vasculature "in a conventional Seldinger technique through a guiding catheter (not shown)." (Ex.1058 col.4:58-61.) First, a guidewire is introduced into the incision and is positioned "across" the damaged vascular section (the treatment site) and then the catheter containing the stent is "threaded" onto the guidewire, usually through a central bore in the catheter, which also traverses the stent. (*See id.* FIG.1 — guidewire is fed through the stent and delivery catheter.) It is then

advanced over the guidewire, through the incision and the vasculature until the treatment site is reached. In this case, the balloon of the catheter is expanded, thereby expanding the stent against the artery wall. (*Id.* 4:61-68; *see also* Exs.1059 col.5:45-6:26; 1003 ¶43.)

This described procedure used a balloon expandable device, but Lau recognized that other types of stents can be used. For example, the stent could be made of a plastic material that is heat deformable or made from a superelastic material such as nickel titanium alloys (nitinol). Such devices would be self-expanding. (Exs.1058 col.6:7-7:2; 1003 ¶44; *see also* 1060 p.701 ("Description of the Stent.")

This same basic procedure is employed when placing transcatheter heart valves. Obviously valve replacement requires stents containing a flexible valve element ("FVE") attached within the stent. It also implicates a different treatment site. However, the entry point, general equipment, and overall procedure used are the same. (Ex.1003 ¶49.) Indeed, in many ways, the valvular procedures are simpler. In both, one needs to gain access to, for example, the femoral artery, and negotiate through the patient's vasculature, around the aortic arch, and into the ascending aorta. However, from there, less additional navigation is required when implanting a prosthetic aortic valve. When implanting a cardiac stent, however,

entry must be made into the coronary arteries and their various twists and turns must be traversed. (*Id.*)

The implantation procedures for stented valves mirrors earlier arterial stent procedures. The femoral artery approach is most desired for humans. "Obviously, the femoral route should be used in humans, preferentially by a percutaneous approach, alternatively by arteriotomy." (Ex.1061 p.708 (Andersen, *Transluminal Implantation of Artificial Heart Valves . . . ,* 13 Euro. Heart J. 1992, at 704-08) ("Andersen article").) A "conventional catheter-over-guidewire advancement" method is used. (*Id.* p.705.) A guidewire is advanced retrograde into the left ventricle and an introducer sheath is advanced over the guidewire into the descending thoracic aorta. (*Id.* p.706.) A carrier balloon catheter is then pushed out from the sheath and advanced further around the aortic arch. (*Id*.) For subcoronary implantation, the stent valve is positioned in the aortic root/left ventricle outflow track beneath the coronary arteries at the level of the native aortic valve. (*Id.*) When the stent valve is placed in the correct position, implantation via stent-valve expansion is performed. (*Id.*; Ex.1003 ¶50.)

In this Andersen article, implantation was accomplished by balloon inflation. (*See* Ex.1061 p.706.) However, the corresponding Andersen patent (Ex.1006), which details the same type of device (*compare* Ex.1006 FIGS.1 and 2 *and* Ex.1061 FIGS.1(a) and 1(b)), also teaches using a self-expanding version of the

stent. And the Andersen patent describes using the same basic device and a nonballoon procedure. (Exs.1006 cols.2:44-3:4, 7:21-23, 7:30-55; 1003 ¶51.)

The overall procedures used for placement of a transcatheter replacement valve parallel the earlier procedures already used for placement of coronary stents for more than a decade. The use of a guidewire and its positioning at the desired location, the threading of a delivery device over the guidewire and its movement along the guidewire until the proper deployment site is reached, followed by deployment were all well known. (Ex.1003 ¶52.)

VI. THE ’297 PATENT

A. The Specification Of The ’297 Patent

The ’297 Patent is a continuation-in-part of U.S. Patent No. 6,540,782 (Ex.1016), which in turn claims priority to a provisional application (Ex.1011). The parent and the provisional applications are both incorporated by reference into the ’297 Patent, with the provisional application including two detailed appendixes; A and B. (Ex.1011.) Together, these documents describe a stented funnel valve prosthesis, which consists of a conical geodesic ”bird-cage”-styled external supporting wire framework fabricated of any biocompatible metallic material with an internally disposed and congruently fabricated unitary flexible funnel-shaped member located within this cage. (Ex.1011 App.B p.B-5:12-17, *see*

also p.B-7:7-11, FIG.2.) The ’297 Patent’s specification provides a similar general description of this valve. (Ex.1001 cols.5:17-34, 7:7-18, 7:55-66, FIGS.2, 3.)

The outer edge of the FVE’s unitary funnel is “tacked down” to each of the “U-shaped” frame elements or to selected portions of an internal band. (*Id.* 7:55-66.) The rest of the edge is free to move radially inwardly. (*Id.* 7:18-36, 7:66-8:14.) FIG.C illustrates the valve of FIG.2 of the ’297 Patent oriented as it would be in the aortic annulus. FIG.D is based on FIG.3 thereof, looking down into the valve, from the aorta, showing blood flow up out of the page around the unitary FVE.

FIG.C

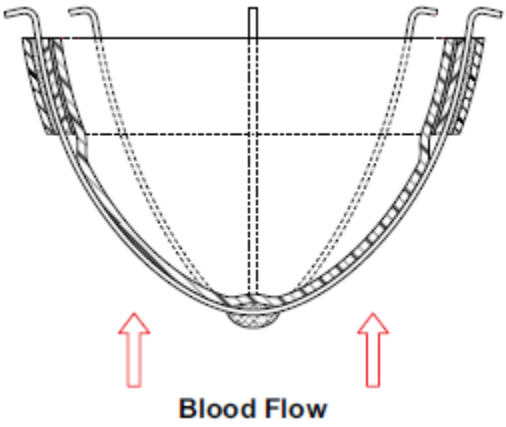
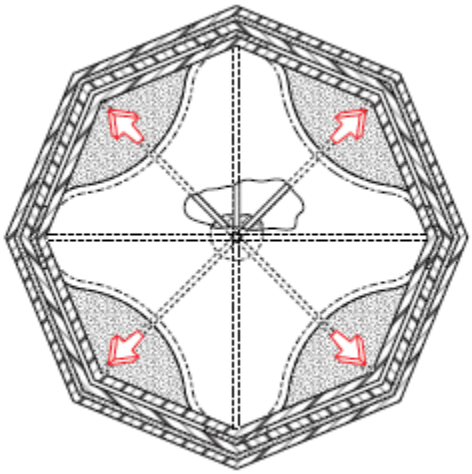


FIG.D



As the left ventricle contracts, blood pushes these free edges centrally, and blood flows around the unitary funnel (shown by the arrows in FIGS.C, D), instead of through the valve's center as is typical with valves that mimic the native architecture. When the contraction stops and blood flow reverses, the funnel fills with blood, forcing the edges to engage the side walls of the vessel or a band sealing off blood flow.

The inventor discussed Bessler (Ex.1008) extensively in the appendixes of the provisional application and also in the nonprovisional application. The inventor acknowledged that Bessler discloses a transcatheter valve that uses a "trileaflet stented valve housing," which is characterized as "a bulky prosthetic valve." (Exs.1011 App.A-3:9-22; *see also* 1001 col.2:18-23; 1003 ¶¶53-57.)

The '297 Patent includes additional disclosure not found in its parent. Generally, that additional disclosure is directed to: particular flap lengths of the

FVE (col.10:62-11:6); providing longitudinal pleats in the FVE (col.11:7-27); band constructions (col.11:28-12:53); an alternate to a band (col.12:54-64); mechanisms for connecting the valve to an instrument (col.12:65-13:35, 14:66-15:11); additional details on the delivery system (col.13:36-14:65); additional details of a delivery guide and vascular catheter sensors (col.15:28-52); and additional delivery methods (col.15:53-18:15).

With regard to the claimed implantation procedures, common to both the ’297 Patent and its parent is a discussion referring to FIGS.4 and 5. (Exs.1001 cols.8:14-51, 9:7-48; 1016 cols.8:9-39, 8:54-67; 1003 ¶58.) For transcatheter placement, an incision is made in a vessel such as the femoral artery. An end of the delivery instrument including a holder is inserted through the incision and pushed through the vessel over a guidewire until the end is adjacent the cusps of the damaged valve. Once in position, the artificial valve is ejected from the end of the instrument between the cusps of the damaged valve. There is additional disclosure in the ’297 Patent, but the above disclosure was common to both the ’297 Patent and its parent.

Nothing in the specification of the ’782 Patent (the parent application) discloses repositioning the valve once initially deployed. That however is described in the ’297 Patent. (Ex.1001 col.17:29-46.) The ’297 Patent first describes a “proper” placement using a device with a particular fastener in

col.16:64-17:28. It then explains that in one particular embodiment, the position of the valve may not be optimal after ejection. (*Id.* 17:28-31.) In such cases, the surgeon may "retrieve" the valve back into the end of the delivery instrument by advancing the manipulator 344 over the installer 328 retrieving the valve to collapse the valve back into the instrument. The valve can then be repositioned and released as previously described. (*Id.* 17:30-46.) There were other changes made in terms of placement procedures in the new subject matter added in the specification of the '297 Patent, but none of that is relevant to this Petition.

B. The Prosecution History Of The '297 Patent

Neither the prosecution history of the issued parent (Ex.1016) nor that of the '297 Patent focused on the specifics of the methods of claims 18 and 20. Those claims depend from independent device claim 1 and prosecution focused almost exclusively on the alleged patentability of the claimed devices. While reviewed by Dr. Dasi (Ex.1003 ¶¶60-69) in general, the prosecution of the '782 Patent is not relevant to the method issues here. There were discussions of Johnson (Ex.1021) as a primary reference but they are not particularly instructive. As for the '297 Patent, claims 1, 2, 8, 9, 16, 17, 26-29, 32, and 33 were rejected as anticipated by Teitelbaum (Ex.1013) in a nonfinal rejection. (Ex.1055 p.3.) Various additional claim objections and rejections for indefiniteness were simultaneously issued. (*Id.* p.2.) In response, no claim amendments were provided to address the anticipation

or indefiniteness rejections. (Ex.1056 pp.2-13.) Instead, the applicant argued that "Teitelbaum fails to disclose or suggest a frame having a plurality of peripheral anchors or a central portion located between the anchors. Further, Teitelbaum fails to disclose a flexible valve element attached to the central portion of the frame." (*Id.* p.14.)

In a final rejection, the Examiner repeated the anticipation rejection, asserting that Teitelbaum teaches a "frame element 12" that "is comprised of a plurality of self-expanding anchors," and further asserting that the claimed central portion located between the anchors "could be any centrally located portion of the frame 12." (Ex.1018 p.2.) The applicant responded by noting that "Applicant appreciates the broad interpretation of the claims the Examiner has obviously chosen" (Ex.1057 p.14) and amended independent claims 1, 17, 26, and 33 (which issued as claims 1, 22, 31, and 38, respectively) (*id.* pp.2-14). Claims 1 and 26 were amended to recite that the central portion of the frame is located "along a centerline extending" between the plurality of peripheral anchors "and between said plurality of cusps when said frame is inserted in the position between the upstream region and the downstream region." (*Id.* pp.2, 7.) The argument included with the amendments in respect to Teitelbaum were cut off, with the response ending with the fragment of "[t]he claims have been amended to." (*Id.* p.14.) The Applicant subsequently filed a supplemental amendment to supply the missing

text, which simply reads that "[t]he claims have been amended to clarify the distinguishing features of the claims of the subject application over the prior art." (Ex.1019 p.14.)

The Examiner allowed the case without comment on reasons for allowance, and with Examiner's amendments not relevant to this Petition. (Ex.1052 p.5.) Again there was nothing in the prosecution history directly relevant to the method step *per se*.

C. Priority

The '297 Patent is a CIP of the '782 Patent and Patent Owner has acknowledged that claim 18, challenged here, is not entitled to a priority date earlier than the filing date of the CIP on April 30, 2002. (Ex.1039 p.3.) However, Petitioner submits that the remaining challenged claim, claim 20, is not entitled to an earlier date either because it does not satisfy 35 U.S.C. § 120.

"In order to gain the benefit of the filing date of an earlier application under 35 U.S.C. § 120, each application in the chain leading back to the earlier application must comply with the written description requirement of 35 U.S.C. § 112." *Lockwood v. Am. Airlines, Inc.*, 107 F.3d 1565, 1571 (Fed. Cir. 1997). As explained in *Lockwood*, in considering entitlement to a filing date, "[t]he question is not whether a claimed invention is an obvious variant of that which is disclosed in the specification. Rather, a prior application itself must describe an invention,

and do so in sufficient detail that one skilled in the art can clearly conclude that the inventor invented the claimed invention as of the filing date sought." *Id.* at 1572 (citing *Martin v. Mayer*, 823 F.2d 500, 504 (Fed. Cir. 1987) (it is "not a question of whether one skilled in the art *might* be able to construct the patentee's device from the teachings of the disclosure. . . . Rather, it is a question whether the application necessarily discloses that particular device.") (emphasis in original). For example, where a grandparent application and the application at issue contained the requisite description, but the intervening parent application did not, the applicant was not entitled to the benefit of the grandparent application. *See In re Seversky*, 474 F.2d 671, 177 U.S.P.Q. 144 (C.C.P.A. 1973); *see also In re NTP, Inc.*, 654 F.3d 1268, 1276-77 (Fed. Cir. 2011).

Claim 20 requires "inserting an end of a guide[wire] through the incision made in the vessel," "pushing the guide[wire] through the vessel," and "threading an elongate flexible instrument having a hollow interior onto the guide[wire]." (Ex.1001 col.21:35-39 (emphasis added).) However, neither the text of the parent '782 Patent nor that of the application leading to the '782 Patent, Serial No. 09/775,360 (Ex.1062), mentions "insertion of a guide[wire] through the incision" or "pushing the guide[wire]" through the vessel. The language used in the specification suggests that the device can be moved "over" the guidewire but

nothing explains that the instrument or valve is placed "onto" the guidewire or that a flexible instrument is "threaded" thereon.

There is no written description provided for these expressly claimed steps in the '297 Patent's parent and the corresponding application (Exs.1016, 1062), and therefore Patent Owner's claim to priority from the application leading to the '782 Patent for claim 20 is inappropriate.

VII. PERSON OF SKILL IN THE ART

Factors relevant to determining the level of skill in the art include: the educational level of the inventors, the types of problems encountered in the art, prior art solutions to those problems, the rapidity with which innovations are made, the sophistication of the technology, and the educational level of active workers in the field. *Mintz v. Dietz & Watson, Inc.*, 679 F.3d 1373, 1376 (Fed. Cir. 2012). The named inventor of the '297 Patent (Ex.1001) as well as named inventors in Andersen (Ex.1006), Bessler (Ex.1008), Letac (Ex.1009), Moulopoulos (Ex.1010), and Imachi (Ex.1020) have an M.D. or Ph.D. in a relevant engineering discipline plus several years of practical heart valve replacement experience. (Ex.1003 ¶¶15-17.) As Dr. Dasi explains, the technology requires advanced knowledge of medical devices, anatomy, surgery, and medicine. (*Id.*) But the technology was developing and innovation was fairly regular. The elements and procedures used were also well established. Thus, a POSA is a medical doctor or has an advanced

degree (at least a master's degree) in a relevant engineering discipline with several years of experience or someone who holds a lesser degree with more experience in the field of artificial heart valves.

VIII. CLAIM CONSTRUCTION

The legal standard applicable in IPR was set forth by the Supreme Court in *Cuozzo Speed Techs. v. Lee,* 579 U.S. ___, 136 S. Ct. 2131 (2016). On July 21, 2017, Patent Owner and Petitioner submitted to the court in Texas their Joint Memorandum on Claim Construction ("Joint Memo") (Ex.1041) for the challenged claims of the '297 Patent and its parent (Ex.1016) under the ordinary and customary meaning standard applicable therein.

Petitioner disagrees with Patent Owner's proposed definitions and will pursue the construction Petitioner set forth in Ex.1041 in court. *See Dish Network L.L.C. v. TQ Delta LLC,* IPR 2016-01470 Institution Decision, Paper No.14, at 6-7 (Feb. 9, 2017) and Petition, Paper No. 1, at 11 (July 20, 2016) ("fine grain parameter") (accepting Patent Owner's court construction in IPR without Petitioner acquiescing in that construction). Patent Owner's proposed constructions are admissions against its interest and Petitioner should have the right to rely upon them in this IPR. *Cf. Aylus Networks, Inc. v. Apple Inc.*, 856 F.3d 1353, 1362 (Fed. Cir. 2017). Moreover, Patent Owner cannot argue for a narrower interpretation

here as it has claimed that its constructions in the district court action allegedly represent the ordinary and customary meaning of these terms.

On May 1, 2017, Patent Owner served infringement contentions (Ex.1039), including an Exhibit 2 (Ex.1040) (the "Contentions") identifying elements of Petitioner's PORTICO® aortic replacement valve allegedly meeting the various claimed elements. In doing so, it identified structures allegedly literally encompassed by the challenged claims as Patent Owner defines and/or construes them.

However, these structures existed in the prior art and therefore anticipate the challenged claims. *See Lewmar Marine, Inc. v. Barient, Inc.*, 827 F.2d 744, 747 (Fed. Cir. 1987) ("That which would *literally* infringe if later in time anticipates if earlier than the date of invention.") (emphasis in original). At the very least, the challenged claims are rendered obvious by that art.

Based on Patent Owner's proposed constructions in the district court action, including those derived from its Contentions (Exs.1040 and 1041, collectively

"Definition(s)" or "Define(s)(d)"), the following terms[1] should be given the following constructions solely for purposes of this IPR:

Term	Construction
Frame	Ex.1041 p.2 Term 3: A structure designed to shape or support Ex.1040 pp.2-4
Peripheral anchor(s)	Ex.1041 p.2 Term 5 Anchor(s): Structure(s) that secures or stabilizes something in place Peripheral: Located on the periphery Ex.1040 pp.4-5
Central portion located along a centerline extending between the plurality of peripheral anchors	Ex.1041 p.2 Terms 7-9: Any location between a plurality of peripheral anchors** Ex.1040 pp.5-6
Flexible valve element	Ex.1041 p.3 Term 12: A flexible part of the valve Ex.1040 pp.6-7
Opening extending through at least one of said frame and said flexible valve element for receiving an implement	Ex.1041 p.3 Term 17: Any opening extending through the flexible valve element and the central portion of the frame** Ex.1040 p.12
Flexibly resilient	Ex.1041 p.4 Term 23: Able to spring back to its original shape, on its own, after being compressed

[1] The Joint Memo (Ex.1041) includes additional terms not provided in the chart below. Construction of those additional terms is not believed necessary for the purpose of this IPR and thus those terms are not separately addressed herein.

Term	Construction
	Ex.1040 pp.2-4

**No explicit construction offered — construction derived from the Contentions (Ex.1040).

All of the challenged claims are anticipated and/or rendered obvious if Patent Owner's Definitions are applied. Indeed, all of the challenged claims are obvious as described in Ground 3 even if a number of the constructions offered by Petitioner in court were adopted.

IX. THERE IS A REASONABLE LIKELIHOOD THAT AT LEAST ONE CLAIM OF THE '297 PATENT IS UNPATENTABLE

A. Anticipation

1. Ground 1: Claims 18 And 20 Are Anticipated By Leonhardt

The validity of claim 1 of the '297 Patent is the subject of a separate IPR filed under attorney docket no. STJUDE 7.1R-004 concurrently with this Petition. However, because the challenged claims here, method claims 18 and 20, depend directly from device claim 1, each of the recitations of claim 1 is addressed before turning to the additional limitations added in these two dependent claims. Both of the challenged claims (18 and 20) as Defined are anticipated by Leonhardt (Ex.1017). *In re Gleave,* 560 F.3d 1331, 1334 (Fed. Cir. 2009).

Leonhardt was filed on May 1, 1997, and issued on September 28, 1999. It is therefore prior art at least pursuant to pre-AIA 35 U.S.C. § 102(e) (and also § 102(a)). However, Patent Owner has acknowledged that the proper priority date

for challenged claim 18 is April 30, 2002. (Ex.1039 p.3.) Leonhardt is therefore § 102(b) prior art for claim 18. And, as explained in Part VI.C, claim 20 should not be entitled to the priority date of the '782 Patent and thus Leonhardt should also be prior art to claim 20 under § 102(b). Leonhardt was not of record. Anticipation is established for the reasons discussed in this Part and through Claim Chart 1.

a. An Artificial Valve For Repairing A Damaged Heart Valve

Leonhardt describes a percutaneously delivered self-expanding artificial heart valve for replacing a damaged heart valve as found in the challenged claims. Valve stent 20 can be positioned within the native aortic or mitral valve. (Ex.1017 cols.3:57-59, 4:14-15, 5:40-52, 9:63-67.) As illustrated in FIG.2, the valve is sized and shaped to be positioned between an upstream and downstream region as claimed. (Ex.1003 ¶71.)

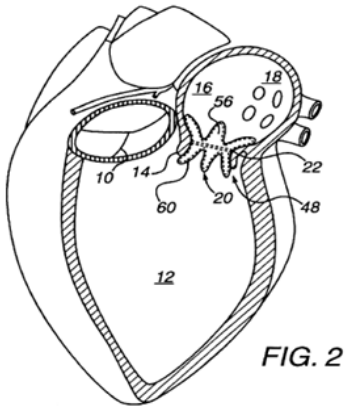


FIG. 2

b. Flexibly Resilient Frame

Each challenged claim requires a flexibly resilient frame. As Defined, the claimed flexibly resilient frame encompasses any structure designed to shape or

support, which is able to spring back to its original shape, on its own, after being compressed. (Ex.1041 p.2 Term 3, p.4 Term 23.) The Leonhardt stent is self-expanding and biases its proximal and distal ends into a fixed engagement with the tissue of the valve or annulus. (Ex.1017 cols.3:33-44, 4:53-5:33, 5:45-52, 10:53-61, FIGS.9A-9D.) It can be made of nitinol. (*Id.* 5:11.) A POSA would appreciate that Leonhardt's stent is a flexibly resilient frame as Defined. (Ex.1003 ¶72; *see also* Claim Chart 1 Leonhardt "Frame-Flexibly Resilient.")

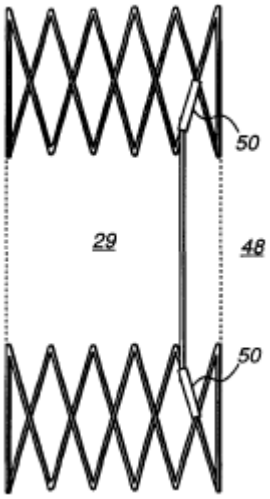
c. Peripheral Anchors And Central Portions

The claimed frame includes a plurality of peripheral anchors. Patent Owner's Definition of peripheral anchors encompasses frame elements found at the stent's periphery. (*See, e.g.,* Exs.1040 pp.4-5; 1041 p.2 Term 5.) And the frame must include a "central portion" located between the peripheral anchors and "located along a centerline." Patent Owner's Contentions identify these limitations as merely a region located between the peripheral anchors and along the longitudinal axis. (Exs.1041 p.2 Terms 7-9; 1040 pp.5-6.)

The Leonhardt stent 26 includes two cylindrical portions disposed at each end of the stent. The cylindrical portions are spaced apart from one another by a connecting bar. (Ex.1017 cols.4:23-40, 4:53-5:52, FIGS.1B-1C, 4.) The peripheral frame elements of this stent are peripheral anchors, at least to the same extent as

the peripheral frame elements of the device illustrated in the Contentions allegedly are. (Ex.1003 ¶74.)

FIG. 1B



Leonhardt also discloses that the stent made from these cylindrical portions can "flair at one or both ends as is shown in FIG.2."

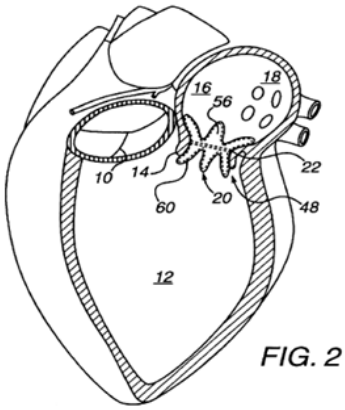


FIG. 2

(Ex.1017 col.6:9-22.) These flared portions also constitute peripheral anchors as Defined. (Ex.1003 ¶74; *see also* Claim Chart 1 Leonhardt "Peripheral Anchors.") Leonhardt's central portion is the portion of the stent between its two cylindrical portions of the stent. (Ex.1017 col.5:22-33, FIGS.1B, 4.) The valve 22 is disposed in and attached to this central portion. Moreover, this central portion of the

Leonhardt stent is located centrally along the centerline — the longitudinal axis as Defined. (Ex.1003 ¶74; *see also* Claim Chart 1 Leonhardt "Central Portion.") And it would be disposed along the centerline of the device when inserted between upstream and downstream regions.

d. Flexible Valve Element

All of the challenged claims require "a flexible valve element" attached to the central portion of the frame. According to the Definitions, this term encompasses any flexible part of a valve. (Ex.1041 p.3 Term 12 (emphasis added).) Leonhardt uses a biological valve 22, which is preferably an intact porcine valve and could be a synthetic leaflet valve. (Ex.1017 col.6:23-34.) Biological valve 22 is presized to fit within the middle of cylindrical portion 48 formed by stent 26. (*Id.*) A POSA would fully appreciate that the biological and synthetic FVEs of Leonhardt are flexible. They are made of tissue and are attached inside a collapsible stent — so they must be flexible. (Ex.1003 ¶75.) And, as noted above, the FVE of Leonhardt is attached to a central portion of the frame as Defined and certainly to the same extent as the FVE illustrated in the Contentions. (Exs.1017 cols.5:45-51, 6:23-31, FIG.4 (numeral 22); 1040 pp.5-6.)

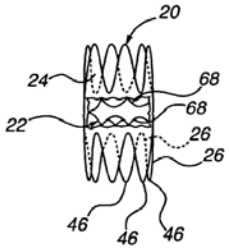


FIG. 4

Thus Leonhardt teaches an FVE attached to the central portion as Defined and claimed. (*See* Claim Chart 1 Leonhardt "Flexible Valve Element.")

The FVE must have upstream and downstream sides facing the upstream and downstream regions, respectively. These limitations as Defined (Ex.1041 p.2 Terms 1, 2) are met by the porcine, tricuspid, leaflet valve of Leonhardt mounted in the aortic or mitral positions of a heart. (Exs.1017 cols.5:40-52, 6:23-34, 9:63-10:21, 10:22-43, FIGS.2, 3, 9D; 1003 ¶76); *see also* Claim Chart 1 Leonhardt "Upstream/Downstream Sides.")

e. Valve Movement Limitations

Claim 1 includes a lengthy recitation merely describing the function of native heart valves and replacement valves, all of which were known *per se*. (Ex.1003 ¶77.) The tricuspid valve cited in Patentee's Contentions allegedly satisfies this claim language. (Ex.1040 pp.9-10.) Leonhardt's biological FVE has the same overall construction of that tricuspid valve and it is clear from the discussions in Leonhardt that its FVE moves as claimed to permit or interrupt

blood flow. (Exs.1017 cols.1:10-21, 3:33-44, 5:50-52, 6:23-34; Ex.1003 ¶77; *see also* Claim Chart 1 Leonhardt "Valve Movement Language.")

f. Valve/Frame Opening Limitations

Claim 1 requires that the artificial valve include an opening extending through the frame and/or the FVE. Patent Owner Contends that this limitation is met by a tricuspid valve mounted within a tubular stent that allows a catheter tip to traverse the interior of the FVE and/or the stent. (Exs.1040 pp.11-12; 1041 p.3 Term 16.) Leonhardt explicitly teaches that the prosthetic valve "should be in an open position when valve stent 20 is loaded into outer sheath 106," which "allows inner catheter 110 to pass through valve 22 . . . ." (Ex.1017 col.7:11-16.) And indeed, Leonhardt actually illustrates its valve with an implement traversing its length through the opening (*Id.* FIGS.9A-D.) Thus, Leonhardt teaches a prosthetic heart valve that includes an opening passing through the center of both the frame and the FVE as Defined, with the opening explicitly being capable of receiving an implement therethrough. (Ex.1003 ¶78; *See* Claim Chart 1 Leonhardt "Valve/Frame Opening.")

g. Claim 18

Claim 18 depends directly from claim 1 and recites a transluminal method for inserting an artificial valve as set forth in claim 1 between a plurality of cusps of a damaged heart valve. Indeed, Patent Owner has admitted that both claims 18

and 20 are dependent claims. (Ex.1041 p.1.) As noted in preceding portions of this Part, Leonhardt anticipates the artificial valve set forth in claim 1. Leonhardt is not only directed to a device, but is also directed to inserting its artificial valve between a plurality of cusps of a damaged heart valve. This is illustrated in, for example, FIGS.2 and 9D. (Exs.1017 cols.3:30-45, 5:40-52, 9:49-11:36, 11:59-12:5, FIGS.2, 3, 9A-9D; 1003 ¶79; *see also* Claim Chart 1, at 18(p).)

Claim 18 requires an incision be made into a vessel leading to the heart. Leonhardt teaches this step. As Leonhardt notes, the site of introduction of the replacement valve will depend on the placement site. If placement is in the aorta or aortic valve, "entry" is made through the largest femoral artery in the groin area and into the aorta. (Ex.1017 col.9:64-67.) If the valve stent is to be placed at the mitral valve, "entry" is made through the right internal jugular vein. (*Id.* 10:22-30.) Thus Leonhardt teaches making an incision in a vessel leading to the heart. (Ex.1003 ¶80.)

While these statements expressly use the term "entry" rather than "incision," based on the discussions of the overall procedures in cols.9-12 and particularly the passage at col.9:49-62, a POSA would know that the reference to "entry" in Leonhardt is a reference to an "incision" using the normal surgical procedures well known to a POSA. (Ex.1003 ¶81.) This is further supported by the passages of Leonhardt at col.12:4-15, describing removal of the delivery device from the entry

site and that it is attended to by "standard procedure" and by "closing the entry site." (*See* Claim Chart 1, at 18(a); Ex.1003 ¶81; *see also* Part V.B, *supra*.)

Claim 18 further requires insertion of an end of an elongate flexible instrument through the incision made in the vessel and pushing the end of the instrument through the vessel. This process is described in Leonhardt as well. Deployment catheter 100 "is then inserted through the entry point and into the patient . . . and slowly advancing the deployment catheter 100 to the placement site." (Exs.1017 cols.10:6-11; *see* 10:31-43, FIG.9A; 1003 ¶82; *see also* Claim Chart 1, at 18(b).)

According to claim 18, the end of the flexible instrument is next positioned adjacent the plurality of cusps of a damaged heart valve. This step is taught by the passages of Leonhardt just cited. And it is illustrated in FIG.9A. (Exs.1017 cols.10:6-21, 10:31-43; *see also* 5:40-52, 10:43-52, FIGS.9A-9D; 1003 ¶83; *see also* Claim Chart 1, at 18(c).)

The artificial valve is then ejected from the end of the flexible instrument, which is positioned adjacent the plurality of cusps of the damaged heart valve and into a position between the plurality of those cusps, without removing the damaged heart valve from the heart. This process is described in Leonhardt as well. (Ex.1017 col.10:53-11:36, FIGS.9A-9D.) Specifically, Leonhardt notes that the

valve is placed in a heart annulus and "within," "at," or "in" various valves. (*Id.* 4:8-11, 5:47-51, 9:64-65, 10:22-30; *see also* Claim Chart 1, at 18(d); Ex.1003 ¶84.)

Nothing in Leonhardt specifically addresses the requirement that this procedure be done without removing the damaged heart valve. However, nothing in Leonhardt teaches or suggests that the damaged heart valve should be removed. And, in fact, Leonhardt illustrates the native valve 14 remains intact during delivery of the prosthetic valve. (Ex.1017 FIGS.9A-9D.) Leonhardt also contemplates using tip balloon 152 "within mitral valve 14" to perform valvuloplasty. (*Id.* col.10:41-43.) Such a procedure would not be necessary if the valve had been removed. Similarly a discussion of applying contrast media during the procedure notes that the deployment catheter is positioned such that the outer sheath is extending through mitral valve 14. Moreover, the deployment catheter is rotated to match the distendable fingers 46 of the structure of the mitral valve 14 if necessary. (*Id.* 10:45-52.) None of this would reference the "mitral valve," nor would the mitral valve be illustrated, if the valve was removed. (Ex.1003 ¶85.)

Finally, claim 18 requires retrieving the artificial valve back into the end of the instrument, repositioning the inserted end of the instrument again adjacent the plurality of cusps of the damaged heart valve and ejecting the repositioned artificial valve from the end of the instrument into another position between the plurality of cusps of the damaged heart valve. This is again accomplished without

removing the damaged heart valve from the heart. This last requirement was just discussed. Leonhardt also describes repositioning the valve.

As Leonhardt explains, "[i]f at any time it is necessary to retrieve valve stent 20 for repositioning or removal, the following procedure may be used. This procedure is applicable whether valve stent 20 is fully or partially deployed from outer sheath 106." (Ex.1017 col.11:36-40.) By taking up slack in suture loops 174 and holding pushrod 112 stationary, the outer sheath 106 is advanced back over valve stent 20 and through the natural valve position until sheath 106 completely covers the valve stent. (*Id.* 40-52.) The valve stent may next be repositioned and/or removed. (*Id.*50-57.) Leonhardt also explains that it may not be necessary to retrieve the complete valve stent if the desire is repositioning as opposed to removal. (*Id.* 52-58.)

Leonhardt does not expressly describe ejecting the valve stent 20 following its repositioning. But that is exactly how a POSA would read this passage. If not removed, the valve stent 20 must be re-ejected — no other choice is available. There is only a single explanation for how that is accomplished and that was described in connection with element 18(d) above. (*See* Claim Chart 1, at 18(e); Ex.1003 ¶¶86-88.) And that subsequent placement would be between the cusps of the damaged valve.

h. Claim 20

Leonhardt anticipates claim 20 for many of the same reasons previously mentioned in connection with claim 18. Unlike claim 18, claim 20 specifically requires the use of a guide or guidewire. It does not, however, require recapturing and repositioning the valve stent once deployed as required in Claim 18.

As noted above, claim 20, like claim 18, relates to a transluminal method of inserting the artificial valve of claim 1 between a plurality of cusps of a damaged heart valve. Leonhardt describes the same method. (Exs.1017 cols.3:15-45, 5:40-52, 9:50-11:36, 11:59-12:5, FIGS.2, 3, 9A-9D; 1003 ¶90; *see also* Claim Chart 1, at 20(p).)

Claim 20, as was also the case for claim 18, requires making an incision in the vessel leading to the heart. As previously described in connection with claim 18(a), this is disclosed by Leonhardt's references to providing "entry" to specified vessels. (Exs.1017 cols.6:60-65, 9:64-67, 10:22-30, FIGS.9A-9D; 1003 ¶91; *see also* Claim Chart 1, at 20(a).)

Claim 20 then requires the insertion of the end of a guide or guidewire through the incision made in the vessel (20(b)) and pushing the guidewire through the vessel (20(c)). Leonhardt describes these steps as follows: "[a] flexible guide wire with a tip balloon 152 is inserted through the same entry point and advanced

to immediately above aortic valve 10 or into left ventricle 12." (Exs.1017 col.10:3-6, FIGS.9A-9D; 1003 ¶92; *see also* Claim Chart 1, at 20(b), 20(c).)

Next, claim 20 requires that an elongate flexible instrument having a hollow interior be threaded onto the guidewire. Leonhardt describes this process as well stating that the deployment catheter 100, which is hollow (Ex.1017 FIGS.5-7, 9A) is inserted through the entry point into the patient by inserting first track 124 of inner catheter 110 over the flexible guidewire and slowly advancing the deployment catheter 100 to the placement site. (Exs.1017 col.10:6-11; *see generally* cols.9:63-10:42, FIGS.5, 9A-9D; 1003 ¶93; *see also* Claim Chart 1, at 20(d).)

Claim 20 further requires inserting an end of the elongate flexible instrument through the incision made in the vessel. This step is disclosed in Leonhardt in the same portion just mentioned, which explains that the deployment catheter is inserted through the entry point into the patient over the guidewire. (Exs.1017 col.10:6-11; *see generally* cols.9:63-10:42, FIGS.5, 9A-9D; 1003 ¶94; *see also* Claim Chart 1, at 20(e).)

Claim 20 requires that the end of the instrument be pushed through the vessel along the guidewire until the end is adjacent the plurality of cusps of the damaged heart valve. This is essentially the recitation of claim element 18(c) noted above. It is disclosed in Leonhardt for the same reasons. As shown in FIGS.9A-D

and specifically described in Leonhardt the deployment catheter is advanced to the treatment site, which can be the aortic or mitral valve. (Exs.1017 col.10:6-21; *see also* 9:64-67, 10:22-25, 10:43-52, 10:53-11:36; 1003 ¶95; *see also* Claim Chart 1, at 20(f).)

Finally the artificial valve is ejected from the end of the instrument which had been positioned adjacent the plurality of cusps of the damaged heart valve into a position between those cusps without removal of the heart valve. This recitation is virtually identical to the recitation of claim 18(d) and is taught by Leonhardt for the same reasons. (Exs.1017 cols.4:8-11, 5:47-52, 9:64-67, 10:22-30; 1003 ¶96; *see also* Claim Chart 1, at 20(g).) Accordingly, Leonhardt anticipates claim 20.

In summation, as the terms of claims 18 and 20 are Defined by the Patent Owner, Leonhardt anticipates the challenged claims.

Claim Chart 1 below reflects the recitations of the challenged claims addressed above, reorganized such that common elements are grouped together. These citations supplement those in the above text. The numbers/letters beginning each entry (*e.g.*, "1(p)") correspond to claim numbers from which each entry originated and the breakdown provided in the Contentions (Ex.1040). Claim Chart 1 identifies where the claimed elements as Defined by Patent Owner can be found in the grounds.

Claim Chart 1

Claim Language	Citation
PREAMBLE 1(p). An artificial valve for repairing a damaged heart valve having a plurality of cusps separating an upstream region from a downstream region, said artificial valve comprising:	**Cl.1** Leonhardt: Exs.1017 cols.3:15-45, 3:57-59, 4:14-15, 5:40-52; cols.9:50-11:36, 11:59-12:5, FIGS.2, 3, 9A-9D; 1003 ¶71. Johnson: Exs.1021 cols.2:62-3:19, 6:8-19, FIGS.7, 8; 1003 ¶111.
Frame – Flexibly Resilient 1(a). a flexibly resilient frame sized and shaped for insertion in a position between the upstream region and the downstream region,	**Cl.1** Leonhardt: Exs.1017 cols.3:33-45, 4:53-5:33, 5:40-52, 9:63-10:21 (aortic), 10:22-42, 10:53-61 (mitral), FIGS.1B, 2, 3, 9A-9D; 1003 ¶72. Johnson: Exs.1021 cols.2:43-50, 4:10-48, 5:20-36, 6:2-7, FIGS.1, 2, 7, 8; 1003 ¶¶113-114.
Peripheral Anchors 1(b). the frame having a plurality of peripheral anchors for anchoring the frame in the position between the upstream region and the downstream region	**Cl.1** Leonhardt: Exs.1017 cols.3:33-45, 4:14-5:52, 5:53-56 (stent 26 coerces it), 6:9-22 ("flare"), 8:42-9:5; FIGS.1B, 1C, 2-4, 9A-9D; 1003 ¶¶74, 115.
Central Portion 1(c). and a central portion located along a centerline extending between the plurality of peripheral anchors and between the upstream region and the downstream region when said frame is inserted in the position between the upstream region and the downstream region;	**Cl.1** Leonhardt: Exs.1017 cols.5:23-35, 6:9-13, 6:23-34, FIGS.1B, 1C, 2, 4; 1003 ¶74, 116. Johnson: Exs.1021 cols.2:47-51, 4:10-15, 4:35-68, FIG.1, 2; 1003 ¶¶116-117.

Claim Language	Citation
Flexible Valve Element 1(d). a flexible valve element attached to the central portion of the frame,	**Cl.1** Leonhardt: Exs.1017 cols.3:33-45, 4:57-58; 5:23-52; 6:23-34; FIGS.1B, 1C, 2, 4; 1003 ¶75. Johnson: Exs.1021 cols.2:43-50, 4:49-68, 5:35-53, 6:2-8, FIGS.2, 4, 5; 1003 ¶¶118-120.
Upstream/Downstream Sides 1(e). having an upstream side facing said upstream region when the frame is anchored in the position between the upstream region and the downstream region and a downstream side opposite the upstream side facing said downstream region when the frame is anchored in the position between the upstream region and the downstream region,	**Cl.1** Leonhardt: Exs.1017 cols.5:40-52; 6:13-19, 6:23-34; 9:63-10:21; 10:22-43; FIG.2, 3, 4, 9A-9D; 1003 ¶76. Johnson: Exs.1021 cols.5:37-53, 6:14-19, FIGS.4, 5, 8; 1003 ¶120.
Valve Movement Language 1(f). said flexible valve element moving in response to a difference between fluid pressure in said upstream region and fluid pressure in said downstream region between an open position in which the flexible valve element permits downstream flow between said upstream region and said downstream region and a closed position in which the flexible valve element blocks flow reversal from said downstream region to said upstream region, wherein the flexible valve element moves to the open position when fluid pressure in said upstream region is greater than fluid pressure in said downstream region to permit downstream flow from said upstream region to said downstream region and the flexible valve	**Cl.1** Leonhardt: Exs.1017 cols.1:5-8, 1:10-21, 3:33-45, 5:50-52, 6:23-34, FIGS.2, 3, 4, 9B; 1003 ¶77. Johnson: Exs.1021 col.3:26-47, 5:37-53, FIGS.4, 5; 1003 ¶¶121-122.

Claim Language	Citation
element moves to the closed position when fluid pressure in said downstream region is greater than fluid pressure in said upstream region to prevent flow reversal from said downstream region to said upstream region; and	
Valve/Frame Opening 1(g). an opening extending through at least one of said frame and said flexible valve element for receiving an implement.	**Cl.1** Leonhardt: Exs.1017 cols.3:33-45, 5:40-52, 6:23-32, 7:11-16, FIG.4, FIGS. 9A-D; 1003 ¶78.) Johnson: Exs.1021 col.5:12-19, 5:45-53, FIG.5; 1003 ¶¶123-125.
18(p). A transluminal method of inserting an artificial valve as set forth in claim 1 between a plurality of cusps of a damaged heart valve, said method comprising the steps of:	**Cl.18** Exs.1017 cols.3:16-45, 5:40-52, 8:23-41, 9:50-11:36, 11:59-12:5; FIGS. 2, 3, 5-7, 9A-9D; 1003 ¶¶79, 126 .
18(a). making an incision in a vessel leading to the heart;	**Cl.18** Exs.1017 cols.6:60-65, 9:49-67, 10:22-30, 12:4-15, FIGS.9A-9D; 1003 ¶¶80, 81, 126.
18(b). inserting an end of an elongate flexible instrument through the incision made in the vessel; pushing the end of the instrument through the vessel;	**Cl.18** Exs.1017 cols.10:6-21, 10:30-52, FIGS.9A-9D; 1003 ¶¶82, 126.
18(c). positioning the end adjacent the plurality of cusps of the damaged heart valve;	**Cl.18** Exs.1017 cols.5:40-52, 10:6-21, 10:43-61, 10:53-11:36, FIGS.2, 9A-9D; 100 ¶¶83, 126.
18(d). ejecting an artificial valve from the end of the instrument positioned adjacent the plurality of cusps of the damaged heart valve into a position between said plurality of cusps of the damaged heart valve without removing the damaged heart valve	**Cl.18** Exs.1017 cols.4:8-11, 5:40-52, 8:23-41, 9:64-65, 10:6-30, 10:41-52, 10:53-11:36, FIGS.9A-9D; 1003 ¶¶84-85, 116.

Claim Language	Citation
from the heart;	
18(e). retrieving the artificial valve into the end of the instrument; repositioning the inserted end of the instrument adjacent the plurality of cusps of the damaged heart valve; and ejecting the repositioned artificial valve from the end of the instrument positioned adjacent the plurality of cusps of the damaged heart valve into position between said plurality of cusps of the damaged heart valve without removing the damaged heart valve from the heart.	**Cl.18** Exs.1017 cols.5:45-50, 11:36-58, FIGS.5-7, 9A-9D; 1003 ¶¶86-88, 116.
20(p). A transluminal method of inserting an artificial valve as set forth in claim 1 between a plurality of cusps of a damaged heart valve, said method comprising the steps of:	**Cl.20** Exs.1017 cols.3:15-45, 5:40-52, 9:50-11:36, 11:59-12:5; FIGS.2, 3, 9A-9D; 1003 ¶¶90, 126-128.
20(a). making an incision in a vessel leading to the heart;	**Cl.20** Exs.1017 cols.6:60-65, 9:64-67, 10:22-30, FIGS.9A-9D; 1003 ¶¶91, 128.
20(b). inserting an end of a guide through the incision made in the vessel;	**Cl.20** Exs.1017 cols.9:63-10:6, 10:3-30, 10:35-42, FIGS.9A-9D; 1003 ¶¶92, 128.
20(c). pushing the guide through the vessel;	**Cl.20** Exs.1017 cols.9:63-10:6, 10:3-30, 10:35-42, FIGS.9A-9D; 1003 ¶¶92, 128.
20(d). threading an elongate flexible instrument having a hollow interior onto the guide;	**Cl.20** Exs.1017 cols.9:63-10:42, FIGS.5, 9A-9D; 1003 ¶¶93, 128.
20(e). inserting an end of the elongate flexible instrument through the incision made in the vessel;	**Cl.20** Exs.1017 cols.9:63-10:42, FIGS.5, 9A-9D; 1003 ¶¶94, 128.

Claim Language	Citation
20(f). pushing the end of the instrument through the vessel along the guide until the end is adjacent the plurality of cusps of the damaged heart valve; and	**Cl.20** Exs.1017 cols.5:40-52, 9:63-67, 10:3-52, 10:53-11:36, FIGS.5, 9A-9D; 1003 ¶¶95, 128.
20(g). ejecting an artificial valve from the end of the instrument positioned adjacent the plurality of cusps of the damaged heart valve into a position between said plurality of cusps of the damaged heart valve without removing the damaged heart valve from the heart.	**Cl.20** Exs.1017 cols.4:8-11, 5:40-52, 9:63-67, 10:3-52, 10:53-11:36, FIGS.5, 9A-9D; 1003 ¶¶96, 128.

B. Obviousness

1. Ground 2: Claims 18 And 20 Are Obvious Over Leonhardt

Leonhardt is prior art for the reasons explained in Ground 1. To the extent one were to argue that Leonhardt's elements were not exactly shown in the manner claimed, the variations would be obvious to a POSA in view of the general knowledge in the art and the limited number of ways of using known elements to achieve expected results. The various claimed elements were all known in the field of collapsible heart valves and interchanging known elements, each having a known function, yielding only expected and predictable results, is "the work of the skillful mechanic, not that of the inventor." *Sundance, Inc. v. Demonte Fabricating Ltd.*, 550 F.3d 1356, 1367 (Fed. Cir. 2008) (quoting *Sakraida v. Ag Pro, Inc.*, 425 U.S. 273, 282 (1976)).

As the Supreme Court has stated

> If a person of ordinary skill can implement a predictable variation, §103 likely bars its patentability. For the same reason, if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill.

KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 417 (2007). ("[w]hen there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp.").)

Patent Owner admits that claims 18 and 20 of the '297 Patent are dependent and therefore include all the limitations of claim 1. (Ex.1041 p.1.) There are several prior art patents teaching the use of an expandable heart valve composed of a stent having a one way valve attached to its interior. (*See* Exs.1006-1009; 1013; 1017; 1024; 1003 ¶98.) Petitioner argues elsewhere in a concurrently filed IPR that claim 1 is invalid as anticipated and/or obvious over some of this very art. But even if that were not the case, claims 18 and 20 of the '297 Patent should nonetheless be obvious.

Claims 18 and 20 are method claims and their obviousness should rest primarily on the obviousness of the recited method steps. This should be particularly true here as none of the recited method steps rely on any particular

feature of the valve claimed in claim 1. These steps could be equally well practiced with any of the valves in any of the references mentioned above. (Ex.1003 ¶98.) Nothing unique about the structure of the device of claim 1 in any way influences or changes the process as claimed. As these are method claims, and not device claims, even if the valve device were somehow unobviously different, which it is not, that difference should be given minimal weight in evaluating the obviousness of the method. The identity, or near identity, of the method steps themselves should render these claims obvious.

To the extent that there are differences in the methods or devices of claims 18 and 20, when compared to Leonhardt, they would amount to relatively minor modifications well within the level of ordinary skill in the art. (Ex.1003 ¶99.) For example, to the extent that one were to conclude that Leonhardt's use of the word "entry" did not sufficiently disclose the use of an "incision," making an incision to gain access to a vessel leading to the heart is a well known method used for same and would be obvious based on the art as demonstrated by the art in Part V.B. Similarly, Leonhardt does not expressly explain ejecting the valve following retrieval. A POSA would nevertheless read the disclosure in context as disclosing doing so. However, even if that were not the case, it would be at least obvious to a POSA to repeat the ejection procedure of Leonhardt described for the initial valve placement. Similarly, to the extent that there were minor differences

between the claimed device and that of Leonhardt, and Petitioner does not believe that to be the case, these differences are obvious and would not influence a POSA's selection of an implantable methodology. For example, even if the claimed valve were interpreted narrowly to include use of only a conical frame and/or a unitary flap inverted funnel valve attached at its apex to the frame, these differences are obvious and would not alter a POSA's selection of the standard implementation techniques described in Leonhardt. (Ex.1003 ¶¶99-100.)

2. Ground 3: Claims 18 And 20 Are Obvious Over Leonhardt In View Of Johnson

Johnson issued in 1995 and qualifies as art pursuant to 35 U.S.C. § 102(b) irrespective of the priority date accorded to the challenged claims. Johnson was of record. Johnson was applied as a primary reference during the prosecution of the parent application but not the '297 Patent. Leonhardt was not of record and is prior art for the reasons outlined in Ground 1.

As noted in Leonhardt and elsewhere, one of the major benefits of percutaneously deliverable prosthetic heart valves is that the procedure can be completed in a minimally invasive manner, reducing risk to the patient. It also expands the number of people who can be helped to include those not candidates for open chest surgery. (Exs.1001 col.1:29-37; 1006 col.1:34-50; 1008 col.1:14-34; 1003 ¶101.) The benefit is particularly salient in view of the invasiveness of open

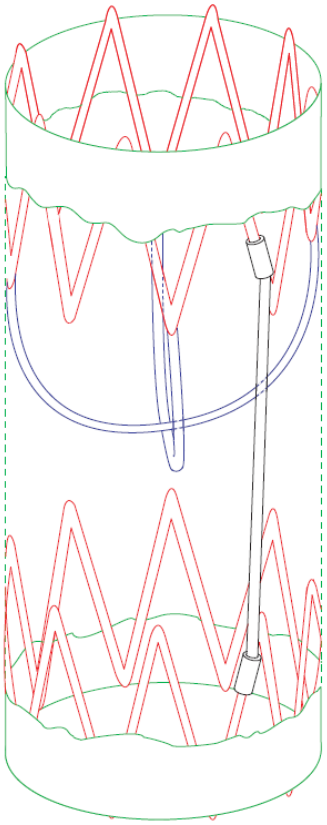
heart surgery. However, the durability of percutaneously deliverable prosthetic heart valves was a recognized issue. (Exs.1008 col.2:11-12; 1021 cols.2:39-42, 3:37-47.) Here, the existence of the problem of durability of prosthetic heart valves supplies motivation for the solution of the use of the unitary-funnel valve of Johnson. *KSR*, 550 U.S. at 420.

A POSA would realize that the patients most in need of transcatheter procedures are the frailest. Not only is open chest surgery to be avoided, but even subsequent transcatheter procedures should be avoided where possible. (Ex.1003 ¶102.) So a POSA would be very interested in durable solutions. One seeking a durable transcatheter valve would be taught that Johnson's valve has the potential to provide improved durability. (Exs.1021 cols.2:39-42, 3:37-47; 1003 ¶102.) Thus there is incentive for their combination.

Specifically, Johnson discloses that natural and synthetic leaflet valves, such as those described in Leonhardt, have had durability problems resulting from, *inter alia*, the fact that the leaflets are attached to a rigid or semirigid fixation ring around the perimeter. "By using a central attachment without an outer fixation ring, the dynamic annulus valve effects closure by leaflet coaptation with the natural or reconstructed tissue annulus. This closing method as well as the flexibility of the structural frame should avoid localized stress points on the leaflets and result in extreme durability." (Ex.1021 col.3:37-47, *see also* col.2:39-42.)

A POSA would be motivated to try the FVE construction of Johnson in place of the leaflet-containing FVE of Leonhardt, based on Johnson's suggestion that doing so could provide a more durable valve. (Ex.1003 ¶105.) The combined structure is illustrated in FIG.H, where the Leonhardt tubular structure performs its known function of holding the entire structure within the anatomy, and the Johnson FVE performs its known function and, indeed the same function as the FVE of Leonhardt. Note that in FIG.H below, portions of the Leonhardt graft 24 and the FVE are removed for clarity of illustration:

FIG.H



The conical birdcage-like frame of Johnson acts as a "seat" to attach the apex of the unitary funnel FVE to a central portion of the framework of Johnson, just as the apex of the funnel valve of the '297 Patent is attached to its central portion 36/junction 32.

In making this combination, a POSA would realize that the apex of Johnson's FVE would need to be attached to a central portion of the frame along the centerline. (*See e.g.*, Exs.1010, 1020, 1021.) Providing structure to do this is a simple engineering exercise which has been practiced in many different analogous situations. (Ex.1003 ¶¶106-107.) An accommodating structure could be added to or integrally formed as part of the Leonhardt stent. (*Id.*) That said, a POSA here would recognize that Johnson already provides a structure that can be used to provide that attachment site — its framework. The framework of Johnson acts as a seat or central portion to allow attachment of the FVE's apex. Both the framework and the FVE are acknowledged by Johnson to be flexible. So a POSA would think to use it in a collapsible device. (Ex.1021 col.2:43-50.) The Johnson framework could be formed as a part of Leonhardt's frame or Johnson's framework could be secured to the tubular stent of Leonhardt by sewing pads 18, 20, 22 as shown in FIG.H, or by other means known to a POSA. (Ex.1003 ¶108.)

The FVE would therefore be attached to the central portions of the framework of Johnson and also to that of Leonhardt. And the FVE would clearly

be attached along the centerline — the central axis of the Leonhardt stent that would pass through the junction point of Johnson's attached framework. (*Id.* ¶109.)

To block upstream flow of blood, the valve element 30 balloons outwardly so that the downstream edges 32, 34, and 36 of the valve element seal against the surrounding annulus 41. (Ex.1021 col.5:37-53, FIGS.2, 4-5.) To allow downstream flow, portions of the valve element 30 between the struts (*e.g.*, the reversing cusps) collapse inwardly, toward the central axis of the cage and valve element, just as occurs in the '297 Patent. (*Id.*; Ex.1003 ¶110.) And the methods claimed for implanting this combined valve are completely obvious for the reasons discussed in Ground 1 and Claim Chart 1.

a. <u>A Valve For Repairing A Damaged Heart Valve</u>

Claim 1, and therefore claims 18 and 20, requires a device suitable for repairing a damaged heart valve and being sized to be disposed within a native valve. As described in Ground 1, Leonhardt describes a percutaneously delivered self-expanding heart valve which can be disposed within the native aortic and mitral valve. (Ex.1017 cols.3:57-59, 4:14-15, 5:40-52, 9:63-67.) And, as also discussed in Ground 1, Leonhardt's valve is sized and shaped to be positioned between an upstream and downstream region as claimed. (*Id.* 5:40-52, 9:49-11:68, FIGS.2, 9A-9D.)

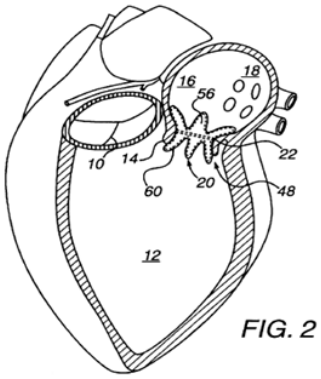
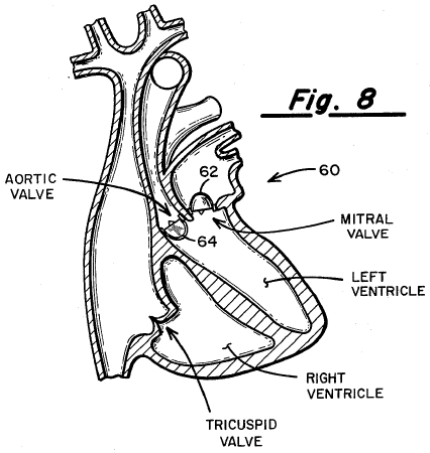


FIG. 2

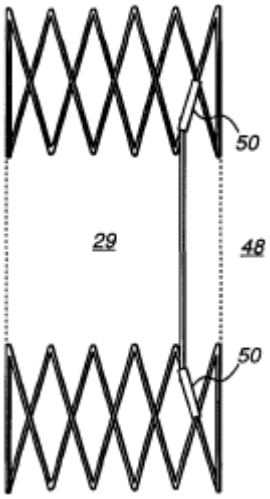
The same is true for the device of Johnson. (Exs.1021 cols.2:62-3:19, 6:14-19, FIG.8; 1003 ¶111; *see also* Claim Chart 1 Leonhardt and Johnson "Preamble.") So the combination meets this claim language.



b. <u>Flexibly Resilient Frame</u>

The challenged claims require a flexibly resilient frame. As explained in Ground 1, the self-expanding stent of Leonhardt can be made of nitinol and biases the proximal and distal ends of the stent valve 20 into a fixed engagement with the tissue of the valve or annulus. (Ex.1017 cols.3:33-44, 4:53-5:33, 5:45-52, FIG.1B.) POSAs know this to be a flexibly resilient frame. This meets Patent Owner's Definitions. (Ex.1003 ¶112.)

FIG. 1B



Johnson also describes a flexibly resilient frame as Patent Owner Defines it — a structure designed to shape or support and able to spring back to its original shape on its own after being compressed. (Exs.1021 cols.2:43-50, 4:10-48, 5:20-36, 6:2-7, FIGS.1, 2, 7; 1041 p.2 Term 3, p.4 Term 23.) The framework of Johnson may be made of resilient or springy material such as titanium or polytetrafluoroethylene (PTFE) or Teflon® polymer. (Ex.1021 cols.4:22-25.) It is even specifically identified as being "flexible." (*Id.* 2:43-50.) And as shown above in FIG.8, it is also sized to be disposed in a heart annulus between upstream and downstream regions. A POSA would know this to be a flexibly resilient frame as Defined. (Ex.1003 ¶113.)

Even if the term "frame" is limited to a conical or geodesic shape which is consistent with Petitioner's proposed claim construction in court (Ex.1041 p.2 Term 3) (the only structure shown and described and is consistent with statements made in the provisional application (Ex.1011 App.B pp.B-5:12-18, B-6:2-5,

B-7:7-16, B-9:17-24)), Johnson's framework still qualifies (Exs.1021 cols.2:43-50, 4:10-48, 5:20-36, 6:2-7, FIGS.1, 2, 7; 1003 ¶114; *see also* Claim Chart 1 Leonhardt and Johnson "Frame-Flexibly Resilient"). Thus the combined structure meets this claim limitation.

c. <u>Frame's Peripheral Anchors/Central Portion</u>

Claim 1, and therefore claims 18 and 20, require that the frame include a plurality of peripheral anchors and a central portion disposed between the peripheral anchors and along a centerline. (Ex.1041 p.2 Terms 5, 8.) As described in Ground 1, Leonhardt's stent includes "peripheral anchors" as Patent Owner Defines. Both the frame elements themselves at the peripheral ends and the fact that the stent can "flair at one or both ends as is shown in FIG.2," meet this limitation as Defined. (Exs.1017 cols.6:9-22, 4:23-40, 4:53-5:52, FIGS.1B-1C, 2; 1003 ¶¶74, 115.)

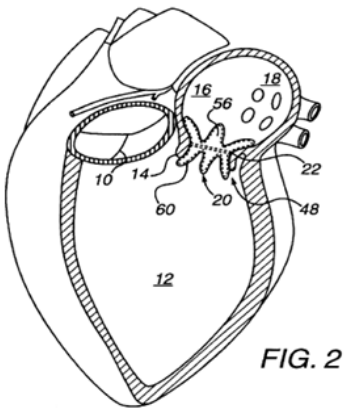


FIG. 2

In fact, Leonhardt's "flared" structure would constitute peripheral anchors even if that term required distinct structures formed outside of the general shape of the

frame used to attach the frame to the native anatomy as Petitioner advocates in district court. (*See* Claim Chart 1 Leonhardt "Peripheral Anchors.")

Patent Owner's Contentions identify the central portion of the accused device as allegedly being located along a centerline and as merely a region of the stent disposed somewhere between the peripheral anchors. (Exs.1041 p.2 Terms 7-9; 1040 pp.5-6.) As noted in Ground 1, as so Defined, the area located between the spaced apart cylinders of Leonhardt's stent, and thus between the peripheral anchors is its central portion. (Exs.1017 FIG.4, wherein the valve is marked by numeral 22; 1003 ¶¶74, 116.)

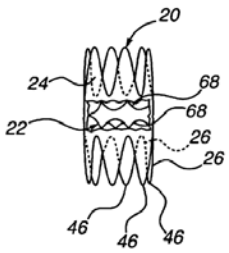


FIG. 4

And the valve is also disposed along the centerline at least to the same extent as the valve identified in the Contentions. (Ex.1040 pp.6-7.)

On the other hand, if the central portion and centerline limitations mean that a portion of the frame must be on the centerline as Petitioner advocates in court (Ex.1041 p.2 Term 8), that structure is found in the combination of Leonhardt and Johnson. The apex of the funnel-shaped valve element or "membrane" 30 of Johnson is attached to the apex of Johnson's framework at the point of joinder 16.

(Ex.1021 cols.2:47-51, 4:10-15, 4:35-68, FIGS.1, 2.) This apex is a portion of the frame on the centerline to which the FVE is attached and is central both radially and longitudinally with respect to the combined structure. And this central portion of Johnson is disposed between the peripheral anchors of Leonhardt, both longitudinally and radially as well. (*See* FIG.H, *supra*; Ex.1003 ¶117; *see also* Claim Chart 1 Leonhardt and Johnson "Central Portion.")

d. Flexible Valve Element

All of the challenged claims require "a flexible valve element" attached to the central portion thereof. (*See* Claim Chart 1 "Flexible Valve Element.") According to Patent Owner's Definition, this envisions any flexible valve, including a tricuspid valve. Indeed, it allegedly encompasses any flexible part of a valve. (Ex.1041 p.3 Term 12.)

The FVE of the combination of Johnson and Leonhardt meets Patent Owner's Definition. Johnson's FVE is a unitary structure and is a funnel or bowl shape, its apex being attached to the central portion (apex) of a correspondingly cage-shaped framework of Johnson. (Ex.1021 cols.4:49-68, 5:35-36, 6:2-8.) And it is expressly identified as "flexible." (*Id.* 2:43-50, 4:49-68.) To block upstream flow of blood, the valve element 30 balloons outwardly so that that the downstream edges 32, 34, and 36 of the valve element seats against the surrounding annulus 41. (*Id.* 5:37-53, FIGS.2, 4, 5.) To allow downstream flow, portions of the valve

element 30 between the struts collapse inwardly, toward the central axis of the cage and valve element, just as occurs in the '297 Patent. (*Id.*) This unitary structure is flexible as described and is a valve. (Ex.1017 col.5:31-52; 1021 col.4:57-68; *see also* Claim Chart 1 Leonhardt and Johnson "Flexible Valve Element.") As described above, mounting Johnson's valve within the stent of Leonhardt results in the FVE being attached to a central portion of the frame — both that of Johnson and of Leonhardt. (*See* FIG.H; Ex.1003 ¶¶118-120.)

The challenged claims require an FVE having upstream and downstream sides facing the upstream and downstream regions, respectively. This limitation is met by the valve of Leonhardt/Johnson mounted in the aortic or mitral position. (Exs.1017 cols.5:40-52, 6:13-19, 6:23-34, 9:63-10:21, 10:22-43, FIGS.2, 3, 8, 9D; 1021 cols.5:37-53, 6:14-19, FIGS.4, 5, 8; 1003 ¶¶76, 120; *see also* Claim Chart 1 Leonhardt and Johnson "Upstream/Downstream Sides.")

e. <u>Valve Movement Limitations</u>

Claim 1, and therefore claims 18 and 20, includes a lengthy recitation which merely describes the general operation of virtually any one-way (or check) valve, including the native heart valve and replacement valves, all of which were known *per se*. (Ex.1003 ¶121.) These features were known to POSAs at the time as discussed in Ground 1.

These limitations are obvious in view of the combination of Leonhardt and Johnson. As explained in Johnson, the flexible valve membrane 30 is attached to the flexible framework in such a manner that the membrane segments freely open inwardly to allow unimpeded forward blood flow through the valve. When the cardiac cycle reverses, the valve bellows outwardly and effect closure against the tissue annulus. This closing method as well as the flexibility of the structural frame should avoid localized stress points on the leaflets and result in extreme durability. (Exs.1021 col.3:26-47, 5:37-53, FIGS.4, 5; 1003 ¶122; *see also* Claim Chart 1 Leonhardt and Johnson "Valve Movement Language.") This meets the claimed language as well.

f. Valve/Frame Opening Limitation

Claim 1, and therefore claims 18 and 20, requires that the artificial valve include an opening extending through at least one of the frame and the FVE "for receiving an implement." This is discussed previously for Leonhardt in Ground 1.

Patent Owner Contends that this limitation is met by a tricuspid valve mounted within a tubular stent that allows a catheter tip or other device to be passed through the interior of both the FVE and the stent. (Ex.1040 pp.11-12.) Since blood must be able to selectively traverse the valve, it must have an opening as Patent Owner Defines it. Leonhardt explicitly teaches that the prosthetic valve "should be in an open position when valve stent 20 is loaded into outer

sheath 106," which "allows inner catheter 110 to pass through valve 22 . . . ." (Ex.1017 col.7:11-16.) This means the device and FVE include an opening. And indeed, Leonhardt actually illustrates its valve with an implement traversing its length through the opening. (*Id.* FIGS.9A-D.) Thus, Leonhardt teaches a POSA a prosthetic heart valve that includes an opening passing through the center of both the frame and the FVE, with the opening explicitly being capable of receiving an implement therethrough. (*See* Claim Chart 1 Leonhardt "Valve/Frame Opening.")

Mounting the FVE and framework of Johnson within the stent of Leonhardt as shown in FIG.H would not change this. There is an area between the FVE and the periphery of the valve when the FVE is contracted into the center. (Ex.1021 col.5:45-53, FIG.5; *see* FIG.D, *supra*.) That opening allows a guidewire or instrument to traverse the FVE and the framework of Johnson and of Leonhardt as shown in FIGS.9A-9D. (Ex.1017 FIGS.9A-9D.) Thus the combined device includes an opening as Defined. (Ex.1003 ¶¶123-125.)

g. Claims 18 And 20

Claims 18 and 20 depend from device claim 1 and that device is obvious over the combination of Leonhardt and Johnson as discussed in Part IX.B.2.a-f. The methods of implanting that obvious device are obvious as well over the procedure described in Leonhardt as discussed above in Ground 1 and Claim Chart 1.

Briefly, claim 18 is obvious because Leonhardt teaches providing "entry" into, *inter alia,* the femoral artery which leads to the heart (Ex.1017 cols.9:64-67, 10:31-52), inserting an elongate flexible instrument through the incision and pushing its end through the vessel (*id.* 10:1-21). Leonhardt also teaches positioning the end of the elongate flexible instrument adjacent the cusps of the damaged native valve (*id.* 5:40-52, 10:6-21, 10:43-61). The ejecting, retrieval, repositioning, and re-ejecting steps are taught as well. (*Id.* 5:40-52, 8:23-41, 10:6-21, 10:43-52, 10:53-11:36, 11:36-57, FIGS.5-7, 9A-9D; Ex.1003 ¶126; *see also* Claim Chart 1.)

Claim 20 also requires an incision, inserting the end of an elongated flexible instrument into the vessel through the incision, and pushing the end until its end is adjacent the cusps of a damaged native heart valve, just as noted above in connection with claim 18. Leonhardt teaches all of these method steps as explained above. And Leonhardt also teaches ejecting the valve from the end of the instrument into a position between the cusps of the damaged valve as explained above.

What claim 20 requires that is not required by claim 18 is the insertion of a guide or guidewire into the incision, feeding it up to the native valve, threading the elongate flexible instrument onto the guidewire and introducing it into the incision and advancing the instrument to the damaged valve along the guidewire. But this use of a guidewire, threading the instrument onto the guidewire, and advancing the

instrument over the guidewire are all taught by Leonhardt. (Exs.1017 cols.9:63-10:6, 10:3-11, 10:21-30, 10:35-42, 10:43-52, 10:53-11:36, FIGS.5-7, 9A-9D; 1003 ¶¶127-128; *see also* Claim Chart 1.) Thus claims 18 and 20 are obvious over the combination of Leonhardt in view of Johnson.

h. Motivation And Reasonable Expectation Of Success

No motivation should be required to substitute equivalent known elements from among the known technology. But here, Leonhardt provides motivation for the combination by teaching that mechanical and synthetic valves and the like could be used in place of the biological valve exemplified. (Ex.1017 col.6:31-34.)

Additional motivation to consider the Johnson valve is provided by Johnson itself. Indeed, Johnson discloses that tissue valves, such as preferred in Leonhardt, have had durability problems resulting from, *inter alia*, the fact that the leaflets are attached to a rigid or semirigid fixation ring around the perimeter. (Ex.1021 col.2:39-42.) "By using a central attachment without an outer fixation ring, the dynamic annulus valve effects closure by leaflet coaptation with the natural or reconstructed tissue annulus. This closing method as well as the flexibility of the structural frame should avoid localized stress points on the leaflets and result in extreme durability." (*Id.* 3:37-47.)

A POSA would be motivated to try the construction of the Johnson valve to replace a native tissue FVE or synthetic leaflet FVE of Leonhardt in hopes of obtaining a more durable valve as discussed previously.

A POSA would also have a reasonable expectation of success from this combination. All of the elements are disclosed in issued U.S. patents, which are presumed enabling. And all use the same basic elements (stent, band, valve), arranged in generally the same way, used for the same purpose. Given the similarity of structure and function, a POSA would reasonably expect that this combination would work. (Ex.1003 ¶¶129-133.) And they would have a reasonable expectation of being able to deliver this valve using the methods of claims 18 and 20.

X. SECONDARY CONSIDERATIONS

It is the Patent Owner's burden to adduce evidence of objective indicia of nonobviousness (unexpected and superior results, commercial success, copying, long-felt but unmet need, skepticism, and industry acclaim), if any such evidence exists and to establish nexus. Patent Owner did not offer any such evidence during prosecution of the '297 Patent. To prove nexus, Patent Owner will have to establish, among other things, that the secondary indicia it advocates was based on patentable features — features of its invention that were not disclosed in the prior art. *See Asyst Techs., Inc. v. Emtrak, Inc.*, 544 F.3d 1310, 1316 (Fed. Cir. 2008);

see also J.T. Eaton & Co. v. Atl. Paste & Glue Co., 106 F.3d 1563, 1571 (Fed. Cir. 1997). And, any showing of secondary considerations must be commensurate with the scope of the claims. *Allergan, Inc. v. Apotex, Inc.*, 754 F.3d 952, 965 (Fed. Cir. 2014).

Before being purchased by Patent Owner, just before filing suit, the technology of the challenged claims was largely ignored. To Petitioner's knowledge, no heart valve using the birdcage-like frame and funnel valve delivered using the claimed methods has ever been commercialized or even brought to a large scale clinical trial. The industry has instead used various iterations of valves generally structured as the native human anatomy. (Ex.1003 ¶¶26-27.) Neither the acquisition of the '297 Patent for purposes of suing industry participants nor settlement of a similar lawsuit brought against Medtronic Corporation, *Snyders Heart Valve LLC v. Medtronic, Inc.*, No. 16-cv-00813 (E.D. Tex. Oct. 25, 2016), constitute such evidence. The terms of the settlement are not publicly available and the settlement could as easily have resulted from the more important business priorities of Medtronic as from a recognition of this technology.

Even if secondary evidence exists, however, it is not relevant to the question of anticipation, is not commensurate, and cannot overbalance the strong showing of *prima facie* obviousness reflected in the various grounds of this Petition.

XI. CONCLUSION

For the foregoing reasons, Petitioner requests that *inter partes* review be instituted for claims 18 and 20 of the '297 Patent and that those claims be held unpatentable over each of the grounds discussed hereof.

Dated: October 23, 2017

By: s/ Michael H. Teschner /
Michael H. Teschner
Reg. No. 32,862

5171644_1.docx

CERTIFICATE OF COMPLIANCE
WITH TYPE-VOLUME LIMITATION

Pursuant to Rule 37 C.F.R. § 42.24(d), the undersigned hereby certifies that, based upon the word count of the word-processing system used to prepare this Petition, the number of words in this Petition is 12,217. Pursuant to 37 C.F.R. § 42.24 (a), this word count does not include "a table of contents, a table of authorities, a certificate of service or word count, exhibits, appendix, or claim listing."

Dated: October 23, 2017

By: s/ Michael H. Teschner /
Michael H. Teschner
Reg. No. 32,862

CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of the foregoing **PETITION FOR *INTER PARTES* REVIEW OF CLAIMS 18 AND 20 OF U.S. PATENT NO. 6,821,297**, together with all exhibits, the Power of Attorney, and all other papers issued therewith was served on October 23, 2017, as follows.

VIA FEDEX

Matthew Antonelli, Esq.
Michael Ellis, Esq.
Zachariah Harrington, Esq.
Larry Thompson, Jr., Esq.
Antonelli, Harrington & Thompson LLP
4306 Yoakum Blvd, Suite 450
Houston TX 77006
Tel: 713.581.3000

Dated: October 23, 2017 By: s/ Michael H. Teschner /
Michael H. Teschner
Reg. No. 32,862

5171644_1.docx