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. IPR2018-00107

PETITION FOR *INTER PARTES* REVIEW OF CLAIMS 1-3, 8, 9, 22, 23, 31-35, 37-39, AND 45 OF U.S. PATENT NO. 6,821,297

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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., Ph.D.
1004	C*urriculum 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")

Exhibit #	Reference
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
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)

Exhibit #	Reference
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)
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

Petitioner, St. Jude Medical, LLC, requests *inter partes* review of claims 1-3, 8, 9, 22, 23, 31-35, 37-39 and 45 ("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 Oct. 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). A second IPR Petition is filed concurrently seeking cancellation of method claims 18 and 20 of the '297 Patent bearing Attorney Docket No. STJUDE 7.1R-005. Two other IPRs are filed concurrently against the parent 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 claims challenged in this petition. Accordingly, Petitioner requests institution of an IPR and cancellation of claims 1-3, 8, 9, 22, 23, 31-35, 37-39, and 45 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 1-3, 8, 9, 22, 23, 31-35, 37-39, and 45 are anticipated by Bessler.

Ground 2. Claims 1-3, 8, 9, 22, 23, 31-35, 37-39, and 45 are anticipated by Leonhardt.

Ground 3. Claims 1-3, 8, 9, 22, 23, 31-35, 37-39, and 45 are obvious over Bessler.

Ground 4. Claims 1-3, 8, 9, 22, 23, 31-35, 37-39, and 45 are obvious over Leonhardt.

Ground 5. Claims 3, 23, and 39 are obvious over Bessler in view of Thompson.

Ground 6. Claims 3, 23, and 39 are obvious over Bessler in view of Taylor.

Ground 7. Claims 1-3, 8, 9, 22, 23, 31-35, 37-39, and 45 are obvious over Bessler in view of Johnson.

Ground 8. Claims 3, 23, and 39 are obvious over Bessler in view of Johnson further in view of Thompson.

Ground 9. Claims 3, 23, and 39 are obvious over Bessler in view of Johnson further in view of Taylor.

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 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. According to Patent Owner's

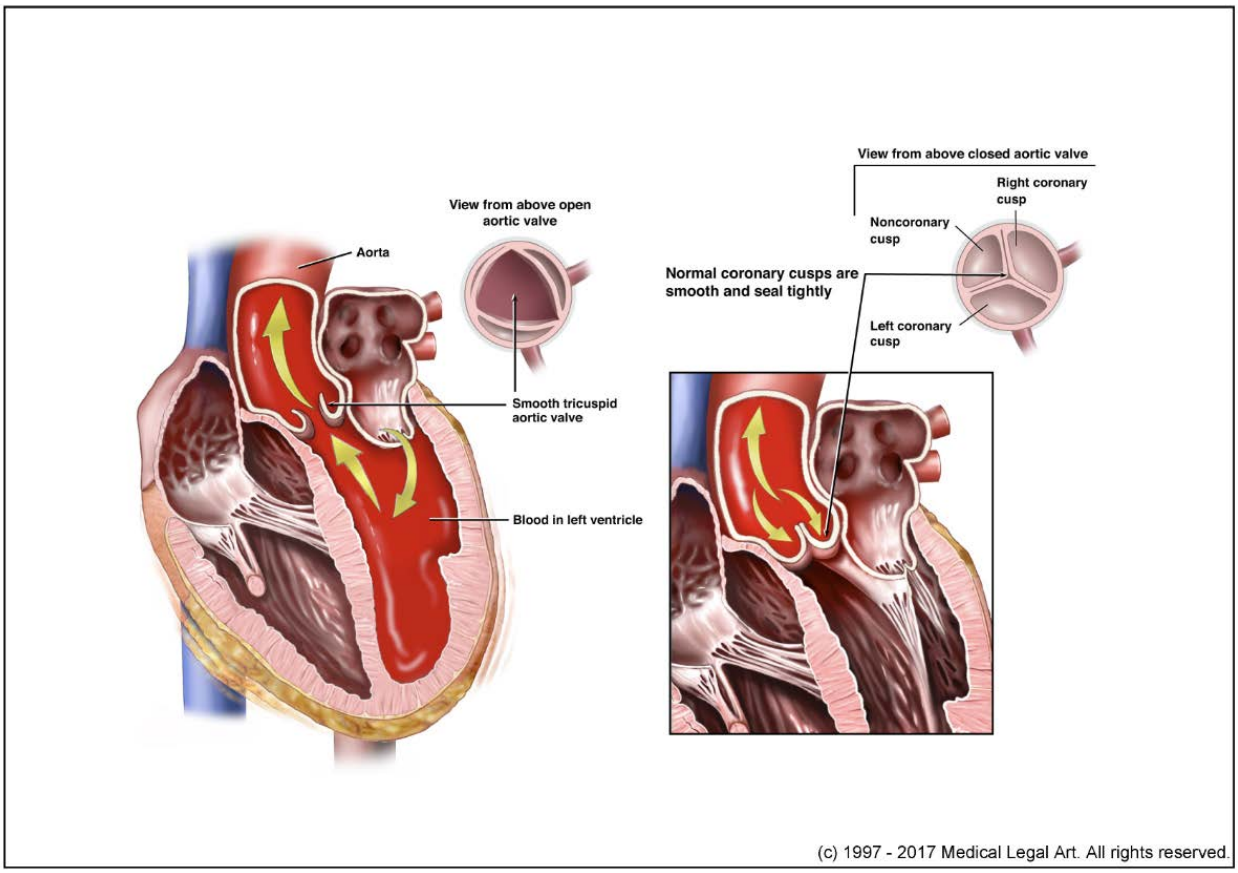
litigation position, the challenged claims read on the very art the inventor sought to improve.

V. BACKGROUND

Surgical replacement valves date back more than a half century, as the references cited in the ’297 Patent established. (Exs.1001 col.1:47-65; 1003 ¶24.) However, valve replacement surgery is extremely invasive. (Ex.1001 col.1:30-46.) 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. (Exs.1001 col.1:66-2:23; 1003 ¶24.)

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

FIG.A



(Ex.1044, with redactions.)

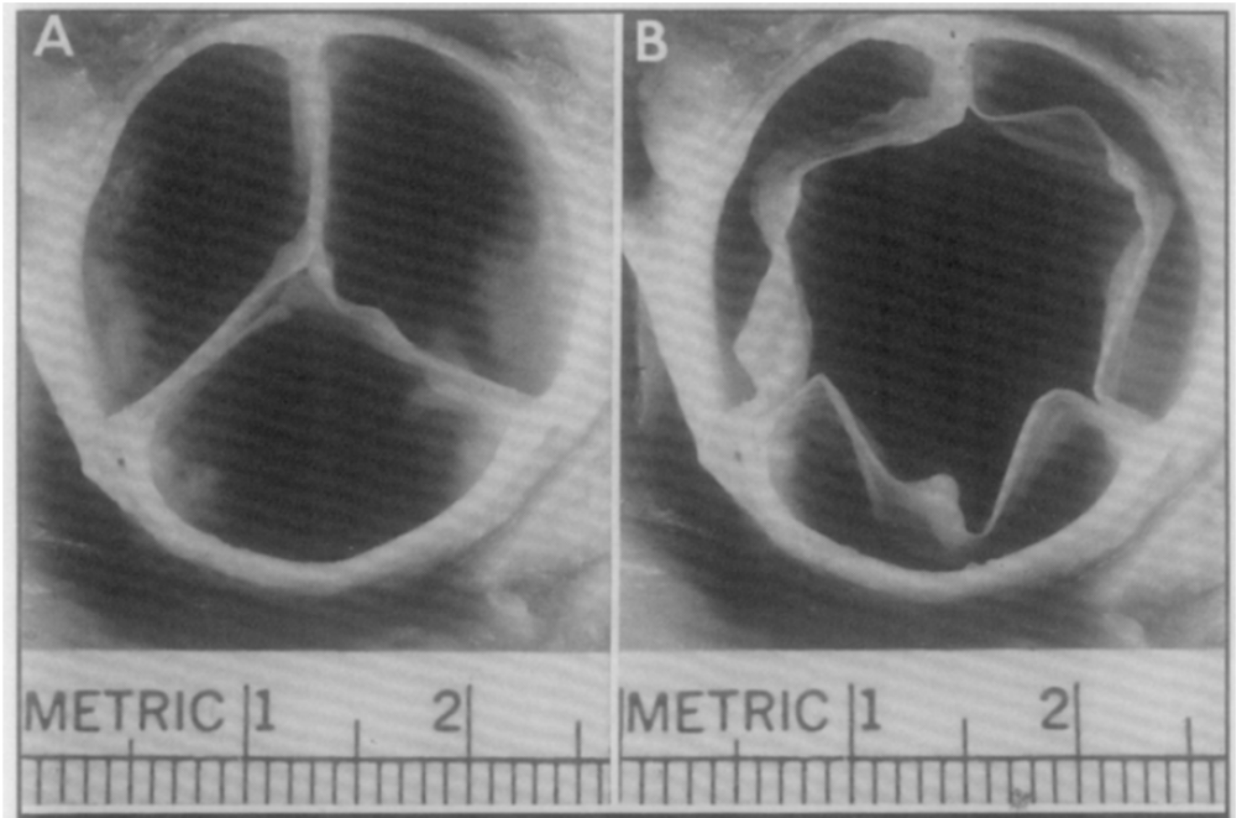
The aortic valve shown in FIG.A is referred to as a "tricuspid" valve because the valve element comprises three separate leaflets or "cusps" which cooperate to permit forward, and prevent reverse, blood flow. Other valves, like the mitral valve, have two leaflets. In the above example, when the left 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 towards 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), preventing upstream blood flow. 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 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.* ¶¶27-28.) Two of the valves cited in the '297 Patent's Background and one of the references cited during prosecution include porcine valves which have the native architecture. (*Id.*) They all include a flexible valve element ("FVE") and a band mounted to a tubular stent.

FIG.B

Native valve



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

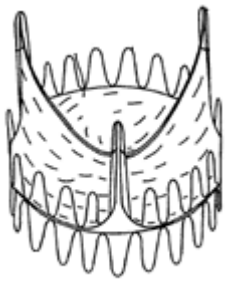


FIG. 2

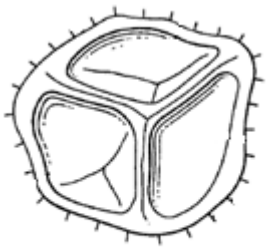


FIG. 12

FIG.4

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

Others have proposed FVEs with designs quite different from the trileaflet design. One suggested a frustoconical FVE structure.

FIG_4b

(Ex.1003 ¶29.) Still others suggested a single flap or inverted funnel shaped valve element. (*Id.* ¶¶30-33.)

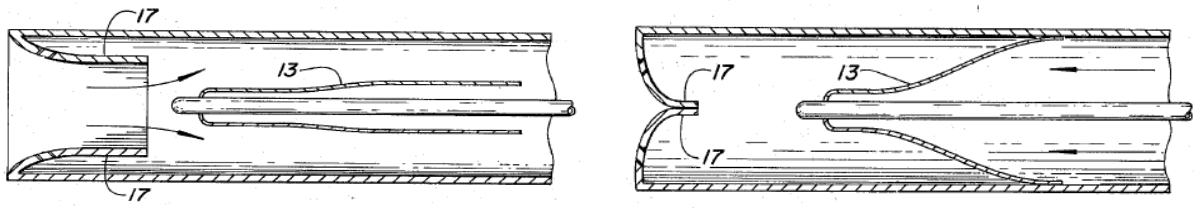


FIG 2A FIG 2B

(Ex.1010 FIGS.2A, 2B.) Indeed, FIGS.2A and 2B of Ex.1010 demonstrate how native valve movement is opposite of funnel valve movement. 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 back flow. In the native valve, the leaflets 17 are forced into the center where they meet and form a seal. In the funnel valve, the flap 13 fills with blood and expands outwardly until the edges meet the vessel.

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

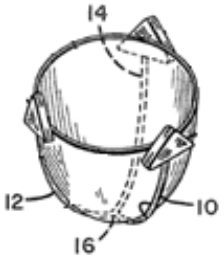


Fig. 2

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 provisional applications are both incorporated by reference into the '297 Patent, with the provisional application including two detailed appendices; A and B. (Ex.1011.) Together, these documents describe a valve of very specific construction. "The fundamental design of the stented funnel valve prosthesis 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 description of the alleged invention. (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 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, looking down into the valve, from the aorta, showing blood flow up out of the page around the unitary FVE.

FIG.C

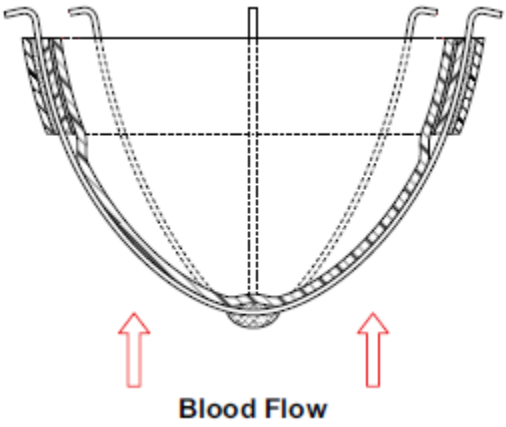
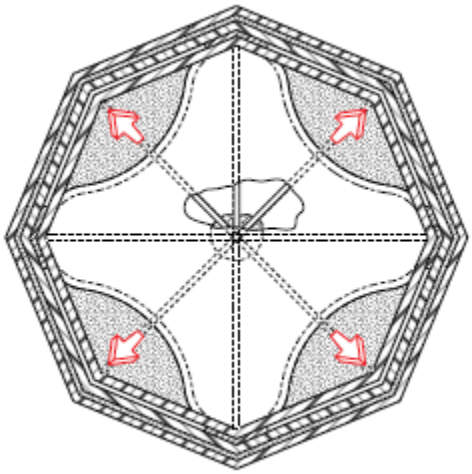


FIG.D



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 and 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. (Ex.1003 ¶¶42-46.)

Bessler (Ex.1008) is discussed and criticized as being "bulky" and as not describing the specific construction of the valve and requiring a surgical procedure to remove the native valve leaflets. (Exs.1001 col.2:18-23; 1011 App.A p.A-3:9-22.) The first criticism is addressed in Ground 1. As to the second, the challenged claims are device claims so such criticism is inapposite. Moreover, a POSA knew that a collapsible valve could be implanted without removal of the leaflets. (Exs.1007 col.9:45-53; 1003 ¶43.)

The ’297 Patent (Ex.1001) 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); longitudinal pleats in the FVE (col.11:7-27); band constructions (col.11:28-12:53); alternates 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 delivery system details (col.13:36-14:65); instrument sensors (col.15:28-52); and additional delivery methods (col.15:53-18:15).

B. The Prosecution History Of The ’297 Patent

The prosecution history of the ’782 parent was reviewed and is discussed by Dr. Dasi. (Ex.1003 ¶¶47-53.) But, except as indicated herein in connection with Johnson (Ex.1021), it is not believed to be particularly relevant to this petition. 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 amending independent claims 1, 17, 26, and 33 (which issued as claims 1, 22, 31, and 38, respectively) (*id.* pp.2-13). 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.) Claims 17, 26, and 33 were amended to recite that the flexible valve element is "fixedly" attached to the frame [or the central portion of the frame] "so that at least a portion of the element is substantially immobile with respect to at least a portion of the frame [or with respect to the central portion of the frame]." (*Id.* pp.5-9.) Regarding the amended language, the applicant merely asserted 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.)

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 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). That said, Patent Owner's proposed constructions are admissions against its interest. Petitioner should have the right to rely upon Patent Owner's constructions made in court 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 constructions in the district court action, including those derived from its Contentions (Exs.1040, 1041, collectively "Definition(s)" or "Define(s)(ed)"), the following terms[1] should be given the following constructions solely for purposes of this IPR:

[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
Frame	Ex.1041 p.2 Term 3: structure designed to shape or support Ex.1040 pp.2-4, 31-32, 45-47, 64-66
Peripheral anchor(s)	Ex.1041 p.2 Term 5 Anchor(s): structure(s) that secure or stabilize something in place Peripheral: located on the periphery Ex.1040 pp.4-5, 32-33, 47-48, 66-67
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, 48-49, 67-68
Band	Ex.1041 pp.2-3 Term 10: A structure generally in the shape of a circular strip or ring; a band can be integrated with the frame Ex.1040 p.16
Flexible valve element	Ex.1041 p.3 Term 12: A flexible part of the valve Ex.1040 pp.6-7, 34-35, 49-51, 68-70
Opening extending through at least one of said frame and said flexible valve element	Ex.1041 p.3 Term 17: Any opening extending through the flexible valve element and the central portion of the frame** Ex.1040 pp.11, 39-40, 54-55, 73-74
Opening extends through the central portion of the frame and the flexible valve element	Ex.1041 p.3 Term 16: Any opening in the frame and/or flexible valve element** Ex.1040 p.12
Releasable fastener	Ex.1041 p.3 Term 18: A fastener that is designed to be released non-destructively Ex.1040 pp.13, 41
Releasably attachable	Ex.1041 p.4 Term 22: Attached in a manner that can be unattached nondestructively

Term	Construction
	Ex.1040 pp.58-59, 76-77
Flexibly resilient	Ex.1041 p.4 Term 23: Able to spring back to its original shape, on its own, after being compressed Ex.1040 pp.2-4, 31-32, 45-47, 64-66
Convex upstream side	Ex.1041 p.4 Term 26: A valve element having an upstream side that bulges out in the upstream direction Ex.1040 pp.36-37
Concave downstream side	Ex.1041 p.4 Term 27: A valve element having a downstream side that bulges away from the downstream direction Ex.1040 pp.36-37

**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. That said, the challenged claims are also obvious as discussed in Grounds 7-9 if many of the Petitioner's constructions are adopted.

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

A. Anticipation

1. Ground 1: Claims 1-3, 8, 9, 22, 23, 31-35, 37-39, And 45 Are Anticipated by Bessler

Based on the claims construed in light of Patent Owner's Definitions, all of the challenged claims are anticipated by Bessler (Ex.1008). (Ex1003 ¶58.) As noted in Part VI, *supra*, the '297 Patent claims benefit of a patent application

(Ex.1016) and a provisional application filed February 2, 2000. (Ex.1011.) Therefore, 35 U.S.C. §§ 102 and 103, as they existed prior to enactment of the AIA apply here. Bessler issued on January 5, 1999, and is prior art pursuant to 35 U.S.C. § 102(b). Bessler was of record but was not applied by the Examiner. (*See* Part VI, *supra*.) As further illustrated in Claim Chart 1, *infra*, Bessler anticipates the challenged claims because, under Patent Owner's Definitions, it teaches each element of the challenged claims arranged as in the claims. *In re Gleave*, 560 F.3d 1331, 1334 (Fed. Cir. 2009).

a. An Artificial Valve For Repairing A Damaged Heart Valve

Bessler describes an artificial replacement valve comprised of a frame, a band surrounding the frame, and a convex/concave FVE sized and shaped to be disposed in a native valve annulus between upstream and downstream regions, all as Defined. (Exs.1008 cols.2:57-67, 3:46-4:21, 7:26-67, FIGS.1-7, 14, 15; 1003 ¶59.)

b. Flexibly Resilient Frame

Each independent claim requires a flexibly resilient frame, which, as Defined is met by any structure designed to shape or support, presumably the FVE, and able to spring back to its original shape after being compressed. (Ex.1041 p.2 Term 3, p.4 Term 23.) The Bessler stent is a self-expanding stent 21 which biases the valve 20 into engagement with the surrounding tissue. (Ex.1008 cols.2:60-63,

3:51-55, 4:63-5:14, 5:19-21, 5:31-35, 5:43-6:18, 7:26-67, FIGS.1-7, 14-15.) It can be made of nitinol. (*Id.* 6:5.) A POSA would appreciate that it is a flexibly resilient frame as Defined. (Ex.1003 ¶60; *see also* Claim Chart 1 Bessler "Frame-Flexibly Resilient.")

The frame must include a plurality of peripheral anchors, which Patent Owner Defines as merely a peripheral structure that secures or stabilizes something in place. (Ex.1041 p.2 Term 5.)A number of Bessler's structures can be considered peripheral anchors as Defined.

FIG. 4

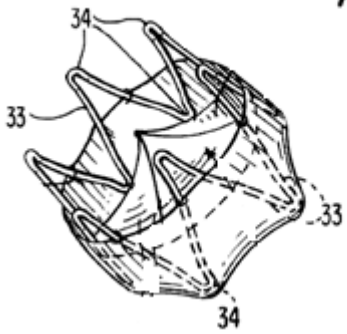
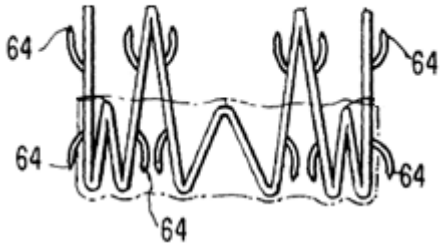


FIG. 7



The barbs 64 which Bessler locates upstream and downstream to maintain implantation are certainly peripheral anchors. (Exs.1008 cols.4:12-21, 5:67-6:2, 7:26-67, FIG.7; 1003 ¶¶61-64.) Moreover, as illustrated in FIG.4, the frame can have a zig-zag or sine wave structure of integral or welded straight 33 and bend sections 34. These bends 34 are also peripheral anchors as Defined. (Exs.1008

cols.5:19-21, 5:28-35, 5:51-60, 6:7-11, FIGS.1-4; 1003 ¶¶63-64; *see also* Claim Chart 1 Bessler "Peripheral Anchors.")

Claims 1, 31, and 38 require the frame to have a "central portion" located between the peripheral anchors, with claims 1 and 31 requiring the central portion to be "located along a centerline." Patent Owner did not feel "central portion" or "centerline" required any construction. Its Contentions identify merely any frame region located between peripheral anchors. (Exs.1041 p.2 Terms 7-9; 1040 pp.5-6, 48-49, 67-68.)

The central portion disclosed in Bessler could be the portion of the stent represented by straight sections 33, 53 between the bends 34, 54 (Ex.1008 cols.5:28-35, 5:55-60, FIGS.1, 4, 6) or the stent portions disposed between the first and second circles of barbs (*id.* 4:12-21, 5:60-6:2, 7:43-67, FIGS.6-7, 14, 15; Ex.1003 ¶65; *see also* Claim Chart 1 Bessler "Central Portion"). Each is centrally located between the plurality of peripheral anchors and is along the central axis of both the valve and the native valve when implanted. It is a central portion along the centerline as Defined.

c. Flexible Valve Element

All of the challenged claims require "a flexible valve element" attached to the frame or to a central portion thereof. Patent Owner Defines this as any flexible part of a valve. (Ex.1041 p.3 Term 12.) According to Bessler "[t]he valve member

is flexible, compressible, host-compatible, and non-thrombogenic." (Ex.1008 cols.6:19-31 (emphasis added).) Bessler also teaches that the valve is mounted to the central portion of the frame extending along a central axis as Defined. Indeed, as illustrated in FIG.7, FVE 63 can be disposed centrally and attached to the centrally located "crowns" or the tops of "smaller waves" 61. (*Id.* 5:60-6:2, FIG.7.) Thus Bessler teaches a FVE attached to the central portion of the frame. (*See* Claim Chart 1 Bessler "Flexible Valve Element"; Ex.1003 ¶70.)

The FVE must also have upstream and downstream sides facing the upstream and downstream regions, respectively. As a replacement valve disposed in a native annulus, the FVE must have sides facing upstream and downstream as Defined. (Exs.1008 cols.3:55-4:3, 4:12-21, 4:63-5:14, 5:20-27, 5:43-51, 7:26-67, FIGS.1, 4; 1003 ¶71, s*ee also* Claim Chart 1 Bessler "Upstream/Downstream Sides.")

Claim 22 further characterizes these upstream and downstream sides as a "convex" upstream side facing the upstream region and a "concave" downstream side opposite the upstream side facing the downstream region. Bessler describes its valve as "arcuate" and illustrates it forming a generally concave downstream side as Defined. (Exs.1008 cols.3:54-64, 5:20-27, 5:36-42, FIG.4; 1003 ¶72.) This necessarily means that Bessler's valve has a complementary convex upstream side. Moreover, it is convex and concave to the same extent as the valve in the

Contentions allegedly is. (Exs.1008 col.6:19-24; 1040 pp.36-40; 1003 ¶72; *see also* Claim Chart 1 Bessler "Convex Upstream/Concave Downstream Sides.")

Claims 22, 31, and 38 require that the FVE is "fixedly attached to the frame [or the central portion of the frame] so that at least a portion of the element is substantially immobile with respect to at least a portion of the frame [or with respect to the central portion of the frame]." The valve member 22 of Bessler, along with its corresponding cuff 25, may be attached to the stent 21 with sutures 26 or other attachment means. (Ex.1008 col.5:24-27, 9:59-61, FIG.2.) At least the portions of the valve member 22 that are fixed to the stent 21 via sutures are immobile with respect to all other portions of the stent, including the central portion as Defined. (Ex.1003 ¶73; *see also* Claim Chart 1 Bessler "Flexible Valve Element.")

d. Valve Movement Limitations

Each independent claim includes lengthy recitations merely describing the function of virtually any one-way (or check) valve, including the native heart valve and replacement valves, all of which were known *per se*. (Exs.1001 col.1:47-2:23; 1003 ¶74.)

Patent Owner alleges that these recitations, all beginning with "said valve element moving" (the "valve movement language") are met by the operation of the tricuspid valve identified in the Contentions. (Ex.1040 pp.9-10, 38-39, 52-54,

71-73.) The FVE of Bessler (as Defined) functions in the same manner. Bessler therefore meets these recitations as Defined. (Exs.1008 cols.3:65-4:3, 4:63-5:14, 5:36-43, 6:19-24, FIG.4; 1003 ¶75; *see also* Claim Chart 1 Bessler "Valve Movement Language.")

e. Valve/Frame Opening Limitations

Each independent claim requires that the artificial valve include an opening extending through the frame and/or the FVE. Claim 1 further recites that the opening is "for receiving an implement." Claim 2 specifies that the opening extends through both the FVE and the central portion of the frame.

Patent Owner Contends that these limitations are met by an artificial tricuspid valve mounted within a tubular stent that allows a catheter tip or guidewire to traverse the interior of both the FVE and the stent. (Ex.1040 pp.11-12, 39-40, 54-55, 73-74.) Bessler teaches a valve attached to the central portion of the frame having such an opening as Defined. (Exs.1008 cols.3:65-4:21, 5:28-35, 5:55-6:2, 7:43-67, FIGS.1, 4, 6-7, 14, 15; 1003 ¶¶76-78.)

As to claims 1 and 2, Bessler teaches a prosthetic heart valve that includes an opening passing through the center of the frame and the FVE as Defined, with the opening explicitly being capable of receiving an implement therethrough. (Ex.1008 col.7:26-42, FIGS.12-13; 1003 ¶78; *see also* Claim Chart 1 Bessler "Valve/Frame Opening.")

f. Flexible Elongate Guide Limitations

Claim 31 requires a combination of both an artificial valve, and a flexible, elongate guide for guiding the valve, the guide being sized for receipt within the opening. As noted above, Bessler teaches the use of a guidewire that traverses the stent and FVE as Defined. (Exs.1008 col.7:26-42, FIGS.12-13; 1003 ¶79.) Thus, Bessler teaches the claimed flexible guide in combination with an artificial valve. (*See* Claim Chart 1 Bessler "Guide.")

g. Delivery Device Limitations

In addition to the valve limitations, just discussed, claim 38 requires a delivery device or "instrument" comprising a holder having a hollow interior for holding the valve, an elongate manipulator attached to the holder for manipulating the holder and an installer received within the holder for installing the valve from the holder. (Ex.1001 col.24:32-45.) Claims 32-34, which all depend from independent claim 31, require the same holder (cl.32), manipulator (cl.33), and installer (cl.34) elements recited in claim 38. (*Id.* col.23:34-48.)

Bessler discloses the claimed instrument(s). Bessler's hollow distal end of its flexible catheter which can be inserted into a vessel is the "holder." (Ex.1008 cols.4:53-58 ("The distal end of the catheter, which is hollow and carries the artificial heart valve . . . in its collapsed configuration"), 7:26-67, FIGS.12-15.) The proximal end of the catheter, element 91 in FIGS. 12-15, is the manipulator

which is used to position the distal holder. (*Id.* 4:63-5:1, 7:26-67, FIGS.12-15.) Finally, Bessler describes a pusher member 93 disposed within the catheter which is activated to install the valve at the delivery site. (*Id.* cols.4:60-66, 5:3-14, 7:26-67, FIGS.12-15.) Those claims are anticipated. (*See* Claim Chart 1 Bessler "Holder," "Manipulator," "Installer"; Ex.1003 ¶80.)

Claim Chart 1 below reflects the recitations of the challenged independent claims, as well as selected dependent 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 the claim number 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 Grounds 1 and 3 (indicated as "Bessler"). The citations for Grounds 2 and 4 include those for Leonhardt entries in the chart. The citations for Ground 7 include those for Johnson entries in the chart.

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:	**All Challenged Claims** Bessler: Exs.1008 cols.2:57-67, 3:46-4:21, 7:26-67, FIGS.1-7; 1003 ¶59. Leonhardt: Exs.1017

Claim Language	Citation
22(p). *see* 1(p) 31(p). In combination, an artificial valve for repairing a damaged heart valve having a plurality of cusps separating an upstream region from a downstream region, and a guide for guiding the artificial valve between the upstream region and the downstream region, said combination comprising: 38(p). In combination, an artificial valve for repairing a damaged heart valve having a plurality of cusps separating an upstream region from a downstream region, and an instrument for inserting the artificial valve between the upstream region and the downstream region, said combination comprising:	cols.3:15-49, 9:50-11:36, 11:59-12:5, FIGS.2, 3, 9A-9D; 1003 ¶90. Johnson: Exs.1021 cols.2:62-3:19, 6:8-19, FIGS.7, 8; 1003 ¶122. **Additional "guide" recitation for cl.31** Bessler: Exs.1008 col.7:26-42, FIGS.12-13 1003 ¶79. Leonhardt: Ex.1017 cols.7:10-17; 10:3-11; FIGS.9A-D; Ex.1008 ¶¶102-103. **Additional "instrument" recitations for cl.38** Bessler: Exs.1008 col.7:26-67, FIGS.12-15; Ex.1003 ¶80. Leonhardt: Exs.1017 cols.4:18-19; 6:34-54; FIGS.5, 7, 9A-9D; Ex.1003 ¶¶104-105.
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, 22(a). *see* 1(a) 31(a). said artificial valve including a flexibly resilient frame sized and shaped for insertion between the upstream region and the downstream region,	**All Challenged Claims** Bessler: Exs.1008 cols.2:60-63, 3:51-55, 4:63-5:14, 5:19-21, 5:31-35, 5:43-6:18, 7:26-67, FIGS.1-7, 14, 15; 1003 ¶60. Leonhardt: Exs.1017 cols.2:43-50, 3:33-45, 4:53-5:33, 5:40-52, 9:63-10:21 (aortic), 10:22-42 (mitral), FIGS.1B, 2, 3, 9A-9D; 1003 ¶91. Johnson: Exs.1021 cols.2:43-50,

Claim Language	Citation
38(a). *see* 31(a)	4:10-48, 5:20-36, 6:2-7, FIGS.1, 2, 7; 1003 ¶¶123-124.
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 22(b). *see* 1(b) 31(b). the frame having a plurality of peripheral anchors for anchoring the frame between the upstream region and the downstream region and 38(b). *see* 31(b)	**All Challenged Claims** Bessler: Exs.1008 cols.4:12-21, 5:19-21, 5:28-35, 5:51-60, 5:67-6:2, 6:7-11, 7:25-67, FIGS.1-7, 13, 14; 1003 ¶¶61-64. Leonhardt: Exs.1017 cols.3:33-45, 4:14-5:52, 5:53-56 (stent 26 coerces it), 6:9-23, 8:42-9:5; FIGS.1B, 2-4, 9A-9D; 1003 ¶¶92-94.
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; 31(c). a central portion located along a centerline extending between the plurality of peripheral anchors, 38(c). a central portion located between the plurality of peripheral anchors, and	**Cls.1, 31, 38** Bessler: Exs.1008 cols.4:12-21, 5:28-35, 5:51-6:2, 7:43-67, FIGS.6-7, 14, 15; 1003 ¶¶62, 65. Leonhardt: Exs.1017 cols.5:22-35, 6:9-22, 6:23-34, FIGS.1B, 1C, 2, 4; 1003 ¶94. Johnson: Exs.1021 cols.4:10-15, 4:35-48, FIG.1; 1003 ¶126.
Flexible Valve Element 1(d). a flexible valve element attached to the central portion of the frame, 22(c). a flexible valve element fixedly	**All challenged claims** Bessler: Exs.1008 cols.3:54-4:3, 5:20-28, 5:35-43, 5:60-6:2, 6:19-31, FIGS.1-4, 7; 1003 ¶70.

Claim Language	Citation
attached to the frame so that at least a portion of the element is substantially immobile with respect to at least a portion of the frame, 31(d). a flexible valve element fixedly attached to the central portion of the frame so that at least a portion of the element is substantially immobile with respect to the central portion of the frame, 38(d). a flexible valve element fixedly attached to the frame so that at least a portion of the element is substantially immobile with respect to the central portion of the frame,	Leonhardt: Exs.1017 cols.3:33-45; 5:23-52; 6:23-34; FIGS.1B, 1C, 2, 4; 1003 ¶95. Johnson: Exs.1021 cols.2:43-50, 4:49-68, 5:35-53, 6:2-8, FIGS.2, 4, 5; 1003 ¶¶127-128. **Additional "fixed" attachment and "substantially immobile" recitations for cls.22, 31, 38** Bessler: Exs.1008 cols.5:24-27, 9:59-61, FIG.2; 1003 ¶73. Leonhardt: Exs.1017 col.6:24-29; 1003 ¶¶91, 98. Johnson: Exs.1021 cols.4:49-5:12, 5:35-53, 6:2-8, FIGS.2, 4, 5; 1003 ¶131.
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, 31(e). said element having an upstream side facing said upstream region when the frame is anchored between the upstream region and the downstream region and a downstream side opposite the upstream side facing said	**Cls.1, 31, 38** Bessler: Exs.1008 cols.3:54-4:3, 4:63-5:14, 5:20-27, 5:36-51, 7:26-67, FIGS.1, 4; 1003 ¶71. Leonhardt: Exs.1017 cols.5:40-52; 6:23-34; 9:63-10:21; 10:22-43; FIG.2, 3, 4, 9A-9D; 1003 ¶96. Johnson: Exs.1021 col.6:14-19, FIG.8; 1003 ¶129.

Claim Language	Citation
downstream region when the frame is anchored between the upstream region and the downstream region, 38(e). *see* 31(e)	
Convex Upstream/Concave Downstream Sides 22(d). said element having a convex upstream side facing said upstream region when the frame is anchored in the position between the upstream region and the downstream region and a concave 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.22** Bessler: Exs.1008 cols.3:54-64, 5:20-27, 5:36-42, 6:19-24, FIG.4; 1003 ¶72. Leonhardt: Exs.1017 col.6:23-34 biologic porcine valve; 1003 ¶97. Johnson: Exs.1021 cols.2:39-61, 4:49-68, 5:37-45, FIGS.2, 7, 8; 1003 ¶130.
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	**All Challenged Claims** Bessler: Exs.1008 cols.3:65-4:3, 4:63-5:14, 5:36-43, 6:19-24, FIG.4; 1003 ¶¶74-75. Leonhardt: Exs.1017 cols.1:5-21, 3:33-45, 5:50-52, 6:23-34, FIGS.2, 3, 4, 9B; 1003 ¶99. Johnson: Exs.1021 cols.3:26-47, 5:37-53, FIGS.4, 5; 1003 ¶132.

Claim Language	Citation
flexible valve 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 22 (e). valve movement limitations — *see* 1(f) 31(f). valve movement limitations — *see* 1(f) 38(f). valve movement limitations — *see* 1(f)	
Valve/Frame Opening 1(g). an opening extending through at least one of said frame and said flexible valve element for receiving an implement. 22(f). an opening extending through at least one of said frame and the flexible valve element. 31(g). an opening extending through at least one of said frame and the flexible valve element; and 38(g). *see* 31(g)	**All Challenged Claims** Bessler: Exs.1008 cols.3:65-4:21, 5:28-35, 5:55-6:2, 7:26-67, FIGS.1, 4, 6-7, 12-15; 1003 ¶¶76-78. Leonhardt: Exs.1017 cols.3:33-45, 5:40-52, 6:23-32, 7:10-17, FIGS.4, 9A-D; 1003 ¶¶100-101.) Johnson: Exs.1021 col.5:12-19, FIG.5; 1003 ¶133-134.
Guide 31(h). said flexible, elongate guide sized for receipt within the opening to guide the valve into position.	**Cl.31** Bessler: Exs.1008 col.7:26-42, FIGS.12-13; 1003 ¶¶79, 135. Leonhardt: Exs.1017 cols.7:10-17, 10:3-11, FIGS.5, 8,

Claim Language	Citation
	9A-D; 1003 ¶¶102-103.
Holder 38(h). an instrument including a holder having a hollow interior sized for holding the artificial valve when the frame is in a collapsed configuration; 32. A combination as set forth in claim 31 further comprising a holder having a hollow interior sized for holding the artificial valve when the frame is in the collapsed configuration	**Cls.32, 38** Bessler: Exs.1008 cols.4:53-58, 7:26-67, FIGS.12-15; 1003 ¶80. Leonhardt: Exs.1017 cols.6:55-61, 7:16-21, FIGS.5-7, 9A-9D; 1003 ¶¶104-105.
Manipulator 38(i). an elongate manipulator attached to the holder for manipulating the holder into position between the upstream region and the downstream region; and 33. A combination as set forth in claim 32 further comprising an elongate manipulator attached to the holder for manipulating the holder into position between the upstream region and the downstream region.	**Cls.33, 38** Bessler: Exs.1008 cols.4:63-5:1, 7:26-67, FIGS.12-15 (element 91) — the proximal portion of the catheter; 1003 ¶80. Leonhardt: Exs.1017 cols.6:34-7:10, 7:21-8:22, FIGS.5-7, 9A-9D; 1003 ¶¶104-105.
Installer 38(j). an installer received within the hollow interior of the holder and releasably attachable to the frame of the artificial heart valve for maneuvering the artificial heart valve from the hollow interior of the holder into position between the upstream region and the downstream region. 34. A combination as set forth in claim 33 further comprising an installer received within the hollow interior of the	**Cls.34, 38** Bessler: Exs.1008 cols.4:60-66, 5:3-14, 7:26-67, FIGS.12-15; 1003 ¶80. Leonhardt: Exs.1017 cols.6:34-49, 8:23-42, FIGS.5-7, 9A-9D; 1003 ¶¶104-105.

Claim Language	Citation
holder and releasably attachable to the artificial heart valve for maneuvering the artificial heart valve from the hollow interior of the holder into position between the upstream region and the downstream region.	

h. Dependent Claims

Claim 2 depends from claim 1 and requires the opening to extend through both the FVE and the central portion of the frame. As addressed in Part IX.A.1.e, *supra*, Bessler teaches an opening extending through both the center of the stent and the FVE as Defined. (Exs.1008 col.7:26-42, FIGS.12-13; 1003 ¶¶78, 81.)

Claims 3 and 23, which respectively depend from claim 2 and independent claim 22, both require a releasable fastener mounted on the frame for selectively connecting the valve to an instrument. Claim 39, which depends from independent claim 38, requires that the frame includes a mount for selectively connecting the valve to the instrument. As noted in Part VIII, *supra*, Patent Owner Contends that "releasable fastener" means "a fastener that is designed to be released non-destructively." (Ex.1041 p.3 Term 18.) Although there is no support for this "non-destructive" construction in the '297 Patent, Bessler nonetheless anticipates.

Bessler teaches that the delivery device includes a pusher member within a catheter adjacent a prosthetic heart valve collapsed within the catheter. (Ex.1008 col.7:43-51, FIGS.14-15.) A pair of sutures 105 have a first end looped through an

opening 106 in the pusher, a middle portion hooked or looped around a peak of the stent of the valve, and a second end with a loop 107 that receives a tension thread 108. (*Id.* col.7:53-61, FIGS.14-15.) The valve is held in place by the sutures until the tension thread is pulled through the loops to fully release the valve from the delivery device without destroying the sutures or the peaks of the stent. (*Id.* col.7:53-67, FIGS.14-15.) The sutures are "releasable fasteners" mounted on the frame as Defined. The peaks of the stent that the sutures are looped around are the frame's "mount," the peaks allowing for non-destructive selective connection to the delivery device. (Ex.1003 ¶¶82-83.)

Claim 8 depends from claim 1, and requires that the frame include frame elements extending outward from the central portion that are biased outward to engage heart tissue and to hold the frame in the expanded configuration in the native annulus. Bessler discloses a self-expandable stent that includes straight portions 33, 53 and a plurality of barbs 64 both of which extend outward from a radial center of the stent. The barbs are "for holding the valve in place once it has been appropriately positioned," and the straight portions bias the stent. (Exs.1008 cols.2:60-62, 3:51-55, 5:61-6:2, FIGS.6-7; 1003 ¶84.) Thus, Bessler anticipates claim 8 as Defined.

Claim 9 depends from claim 8 and requires a band extending around the frame elements to limit outward movement of the frame elements and to sealingly

engage heart tissue. According to Patent Owner's Definitions, a band is a structure generally in the shape of a circular strip or ring, which can be a portion of the frame. (Ex.1041 pp.2-3 Term 10.) The claimed "band" can be the cuff of Bessler, which is depicted as surrounding the frame. (Ex.1008 cols.3:54-64, 4:4-11, 5:24-27, FIGS.1-5, 7.) The cuff of Bessler is shown as being tight against the self-expanding stent. (Ex.1008 cols.5:15-27, 5:40-43, FIGS.1, 4, 7.) This cuff would restrict the expansion of the self-expanding stent, including the barbs attached thereto. (Ex.1003 ¶¶66-69, 85.)

Dependent claims 32-34 are respectively directed to the holder, manipulator, and installer of a delivery device. As addressed above in Part IX.A.1.g, *supra*, Bessler teaches each of these elements. (*Id.* ¶¶80, 86.)

Claim 35 depends from claim 32 and requires the holder to include an outwardly flared end for receiving the artificial valve. Claim 45, which depends from independent claim 38, requires the holder to have an outwardly flared end for receiving peripheral anchors. According to Patent Owner's Contentions, these limitations are met by an atraumatic tip extending from a catheter shaft passing through the valve. (Ex.1040 pp.59-60, 78-79.) Bessler teaches that the delivery device 90 may include a guidewire 94 disposed through the catheter lumen and collapsed heart valve. (Ex.1008 col.7:26-42, FIGS.12-13.) The guidewire includes a blunt end 95 (*id.*) that is flared to the same extent as the device identified in

Patent Owner's Contentions (Ex.1040 pp.59-60, 78-79). Thus, Bessler anticipates claims 35 and 45 as Defined. (Ex.1003 ¶87.)

Claim 37 depends from claim 31 and requires the combination to include a vascular catheter. Bessler discloses that the flexible catheter 91 is "for percutaneous and transluminal delivery." (Ex.1008 col.7:28-30.) The word "transluminal" refers to passing through a lumen of a blood vessel (*i.e.*, vasculature), with Bessler clarifying that the "present invention" is directed to "endovascular placement of heart valves." (*Id.* 2:48-50; Ex.1003 ¶88.)

In summation, Bessler anticipates all of the challenged claims as the terms are Defined by the Patent Owner.

2. Ground 2: Claims 1-3, 8, 9, 22, 23, 31-35, 37-39, And 45 Are Anticipated By Leonhardt

All of the challenged claims as Defined are anticipated by Leonhardt (Ex.1017). (Ex.1003 ¶89.) 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). Further, as admitted by Patent Owner, claims 3, 23 and 39 are only entitled to a priority date of the April 30, 2002 filing of the '297 Patent. (Ex.1039 p.3.) As to those claims, Leonhardt is prior art pursuant to pre-AIA 35 U.S.C. § 102(b). Leonhardt was not of record. As further illustrated in Claim

Chart 1, *supra*, Leonhardt anticipates the challenged claims as Defined. *See Gleave*, 560 F.3d at 1334.

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. 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 ¶90.)

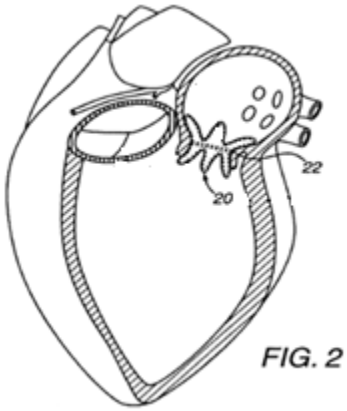


FIG. 2

b. Flexibly Resilient Frame

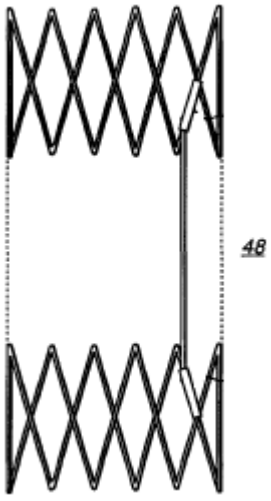
Each claim requires a flexibly resilient frame. As Defined, this is any structure designed to shape or support, and able to spring back to its original shape after being compressed. The Leonhardt stent is self-expanding and biases its proximal and distal ends into a fixed engagement with the tissue of the valve or annulus. (Ex.1017 cols.3:33-45, 4:53-5:33, 5:45-52.) It can be made of nitinol. (*Id.* 5:11.) A POSA would read Leonhardt's teaching as disclosing a flexibly resilient

frame as Defined. (Ex.1003 ¶91; *see also* Claim Chart 1 Leonhardt "Frame-Flexibly Resilient.")

The frame includes a plurality of peripheral anchors. Patent Owner's Definition of peripheral anchors encompasses frame elements found, *inter alia,* at the stent's periphery. (*See, e.g.*, Exs.1040 pp.4-5; 1003 ¶92.)

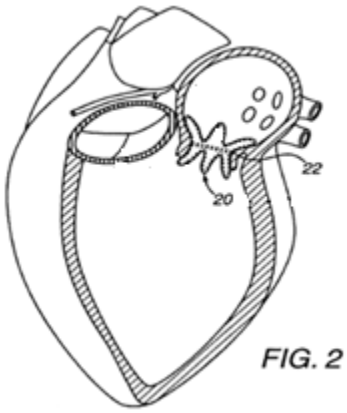
Claims 1, 31, and 38 also require the frame to have a "central portion" located between the peripheral anchors, with claims 1 and 31 requiring the central portion be "located along a centerline." As noted in Part IX.A.1.b, *supra*, Patent Owner's Contentions identify these limitations as merely a region of a cylindrical frame located between peripheral anchors. (Exs.1041 p.2 Terms 7-9; 1040 pp.5-6, 48-49, 67-68.)

FIG. 1B



The Leonhardt stent includes two spaced apart cylindrical portions disposed at each end of the stent. (Ex.1017 cols.4:23-40, 4:53-5:52, FIGS.1B-1C, 4.)

Leonhardt discloses that the stent can "flair at one or both ends as is shown in FIG.2."



(Ex.1017 6:9-22.) The peripheral frame elements of Leonhardt's stent and in particular, these flared portions, constitute peripheral anchors as Defined. (Ex.1003 ¶¶92-94; *see also* Claim Chart 1 Leonhardt "Peripheral Anchors.") Leonhardt's central portion is located along a centerline between the cylindrical portions, at least in that the central portion is located longitudinally along the central axis. (Ex.1017 col.5:22-35, FIGS.1B, 4.) This is true as well when the device is disposed in a native annulus between upstream and downstream regions. (*See* the "waist" of the Leonhardt device in FIG.2 above.) And, the entirety of Leonhardt's valve 22 is attached to and disposed between these peripheral anchors — within the "central portion" in FIG.4. (Ex.1003 ¶94; *see also* Claim Chart 1 Leonhardt "Central Portion.")

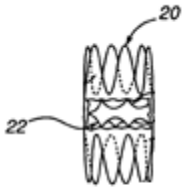


FIG. 4

c. Flexible Valve Element

All of the challenged claims require "a flexible valve element" attached to the frame or to a central portion thereof. According to the Definitions, this term encompasses any flexible part of a valve. Leonhardt uses a biological valve, which is preferably an intact porcine valve. (Exs.1017 col.6:23-34; 1003 ¶95.) It is presized to fit within the middle of the cylindrical portions of stent 26. (Exs.1017 col.6:23-34; 1003 ¶95.) A POSA knows that a biological valve is flexible. It is attached to a central portion of the frame. (Ex.1017 cols.5:45-51, 6:23-32, FIG.4.) Thus Leonhardt teaches a FVE attached to the frame/central portion as Defined. (*See* Claim Chart 1 Leonhardt "Flexible Valve Element.")

The FVE must have upstream and downstream sides facing the upstream and downstream regions, respectively. This limitation, as Defined, is 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 ¶96; *see also* Claim Chart 1 Leonhardt "Upstream/Downstream Sides.")

Claim 22 further characterizes these sides as a "convex" upstream side facing the upstream region and a "concave" downstream side opposite the upstream side facing the downstream region. As discussed in Part IX.A.1.c, *supra*, and as explained by Dr. Dasi, to the extent that the FVE in the Contentions allegedly has convex upstream and concave downstream sides, the biological valve 22 of Leonhardt does as well. (Exs.1017 col.6:23-34;1003 ¶97; *see also* Claim Chart 1 Leonhardt "Convex Upstream/Concave Downstream Sides.")

Claims 22, 31, and 38 require that the FVE is "fixedly attached to the frame [or the central portion of the frame] so that at least a portion of the element is substantially immobile with respect to at least a portion of the frame [or with respect to the central portion of the frame]." Biological valve 22 of Leonhardt is attached to the stent 26 and/or to the graft 24 with sutures 60 and/or adhesives. (Ex.1017 col.6:24-29.) At least these portions are immobile with respect to all other portions of the stent, including the central portion. (Ex.1003 ¶98; *see also* Claim Chart 1 Leonhardt "Flexible Valve Element.")

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

As discussed in Part IX.A.1.d, *supra*, each independent claim includes lengthy recitations merely describing the function of native heart valves and replacement valves, all of which were known *per se*. The porcine valve of Leonhardt functions in the same manner as the tricuspid valve cited in Patent

Owner's Contentions. Leonhardt therefore meets these recitations to the same extent. (Exs.1017 cols.1:10-21, 3:33-45, 5:50-52, 6:23-34; 1003 ¶99; *see also* Claim Chart 1 Leonhardt "Valve Movement Language.")

e. Valve/Frame Opening Limitations

Each independent claim requires that the artificial valve include an opening extending through the frame and/or the FVE. Claim 1 further recites that the opening is "for receiving an implement." Claim 2 specifies that the opening extends through both the FVE and the central portion of the frame.

Patent Owner Contends that these limitations are met by a tricuspid valve mounted within a tubular stent that allows a catheter tip to traverse the interior of the FVE and the stent. (Ex.1040 pp.11-12, 39-40, 54-55, 73-74.) 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.7:10-17.) 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 ¶¶100-101; *see also* Claim Chart 1 Leonhardt "Valve/Frame Opening.")

f. Flexible Elongate Guide Limitations

Claim 31 requires a combination of an artificial valve and flexible guide sized for receipt in the opening of the valve and/or frame. Patent owner Contends that this limitation is met by a catheter shaft onto which a prosthetic tricuspid valve is loaded. (Ex.1040 p.56.) Leonhardt discloses this limitation at least to the extent that the tricuspid valve in Patentee's Contentions does. As noted above, Leonhardt teaches passing an inner catheter through the valve opening when loading the valve into an outer sheath for delivery. (Exs.1017 col.7:10-17, FIGS.5, 8, 9A-D; 1003 ¶102.)

Leonhardt additionally teaches the use of a "flexible guide wire." (*Id.* col.10:3-6.) The inner catheter of Leonhardt, around which the artificial valve is collapsed, includes an inner track which is positioned over that guidewire to guide the delivery device to the native aortic valve. (*Id.* col.10:6-11, FIGS.9A-D.) Thus, Leonhardt teaches the use of the claimed flexible guide in combination with an artificial valve as Defined. (Ex.1003 ¶103; *see also* Claim Chart 1 Leonhardt "Guide.")

g. Delivery Device Limitations

As described in Part IX.A.1.g, *supra*, independent claim 38 and dependent claims 32-24 additionally require a delivery device or "instrument" comprising a holder (cl.32), an elongate manipulator (cl.33) and an installer (cl.34).

Leonhardt describes such an instrument. (Ex.1017 *see generally* 6:34-8:42, FIGS.5-7A, 9A-9C.) The valve stent 20 resides in the distal end of outer sheath 106, such that the distal end of 106 constitutes the "holder." (*Id.* 6:55-61, 7:17-21.) The portion of outer sheath 106 proximal to the distal end is usable to manipulate the distal end or holder and is the "manipulator." (*Id.* 6:34-7:10, 7:21-8:22.) The "push rod 112" serves to eject the stent from the distal end of the sheath and is the claimed "installer." (*Id.* 6:34-49, 8:23-42.) Because Leonhardt meets all of the limitations of the above-referenced claims of the '297 Patent, those claims are anticipated. (Ex.1003 ¶¶104-105; *see also* Claim Chart 1 Leonhardt "Holder," "Manipulator," "Installer.")

h. <u>Dependent Claims</u>

Claim 2 depends from claim 1 and requires the opening to extend through both the FVE and the central portion of the frame. As addressed in Part IX.A.2.e, *supra*, Leonhardt teaches an opening extending through both the center of the stent and the FVE as Defined. (Exs.1017 col.7:10-17; 1003 ¶106.)

Claims 3 and 23, which respectively depend from claim 2 and independent claim 22, both require a releasable fastener mounted on the frame for selectively connecting the valve to an instrument. Claim 39, which depends from independent claim 38, requires that the frame includes a mount for selectively connecting the valve to the instrument. As noted in Part VIII, *supra*, Patent Owner Contends that

"releasable fastener" means "a fastener that is designed to be released non-destructively." (Ex.1041 p.3 Term 18.) Although there is no support for this "non-destructive" construction in the '297 Patent, Leonhardt nonetheless anticipates.

Leonhardt teaches a spool apparatus 170 for use with a deployment catheter 100 to allow for retrieval of the valve stent 20 if repositioning or removal is desired. (Ex.1017 col.9:6-10, FIGS.7A-B.) The spool includes suture loops 174 extending around peaks of the stent 26, and a blade 180 to cut the suture loops to release the stent non-destructively. *(Id.* col.9:12-25.) The suture loops are "releasable fasteners" mounted on the frame as Defined. The peaks of the stent that the suture loops connect to are the frame's "mount," the peaks allowing for selective connection to the delivery device without destruction of the stent peaks. (Ex.1003 ¶¶107-108.)

Claim 8 depends from claim 1, and requires that the frame include frame elements extending outward from the central portion (cylindrical portions on either side of the central portion) that are biased outward to engage heart tissue. (Ex.1017 col.5:47-51, FIGS.1B, 2, 9D.) The cylindrical portions on either side of Leonhardt's stent's central portion will "flair sufficiently" to conform and seal to the tissue. (*Id.* col.6:19-23, FIG.2.) These elements extend outwardly from the central portion. Thus, Leonhardt anticipates claim 8 as Defined. (Ex.1003 ¶109.)

Claim 9 depends from claim 8 and requires a band extending around the frame elements to limit outward movement of the frame elements and to sealingly engage heart tissue. Patent Owner's definition of band is a structure generally in the shape of a circular strip or ring. (Ex.1041 pp.2-3 Term 10.) Leonhardt's graft material 24, which surrounds the frame, is a band. (*Id.* 5:45-48, 5:61-63, 6:9-13, 6:23-34, FIGS.2, 4.) That the graft material 24 of Leonhardt restricts the expansion of the self-expanding frame, is confirmed by Leonhardt's instruction to "cut out" the graft material to allow further outward expansion to form "distensible fingers" if desired. (Exs.1017 col.6:9-13; 1003 ¶110.) The uncut graft material limits outward movement of the frame elements as claimed.

Dependent claims 32-34 are respectively directed to the holder, manipulator, and installer of a delivery device. As addressed above in Part IX.A.2.g, *supra*, Leonhardt teaches each of these elements. (Ex.1003 ¶111.)

As noted in Part IX.A.1.h, *supra*, claims 35 and 45 require the holder to include an outwardly flared end for receiving the artificial valve (cl.35) or for receiving peripheral anchors (cl.45). According to Patent Owner's Contentions, these limitations are met by an atraumatic tip extending from an inner shaft over which the valve is collapsed. (Ex.1040 pp.59-60, 78-79.) Leonhardt teaches that the deployment catheter may include a tapered head 156 at the distal end of inner catheter 110. (Ex.1017 col.8:10-14.) The tapered head may include an abutment lip

158 that engages the outer sheath 106, fully consistent with the Patent's Owners Contentions. (*Id.* col.8:14-17.) Thus, at least to the extent that the instrument in the Contentions teaches a holder with an outwardly flared end, so too does Leonhardt. (Ex.1003 ¶112.)

Claim 37 depends from claim 31 and requires the combination to include a vascular catheter. Leonhardt discloses that deployment catheter 100 may be inserted into the femoral artery and advanced to the native aortic valve. (Ex.1017 col.9:63-10:11.) The femoral artery is part of a patient's vasculature, thus the deployment catheter 100 is a vascular catheter as claimed. (Ex.1003 ¶113.)

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

B. Obviousness

1. Ground 3: Claims 1-3, 8, 9, 22, 23, 31-35, 37-39, And 45 Are Obvious Over Bessler

To the extent one were to argue that Bessler'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 predictable results.

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).

In this case, given Bessler's use of the same types of components, organized and operating in the same way as claimed, and in view of the breadth of these claims, minor modifications to the stent and the FVE as Defined to achieve predictable improvements is the application of routine engineering, characteristic of obviousness; nothing more. (Ex.1003 ¶156.)

For example, to the extent that one argues that the cuff 25 of Bessler is not explicitly described as limiting outward movement of the frame elements as recited in claim 9, the limited options of forming the cuff would make such a configuration at least obvious to try. Bessler's cuff extends along the outer periphery of the circular portion of the stent, and is attached thereto. (*Id.* col.5:24-27, FIG.4.) The only options for such a cuff would be a greater, lesser or equal circumference compared to the stent. The use of a cuff having a circumference smaller than the circumference of a stent would necessarily satisfy the limitations of claim 9. (Ex.1003 ¶69.) Thus, at least because there are at most three options in forming the cuff, and at least one of those options would satisfy the limitations of claim 9, claim 9 is obvious in view of Bessler. *See KSR*, 550 U.S.

at 421 ("When 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."). This is true of Leonhardt as well.

2. Ground 4: Claims 1-3, 8, 9, 22, 23, 31-35, 37-39, And 45 Are Obvious Over Leonhardt

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 as noted in Ground 3.

For example, to the extent that one argued that the suture loops 174 were not "releasable fasteners" as recited in claims 3 and 23 because Leonhardt discloses that those loops are destroyed by being cut by blade 180, the claims would still be obvious over Leonhardt. The "blade 180" of Leonhardt is disclosed as being "optional," so Leonhardt contemplates the ability to remove the suture loops 174 from the stent without a cutting blade. (*See* Ex.1017 col.9:20-24.) It would be obvious to non-destructively remove each suture loop individually from the stent to selectively release the valve from the deployment catheter. (*See id.* Ex.1003 ¶156.)

3. Ground 5: Claims 3, 23, And 39 Are Obvious Over Bessler In View Of Thompson

Thompson (Ex.1053) was filed on February 26, 2001. As noted in Part IX.A.1, *supra*, claims 3, 23, and 39 are directed to releasable fasteners and mounts for selective attachment to a delivery device and have an earliest priority date of April 30, 2002. (Ex.1039 p.3.) Therefore, Thompson is available as 35 U.S.C. § 102(e) art against these claims.

Thompson is directed to systems for delivering self-expandable implants such as stents, as well as the stents themselves. (Ex.1053 col.1:7-11.) The scope of Thompson also expressly includes "percutaneous valves," such as the percutaneous heart valve of Bessler. (*See id.* col.11:30-38; Ex.1003 ¶149.)

Thompson and Bessler both appreciate an identical problem but provide alternate solutions. Thompson explains the problem of a stent "prematurely" deploying from a delivery device "as the outer tube is retracted." (*Id.* col.1:65-66.) The premature deployment may arise from a lack of control, where "the exposed portion of the stent may expand resulting in the remainder of the stent being squeezed out of the outer tube." (*Id.* col.1:67-2:2.) Thompson provides the desired control via "male interlock structures 82" on an end of the stent. (*Id.* col.6:37-43, FIG.2A.) These male interlock structures are received within corresponding

"female interlock structures 84" on a collar 27 which is part of an inner delivery catheter. (*Id.* col.6:42-56, FIG.2A; Ex.1003 ¶151.)

Thus, Thompson teaches releasable fasteners as Defined mounted on a stent (as in claims 3 and 23) and mounts (as in claim 39) for selectively and non-destructively connecting the stent frame to a delivery device in the form of male interlock structures. (Ex.1003 ¶153.)

A POSA would find it obvious to replace the suture fasteners of Bessler with the interlock fasteners of Thompson because they are similar solutions to a common problem. Additionally, replacing the suture fasteners of Bessler with the interlock fasteners of Thompson would desirably eliminate moving elements from the Bessler system, as the interlock fasteners are integral with stent and delivery device of Thompson. (*Id*. cols.9:2-7, 14:48-50; Ex.1003 ¶154.) This would also desirably reduce the number of structures extending through the proximal end of the catheter, increasing available space and reducing complexity of the system at the point where a user manipulates the delivery system. (Ex.1003 ¶154.) Since "a technique has been used to improve one device [the Thompson device], and a person of ordinary skill in the art would recognize that it would improve similar devices [the Bessler device] in the same way, using the technique is obvious." *KSR*, 550 U.S. at 417.

At least for these reasons, claims 3, 23, and 39 are obvious over Bessler in view of Thompson. (Ex.1003 ¶155.)

4. Ground 6: Claims 3, 23, And 39 Are Obvious Over Bessler In View Of Taylor

Taylor (Ex.1054) published on May 9, 1997, and is available as prior art under 35 U.S.C. § 102(b). Taylor, like Thompson, is directed to systems for delivering self-expandable implants including stents, as well as the stents themselves. (Ex.1054 p.1:3-5.) The stents of Taylor may be used for "transluminal implantation in body lumen, especially found in peripheral and coronary blood vessels." (*Id.*) Thus, Taylor's field of endeavor is analogous to that of Bessler and a POSA would readily look to solutions provided by transluminal self-expanding stents when considering similar problems encountered in transluminal self-expanding stented heart valves. (Ex.1003 ¶150.) Moreover, the problem to be solved by Taylor is the same as the problem solved by the suture fasteners of Bessler.

According to Taylor, beads at either end of a stent allow retention in an annular space between an outer sleeve and a pusher tube that has a guidewire lumen. (Ex.1054 pp.17:22-35, 25:13-16, FIG.8.) The pusher tube includes a "circumferential groove 35" sized and shaped to receive "the beads 8 of the stent at its proximal end 36." (*Id.* p.25:16-20, FIG.8.) As the stent is partially deployed, the

beads remain fixed in the groove of the pusher so that the stent does not inadvertently fully release from the delivery device. (*Id.* p.25:28-26:9, FIGS.8-9; Ex.1003 ¶¶150, 152.)

Thus, Taylor teaches releasable fasteners as Defined mounted on a stent (as in claims 3 and 23) and mounts (as in claim 39) for selectively and non-destructively connecting the stent to a delivery device in the form of beads. The motivation to apply Taylor's fastener solution to the system of Bessler is the same as that described above in Ground 5 with respect to the Thompson fasteners. At least for these reasons, claims 3, 23, and 39 are obvious over Bessler in view of Taylor. (Ex.1003 ¶¶153-154.)

5. Ground 7: Claims 1-3, 8, 9, 22, 23, 31-35, 37-39, And 45 Are Obvious Over Bessler In View Of Johnson

Johnson (Ex.1021) issued in 1995 and qualifies as art pursuant to 35 U.S.C. § 102(b). Johnson was of record. Johnson was applied as a primary reference during the prosecution of the parent application but not the '297 Patent.

One of the benefits of percutaneously deliverable prosthetic heart valves is that the procedure can be completed in a minimally invasive manner, reducing risk to the patient and recovery time. (Ex.1008 col.1:14-34.) The benefit is particularly salient in view of the invasiveness of open heart surgery. (*Id.* col.1:28-29.) However, durability of percutaneously deliverable prosthetic heart valves was a

problem recognized by Bessler and Johnson. (Ex.1008 col.2:11-12; 1021 col.3:37-47.) Here, the existence of the problem of durability of prosthetic heart valves supplied the motivation for the solution of the use of the funnel-type valve of Johnson. *KSR*, 550 U.S. at 420.

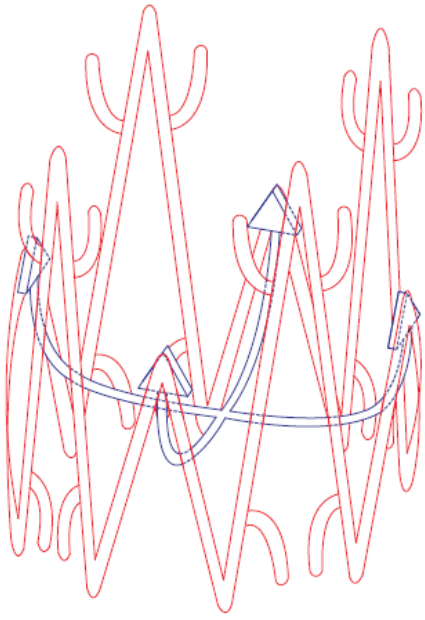
A POSA would realize that the patients most in need of transcatheter procedures are the frailest. Not only is open chest surgery to be avoided, but even subsequent transcatheter procedures should be avoided where possible. (Ex.1003 ¶¶115-116.) So a POSA would be very interested in durable solutions. Johnson's valve provides that opportunity. (Exs.1021 cols.2:39-42, 3:37-47; 1003 ¶116.)

The "optimal" material useful for producing Bessler's tricuspid FVE is synthetic and made of polyester or PTFE. (Ex.1008 cols.3:65-4:11, 5:21-24, 6:18-31, *see also* Ground 1.) Johnson also describes a synthetic FVE produced from PTFE. (Exs.1021 col.4:49-56; 1003 ¶117.) Johnson discloses that leaflet valves 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 affects 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." (Exs.1021 col.3:37-47, *see also* col.2:39-42; 1008 col.2:10-11.)

A POSA would be motivated to try the construction of the Johnson valve to replace the synthetic valve of Bessler which have leaflets in hopes of obtaining a more durable valve. (Ex.1003 ¶¶118-119.) This is particularly important here since transcatheter valves were originally indicated for patients who are too old or weak to survive open chest surgery.

In the combined structure of FIG.E, the Bessler tubular structure (stent and cuff) performs its known function of holding the entire structure within the anatomy, whereas the Johnson valve performs its known function and, indeed the same function as the valve of Bessler. The FVE is not illustrated to aid visualization.

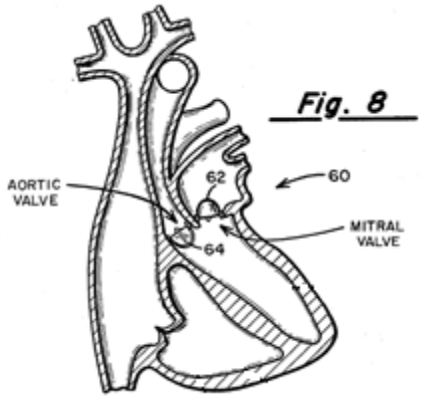
FIG.E



A POSA would know that to use a funnel valve, the apex of the FVE must be attached to the central axis of the frame. This is a simple engineering exercise which has been practiced in many different analogous situations. (Ex.1003 ¶¶120-121.) An accommodating structure could be added to or integrally formed as part of the Bessler stent. (*Id.*) That said, a POSA here would recognize that Johnson provides a structure that already can be used to provide that attachment — 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. (Exs.1021 col.2:43-50; 1003 ¶121.)

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

Bessler and Johnson both describe replacement valves to be disposed in a native valve annulus between upstream and downstream regions. This was discussed for Bessler in Ground 1. (Ex.1008 cols.2:25-28, 2:55-60, 3:46-64, 7:26-67, 8:46-49.) Johnson shows disposing the valve in the mitral or aortic heart annulus as well. (Exs.1021 cols.2:62-3:19, 6:14-19, FIG.8; 1003 ¶122.)



b. Flexibly Resilient Frame

The claims require a flexibly resilient frame. Bessler's stent meets Patent Owner's Definition as discussed in Ground 1. (Ex.1008 cols.2:60-62, 3:51-55, 4:63-5:14, 5:19-21, 5:31-36, 5:43-6:18, 7:26-67, FIGS.1 7, 13-14.) Johnson's framework does as well. (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.) Johnson's framework may be made of resilient or "springy" material such as titanium or polytetrafluoroethylene (PTFE) or Teflon® polymer and is acknowledged as flexible. (Ex.1021 cols.2:43-50, 4:22-25.) And, as shown in, *inter alia*, FIG.8, the valve, including the frame and FVE, is sized and shaped for insertion or placement between upstream and downstream regions.

Even if the frame of the '297 Patent is construed consistent with the construction suggested by Petitioner in court and in the intrinsic record, the frame of Johnson is a flexible, conical, geodesic, birdcage structure, just like that shown in FIG.2 of the '297 Patent. (Exs.1021 cols.2:43-50, 4:10-48, 5:20-36, 6:2-7,

FIGS.1, 2, 7; 1003 ¶¶123-124; *see also* Claim Chart 1 Bessler and Johnson "Frame-Flexibly Resilient.")

The frame must also include a plurality of peripheral anchors. Bessler's stent includes peripheral anchors as discussed in Ground 1. (Ex.1003 ¶125; Part IX.A.1.b., *supra; see also* Claim Chart 1 Bessler "Peripheral Anchors.")

Claims 1, 31, and 38 also require the frame to have a "central portion" located between the peripheral anchors, with claims 1 and 31 requiring the central portion to be "located along a centerline." Patent Owner's Contentions identify these limitations as merely a region of the frame located between the peripheral anchors. (Exs.1041 p.2 Terms 7-9, 1040 pp.5-6, 48-49, 67-68.) This recitation as Defined is met by Bessler as described in Part IX.A.1.b, *supra*. (*See* Claim Chart 1 Bessler "Central Portion.") However, even if the centerline/central portion terms are construed to refer to an apex of the frame along the central axis of the valve as Petitioner suggested (Ex.1041 p.2 Term 8), Johnson combined with Bessler teaches those features. The "central portion" of Johnson is the junction 16 of its framework. (Ex.1021 cols.4:10-15, 4:35-48, FIG.1.) The apex of the valve is mounted to this framework's apex. And the frame of Johnson is mounted or formed centrally between Bessler's first and second circles of barbs, and is central both radially and longitudinally — located in a central portion. (Ex.1008 cols.4:12-21, 5:60-6:2, 7:43-67, FIGS.6, 7, 14, 15; *see* FIG.E, *supra*.) Thus, both

references teach a central portion along a centerline as Defined by Patent Owner. (Ex.1003 ¶126; *see also* Claim Chart 1 Bessler and Johnson "Central Portion.") This is true when the device is implanted as well.

c. Flexible Valve Element

All challenged claims require "a flexible valve element" attached to the frame or to a central portion thereof. An FVE according to Patent Owner is any flexible part of a valve. (Ex.1041 p.3 Term 12.) Even if the term is construed to require a unitary reverse-funnel type of valve element, as Petitioner argued in court, the structure is taught by Johnson.

The FVE in Johnson is a flexible funnel. The FVE's apex is attached along its central axis to the central portion of the framework of Johnson – the frame's apex. (Ex.1021 cols.2:43-50, 4:49-68.) And the FVE of the combined structure would be mounted centrally in Bessler's stent. (Ex.1003 ¶¶127-128; *see also* Claim Chart 1 Bessler and Johnson "Flexible Valve Element"; FIG.E.)

The FVE must have upstream and downstream sides facing the upstream and downstream regions, respectively. This claim element is taught in Bessler as discussed in Ground 1. The Johnson valve also discloses this claim element. The Johnson valve would be mounted within Bessler's stent much the same way as the FVE (as Defined) illustrated in Bessler would be and it therefore has upstream and

downstream facing sides. (*See* FIG.C; Exs.1021 col.6:14-19, FIG.8; 1003 ¶129; *see also* Claim Chart 1 Bessler and Johnson "Upstream/Downstream Sides.")

Claim 22 further characterizes these upstream and downstream sides as a "convex" upstream side facing the upstream region and a "concave" downstream side opposite the upstream side facing the downstream region. This limitation is met by the FVE of Johnson wherein the valve element is "parabolic." (Exs.1021 cols.2:39-61, 4:49-68, 5:37-45, FIGS.2, 7, 8; 1003 ¶130.)

Finally, claims 22, 31, and 38 require that the FVE is "fixedly attached to the frame [or the central portion of the frame] so that at least a portion of the element is substantially immobile with respect to at least a portion of the frame [or with respect to the central portion of the frame]." The FVE of Johnson is attached to struts of the frame by sutures or heat and/or pressure bonding. (*Id.* col.4:61-5:12.) At least the portions of the FVE valve member that are attached to the stent are immobile with respect to all other portions of the stent, including the central portion. (Ex.1003 ¶131; s*ee also* Claim Chart 1 Johnson "Flexible Valve Element.")

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

As discussed in Part IX.A.1.d, *supra*, each independent claim includes lengthy recitations merely describing the known function of native heart valves and replacement valves. (Ex.1003 ¶132.) The valve movement language is met by the

operation of the Johnson valve disposed in Bessler's stent. As explained in Johnson, the flexible valve membrane is attached to the flexible framework so that the membrane segments or leaflets move inwardly to allow downstream blood flow through the valve. When the cardiac cycle reverses, leaflets bellow outwardly and effect closure against the tissue annulus, preventing upstream blood flow. (Ex.1021 cols.3:26-47, 5:37-53, FIGS.4, 5.) This movement meets the claim limitations.

e. Valve/Frame Opening Limitations

The claims require that the artificial valve include an opening extending through the frame and/or the FVE. Claim 1 further recites that the opening is "for receiving an implement." Claim 2 specifies that the opening extends through both the central portion of the frame and the FVE.

As addressed in Ground 1, Bessler discloses a stent with a center opening as Defined that is capable of receiving an implement therethrough. Further, Bessler discloses that an implement may be passed through the FVE when in the open condition (FVE pushed outwardly toward the stent). The combined structure including the stent of Bessler with the framework and FVE of Johnson would be similarly capable of receiving an implement therethrough when the FVE is in the open condition (FVE pushed inwardly toward central axis of the stent). (Exs.1008 col.7:26-42, FIGS.12-13; 1003 ¶¶133-134.) In particular, in the combined structure, the stent would include openings as Defined both along the center of the

Bessler stent, as well as between circumferentially adjacent struts of the Johnson framework. The openings in the FVE would be the openings through which blood flows downstream, between the folded free edges of the FVE when in the open condition. (Ex.1021 col.5:12-19, FIG.5; FIG.D, *supra*.) Thus, the combination teaches a prosthetic heart valve that includes an opening as Defined passing through both the FVE and the center of the frame.

f. Flexible Elongate Guide Limitations

Claim 31 requires a combination an artificial valve and a flexible guide for receipt within the opening. As noted above, Bessler teaches a guidewire passing through the FVE when in the open condition and also through the stent, the guidewire "used to guide the distal end of the catheter 91 to the desired site." (Ex.1008 col.7:26-42, FIGS.12-13.) The combined structure of Bessler and Johnson would similarly include a guidewire traversing the FVE, the guidewire being positioned between one of the free edges of the FVE and the interior of the Bessler stent. (Ex.1003 ¶135.)

g. Delivery Device Limitations

In addition to the valve limitations, independent claim 38 and dependent claims 32-34 additionally require a delivery device or "instrument" comprising a holder (cl.32), an elongate manipulator (cl.33) and an installer (cl.34). (Ex.1001 col.23:34-48.)

As described in Part IX.A.1.g, *supra,* Bessler discloses the claimed holder (Ex.1008 cols.4:53-58, 7:26-67, FIGS.12-15), manipulator (*id.* 4:63-5:1, 7:26-67, FIGS.12-15), and installer (*id.* cols.4:60-66, 5:3-14, 7:26-67, FIGS.12-15). The combined stent of Bessler and FVE of Johnson would interact with the delivery device of Bessler in essentially the same way as the stent and FVE of Bessler. The combination of the prosthetic heart valve and instrument(s) is thus obvious over Bessler in view of Johnson. (Ex.1003 ¶¶136-137.)

h. <u>Dependent Claims</u>

Claim 2 depends from claim 1 and requires the opening to extend through both the FVE and the central portion of the frame. As addressed in Part IX.B.5.e, *supra*, the combined structure includes an opening as Defined extending through both the FVE and the central portion of the stent. (Ex.1003 ¶138.)

Claims 3 and 23, both require a releasable fastener mounted on the frame for selectively connecting the valve to an instrument. Claim 39 requires that the frame includes a mount for selectively connecting the valve to the instrument. As described in Parts IX.A.1.h and IX.B.1, *supra*, the sutures of Bessler are releasable fasteners as Defined, and the stent peaks of Bessler's frame are mounts. Since these elements would be identical in the combined Bessler and Johnson structure, these claims are rendered obvious over Bessler in view of Johnson. (Ex.1003 ¶139.)

Claim 8 depends from claim 1, and requires that the frame include frame elements extending outward from the central portion that are biased outward to engage heart tissue and to hold the frame in the expanded configuration in the native annulus. As described in Parts IX.A.1.h and IX.B.1, *supra,* Bessler discloses this recitation as Defined. The framework of Johnson includes struts extending radially outward from a junction. (Ex.1021 col.4:35-48, FIGS.1-2.) In the combined structure, the barbs or straight sections of the Bessler stent or the struts of the Johnson frame would be the frame elements of claim 8. Thus, claim 8 is obvious over Bessler in view of Johnson. (Ex.1003 ¶140.)

Claim 9 depends from claim 8 and requires a band extending around the frame elements to limit outward movement of the frame elements and to sealingly engage heart tissue. As described in Parts IX.A.1.h and IX.B.1, *supra,* Bessler's cuff is a band. The cuff of Bessler would exist identically in the combined Bessler stent and FVE of Johnson, and the cuff is shown as being tight against the self-expanding stent. (Exs.1008 cols.5:15-27, 5:40-43, FIGS.1, 4, 7; 1003 ¶141.) This cuff would restrict the expansion of the self-expanding stent. Thus, claim 9 is obvious over Bessler in view of Johnson.

Dependent claims 32-34 are respectively directed to the holder, manipulator, and installer of a delivery device. As addressed above in Part IX.B.5.g, *supra*, these claims are obvious over Bessler in view of Johnson. (Ex.1003 ¶142.)

Claims 35 and 45 require the holder to include an outwardly flared end for receiving the artificial valve (cl.35) or for receiving peripheral anchors (cl.45). As described in Parts IX.A.1.h and IX.B.1, *supra*, Bessler discloses this feature as Defined. The combined structure of Bessler's stent with the FVE and framework of Johnson could be used with the disclosed delivery device of Bessler in the same way as the stent and FVE of Bessler (as Defined) would be. Thus, claims 35 and 45 are obvious over Bessler in view of Johnson. (Ex.1003 ¶143.)

Claim 37 depends from claim 31 and requires the combination to include a vascular catheter. As described in Part IX.A.1.h, *supra*, Bessler discloses that the flexible catheter is "for percutaneous and transluminal delivery . . . ." (Ex.1008 col.7:28-30.) The combined structure of Bessler's stent with the FVE and frame of Johnson could be used with the disclosed delivery device of Bessler in the same way as the stent and FVE of Bessler (as Defined) would be. Thus, claim 37 is obvious over Bessler in view of Johnson. (Ex.1003 ¶144.)

In summation, the challenged claims are obvious over Bessler in view of Johnson under the broad Definitions of the Patent Owner, as well as under narrower constructions.

i. Motivation And Reasonable Expectation Of Success

As discussed in greater detail in Part IX.B.5, *supra*, Bessler teaches the desirability of a percutaneously deliverable prosthetic heart valve, but notes the

problem of such valves not being sufficiently durable. Johnson supplies a teaching of heightened durability of its funnel-type valve compared to Bessler's tricuspid valve. Thus, as described above, a POSA would be motivated to combine the valve of Johnson with the stent of Bessler to achieve a percutaneously deliverable durable prosthetic heart valve. (Ex.1003 ¶¶145-147.) And, both references are U.S. patents and presumed enabling. Moreover, the substitution of one valve for another to be used in the very same way, and for the very same purpose, would provide a reasonable expectation of success. (*Id.* ¶41.)

6. Ground 8: Claims 3, 23, And 39 Are Obvious Over Bessler In View Of Johnson Further In View Of Thompson

As described in Parts IX.A.1.h and IX.B.5.h, *supra*, the combined Bessler and Johnson structure teaches the releasable fasteners as Defined (Bessler's sutures) of claims 3 and 23 and the mount (Bessler's stent peak) of claim 39. Further, as described in Part IX.B.3, *supra*, it would be obvious to modify the stent of Bessler to include the male and female interlock structures of Thompson, which are releasable fasteners and mounts as Defined. (Ex.1003 ¶¶149, 151, 153, 155.) Because the combined Bessler and Johnson structure includes the stent of Bessler, it would be similarly obvious to modify the stent of the combined structure to include the male and female interlock structures of Thompson, for the same

reasons provided in Ground 5. Thus, claims 3, 23, and 39 are obvious over Bessler in view of Johnson further in view of Thompson.

7. Ground 9: Claims 3, 23, And 39 Are Obvious Over Bessler In View Of Johnson Further In View Of Taylor

As described in Parts IX.A.1.h and IX.B.5.h, *supra*, the combined Bessler and Johnson structure teaches the releasable fasteners as Defined (Bessler's sutures) of claims 3 and 23 and the mount (Bessler's stent peak) of claim 39. Further, as described in Part IX.B.4, *supra*, it would be obvious to modify the stent of Bessler to include the bead structures of Taylor, which are releasable fasteners and mounts as Defined. (Ex.1003 ¶¶150-154.) Because the combined Bessler and Johnson structure includes the stent of Bessler, it would be similarly obvious to modify the combined structure to include the beads of Taylor, for the same reasons provided in Ground 6. Thus, claims 3, 23, and 39 are obvious over Bessler in view of Johnson further in view of Taylor.

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 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 ¶¶27-28.) 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 publically 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 1-3, 8, 9, 22, 23, 31-35, 37-39, and 45 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

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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 13,851. 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 1-3, 8, 9, 22, 23, 31-35, 37-39, AND 45 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