IPR2018-00105
Patent No. 6,540,782
Petition for *Inter Partes* Review
Attorney Docket No. STJUDE 7.1R-002

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. 6,540,782 to Robert V. Snyders
Issue Date: April 1, 2003
Title: ARTIFICIAL HEART VALVE

Inter Partes Review No. IPR2018-00105

PETITION FOR *INTER PARTES* REVIEW OF CLAIMS 1, 2, 4-8, 10-13, 17-19, 21, 22, AND 25-30 OF U.S. PATENT NO. 6,540,782

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EXHIBIT LIST

Exhibit #	Reference
1001	U.S. Patent No. 6,540,782
1002	Complaint, *Snyders Heart Valve LLC v. St. Jude Med. S.C., Inc. et al.*, Civil Action No. 4:16-cv-00812 (E.D. Tex. Sherman Div. Oct. 25, 2016)
1003	Declaration of Lakshmi Prasad Dasi, Ph.D.
1004	*Curriculum Vitae* of Lakshmi Prasad Dasi, Ph.D.
1005	Lyle J. Olsen *et al.*, *Aortic Valve Stenosis: Etiology, Pathophysiology, Evaluation, and Management,* 12 Curr Probl Cardiol (August 1987), at 458-508 ("Anatomical Drawing Source")
1006	U.S. Patent No. 5,411,552 (issued May 2, 1995) ("Andersen")
1007	U.S. Patent No. 5,545,214 (issued Aug. 13, 1996) ("Stevens")
1008	U.S. Patent No. 5,855,601 (issued Jan. 5, 1999) ("Bessler")
1009	International Publication No. WO 98/29057 (published July 9, 1998) ("Letac")
1010	U.S. Patent No. 3,671,979 (issued June 27, 1972) ("Moulopoulos")
1011	Provisional Application No. 60/179,853 — Specification, Appendix A, Appendix B, Cover Sheet
1012	Rejection, U.S. Serial No. 09/775,360, Apr. 10, 2002
1013	U.S. Patent No. 5,332,402 (issued July 26, 1994) ("Teitelbaum")
1014	Response, U.S. Serial No. 09/775,360, July 10, 2002
1015	Amendment After Final, U.S. Serial No. 09/775,360, Dec. 16, 2002
1016	U.S. Patent No. 6,821,297 (issued Nov. 23, 2004) ("CIP 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. 10/135,74, July 9, 2004
1020	U.S. Patent No. 5,413,599 (issued May 9, 1995) ("Imachi")
1021	U.S. Patent No. 4,339,831 (issued July 20, 1982) ("Johnson")
1022	U.S. Patent No. 5,397,351 (issued Mar. 14, 1995) ("Pavcnik")
1023	U.S. Patent No. 3,657,744 (issued Apr. 25, 1972) ("Ersek")
1024	U.S. Patent No. 6,458,153 (issued Oct. 1, 2002) ("Bailey")
1025	Jerald L. Cohen *et al.*, *Two-dimensional echocardiographic preoperative prediction of prosthetic aortic valve size*, 107(1) Am. Heart J. (Jan. 1984), at 108-112

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

Exhibit #	Reference
1041	Joint Claim Construction & Prehearing Statement, *Snyders Heart Valve LLC v. St. Jude Med. S.C., Inc. et al.*, Civil Action No. 4:16-cv-00812 (E.D. Tex. Sherman Div. July 24, 2017), ECF No. 153
1042	N. Zuhdi, M.D. *et al., Porcine Aortic Valves as Replacements for Human Heart Valves,* 17(5) Annals Thoracic Surg. (May 1974), at 479-491
1043	Edward B. Stinson *et al., Long-term experience with porcine aortic valve xenografts,* 73(1) J. Thoracic & Cardiovascular Surg. (Jan. 1977), at 54-63
1044	Aortic Valve© 1997-2017 Medical Legal Art.
1045	U.S. Patent No. 17,520 (issued June 9, 1857)
1046	U.S. Patent No. 3,543,674 (issued Dec. 1, 1970)
1047	U.S. Patent No. 4,783,662 (issued Nov. 8, 1988)
1048	U.S. Patent No. 6,267,776 (issued July 31, 2001)
1049	U.S. Patent No. 1,466,114 (issued Aug. 28, 1923)
1050	U.S. Patent No. 2,282,285 (issued May 5, 1942)
1051	U.S. Patent No. 3,253,326 (issued May 31, 1966)

Petitioner, St. Jude Medical, LLC, requests *inter partes* review of claims 1, 2, 4-8, 10-13, 17-19, 21, 22, and 25-30 ("challenged claims") of U.S. Patent No. 6,540,782 ("the '782 Patent") (Ex.1001).

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

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

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

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

Patent Owner, Snyders Heart Valve LLC, filed suit against Petitioner on October 25, 2016, in the Eastern District of Texas, Sherman Division (Civil Action No. 4:16-cv-00812), alleging infringement of the challenged claims of the '782 Patent (Ex.1002) and its child, U.S. Patent No. 6,821,297 (Ex.1016). A second IPR Petition is filed concurrently seeking cancellation of the same claims using different primary references bearing Attorney Docket No. STJUDE 7.1R-003. Three other IPRs are being filed concurrently against Ex.1016 bearing Attorney Docket Nos. STJUDE 7.1R-004 and STJUDE 7.1R-005.

NOTICE OF LEAD AND BACKUP COUNSEL

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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 '782 Patent is available for IPR; and (2) Petitioner is not barred or estopped from requesting IPR of the '782 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, 2, 4-8, 10-13, 17-19, 21, 22, and 25-30 of the '782 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, 2, 4-8, 10-13, 17-19, 21, 22, and 25-30 are anticipated by Leonhardt.

Ground 2. Claims 1, 2, 4-8, 10-13, 17-19, 21, 22, and 25-30 are obvious over Leonhardt in view of Andersen.

Ground 3. Claims 1, 2, 4-8, 10-13, 17-19, 21, 22, and 25-30 are obvious over Leonhardt in view of Johnson and Imachi.

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), setting forth his definition of a person of ordinary skill in the art ("POSA") and explaining what the art would have conveyed to a POSA at the time of the invention. Dr. Dasi's *curriculum vitae* is included as well (Ex.1004).

IV. INTRODUCTION AND SUMMARY OF ARGUMENT

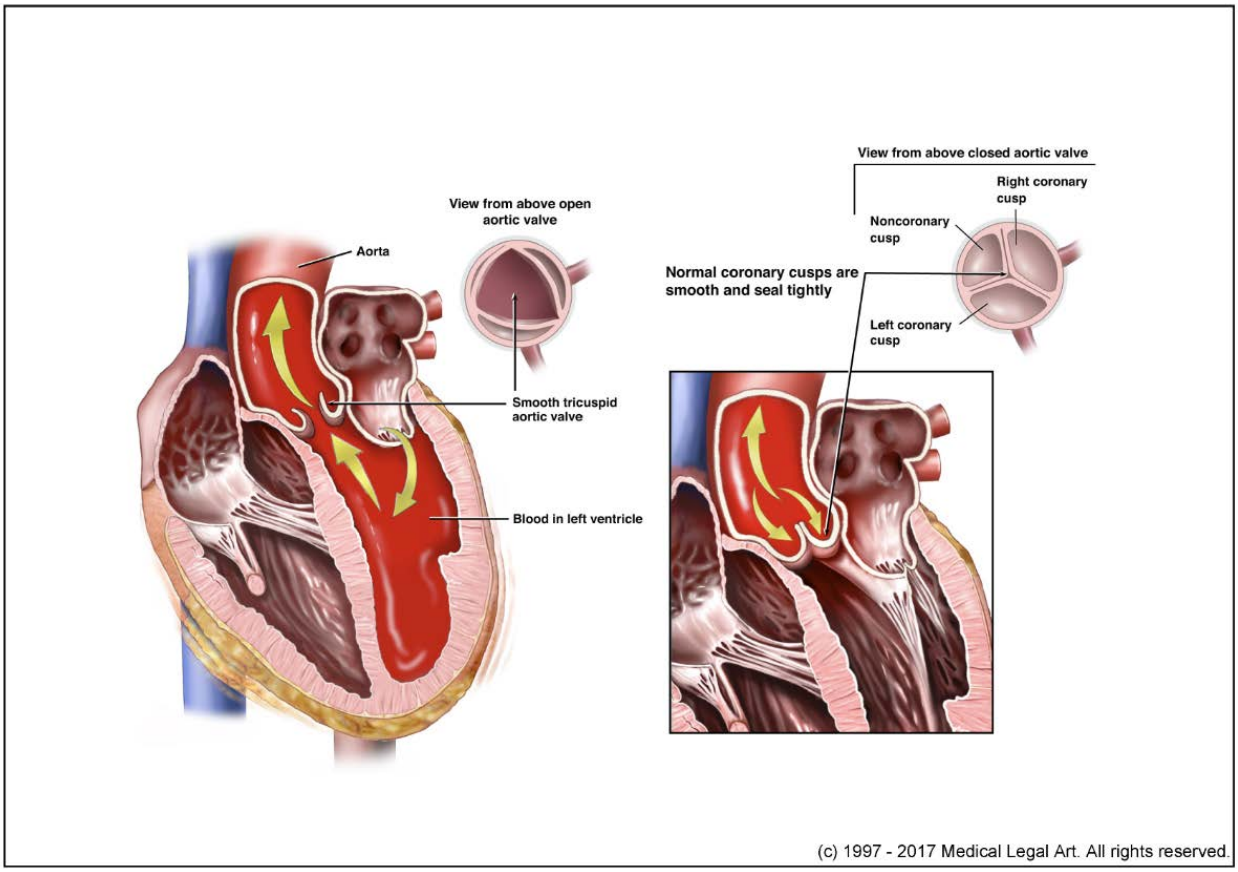
Some artificial heart valves can be collapsed, inserted into the heart, and expanded in the annulus of a defective native valve to take over that valve's function. These collapsible valves are implanted much like cardiac stents, through the patient's vasculature, avoiding invasive open chest surgery. The described invention relates to one specific collapsible implantable valve architecture. But, according to Patent Owner, who purchased this patent and its child Ex.1016, just prior to commencing litigation, the claims are now 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 '782 Patent established. (Exs.1001 col.1:42-61; 1003 ¶24.) However, valve replacement surgery is invasive. (Ex.1001 col.1:25-42.) 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.1:62-2:19; 1003 ¶24.)

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

FIG.A



(Ex.1044, with redactions.)

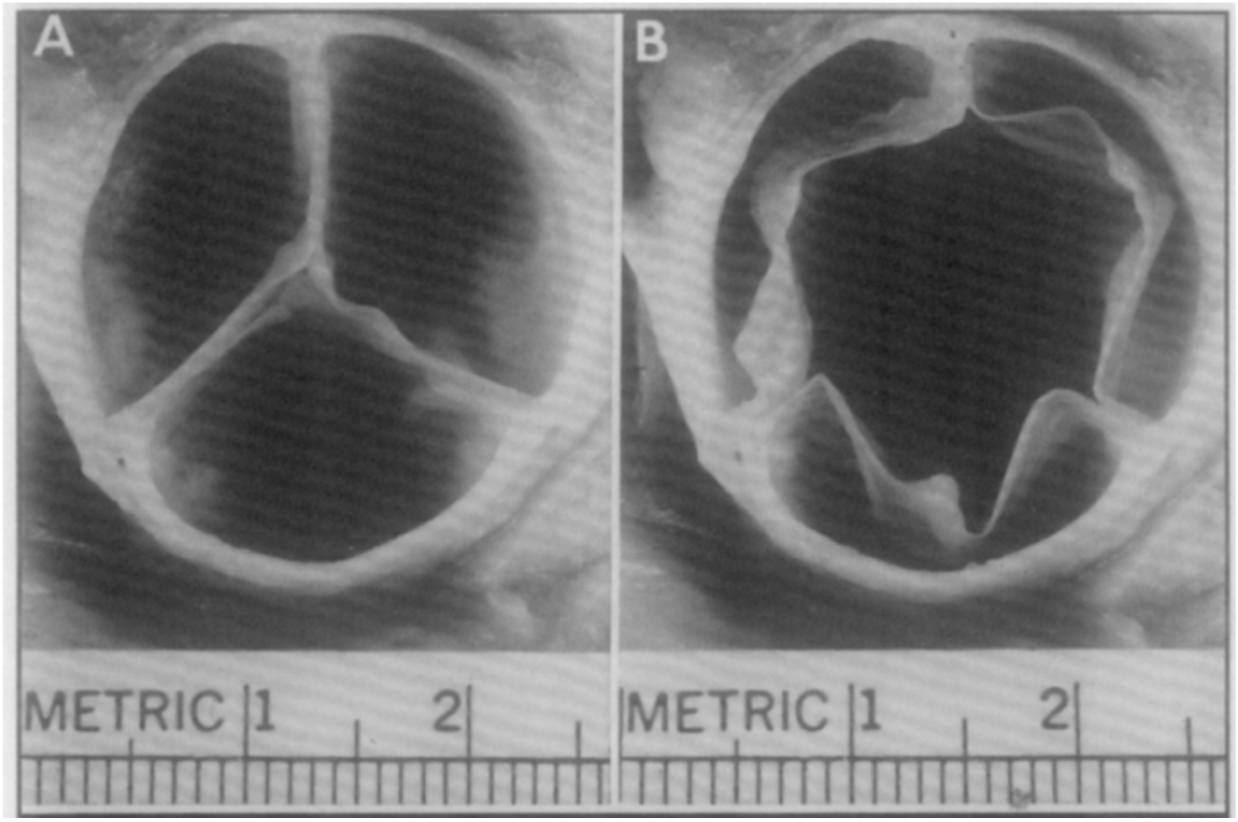
The aortic valve shown in FIG.A is referred to as a "tricuspid" valve because the valve element comprises three separate leaflets or "cusps" which cooperate to control blood flow. Other valves, like the mitral valve, have two leaflets. In FIG.A, when the left ventricle contracts, the resulting pressure 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. Blood forces the leaflets 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 of the designs for collapsible replacement valves, including those approved in the U.S. and those disclosed in prior art patents (shown below the photos of the native valve), mimic this natural trileaflet architecture. (*Id.* ¶¶27-28.) Indeed, two of the valves cited in the '782 Patent's Background and one reference cited during prosecution include porcine valves that have the native architecture. (*Id.*) They all include a flexible valve element ("FVE") and a band mounted to a generally tubular shaped stent.

FIG.B

Native valve



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

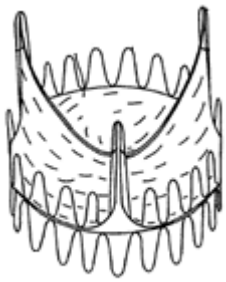


FIG. 2

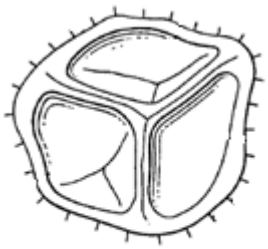


FIG. 12

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.* ¶¶30-32.)

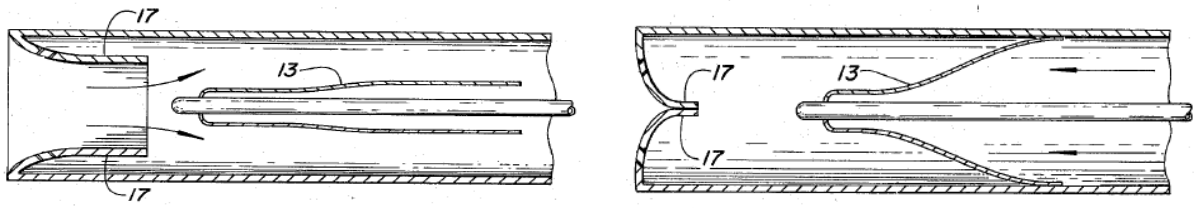


FIG 2A FIG 2B

(Ex.1010 FIGS.2A, 2B.) Indeed, FIGS.2A and 2B of Ex.1010 demonstrate how native valve movement is opposite when compared to a funnel valve. 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 are forced into the center where they meet and form a seal. In the funnel valve, the flap 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 U-shaped 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.)

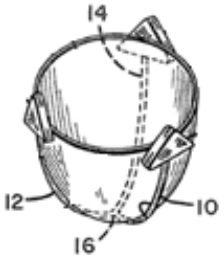


Fig. 2

VI. THE '782 PATENT

A. The Specification Of The '782 Patent

The '782 Patent is based on, and incorporates by reference, a provisional application which itself included 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 '782 Patent's

specification provides a similar description of the alleged invention. (Ex.1001 cols.4:47-65, 6:24-35, 7:1-12, 9:1-15, FIGS.2, 3.)

The outer edge of the FVE's unitary flap is "tacked down" to each of the "U-shaped" frame elements or to selected portions of an internal band. (*Id.* 7:1-12.) The rest of the edge is free to move radially inwardly. (*Id.* 6:35-51, 7:12-20.) FIG.C illustrates the valve of FIG.2 of the '782 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 flap.

FIG.C

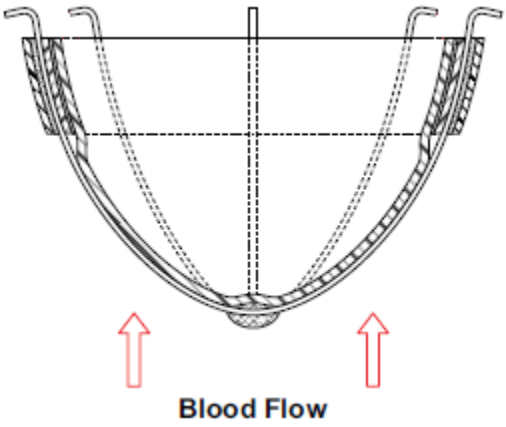
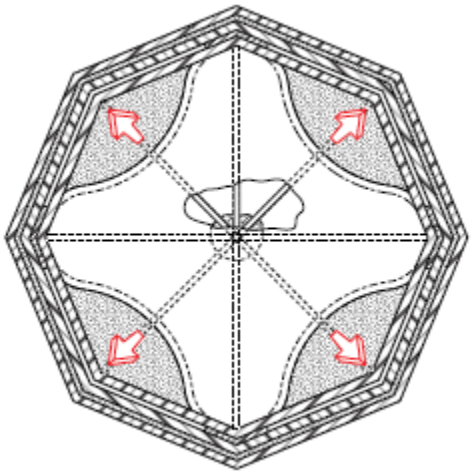


FIG.D



When in the aortic valve position (FIG.C), as the left ventricle contracts, blood pushes these flaps centrally, and blood flows around the unitary funnel instead of through the valve's center (shown by the arrows in FIGS.C, D), as is typical with valves that mimic the native architecture. When contraction stops and blood flow reverses, the funnel fills with blood, forcing the flaps to engage the side walls of the vessel or a band preventing upstream blood flow. (Ex.1003 ¶¶41-45.)

The inventor discussed Bessler (Ex.1008) extensively in the appendices of the provisional application and also in the nonprovisional application. The inventor acknowledged Bessler as disclosing a transcatheter valve that uses a "trileaflet stented valve housing," which is characterized as being "a bulky prosthetic valve." (Ex.1011 App.A-3:9-22; *see also* Ex.1001 col.2:14-19.)

B. The Prosecution History Of The Snyders Patent

Claims 1, 6-10, 13-16, 18-20, 24, 25, and 28 were rejected as anticipated by Johnson (Ex.1021). (Ex.1012 p.3.) Claims 2-5, 11-12, 21-23, and 29-30 were

rejected over Johnson in view of Stevens, U.S. Patent No. 5,545,214 (Ex.1007). (Ex.1012 p.4.) Claim 17 was rejected as being obvious over Johnson in view of Angell, U.S. Patent No. 5,861,028. (*Id.* at 5.) Not all of the rejections are relevant to this Petition.

In response to these rejections, claims 1 and 29 were amended to add the phrase "adjacent the band, said valve element being substantially free of connections except at the central portion of the frame and adjacent the band . . . ." (Ex.1014 pp.1, 4.) Applicant asserted that its valve element is substantially free of connections except at the frame's central portion and adjacent the band. Johnson's valve element is attached to the arms (10, 12, 14) along their entire lengths. (*Id*. at 8.) As to claim 10 and the claims dependent therefrom, Snyders cited an internal strip limiting spacing between adjacent anchors. Johnson allegedly did not disclose such a strip or a second band. (*Id.* pp.8-9.) Johnson also allegedly did not teach a plurality of U-shaped frame elements. Claim 18 was allegedly not anticipated because it required a second band, and claims 19, 20, 24, 25, and 28, because they required U-shaped elements. (*Id.* p.9.)

In responding to one of the obviousness rejections, Applicant argued that Stevens did not disclose a valve with an internal strip positioned inside and attached to the frame limiting spacing between the anchors. Johnson and Stevens were also elsewhere characterized as not disclosing U-shaped frame elements or a

valve element that is substantially free of connections except at the central portion of the frame adjacent the band. This last feature was also not shown, allegedly, in Teitelbaum (Ex.1013) either. (Ex.1014 pp.11-12.)

The claims were subsequently finally rejected. However, claims 10-17, 19-28, and 30 were indicated as allowable. An interview followed on December 16, 2002, and further amendments were proffered. Those amendments were formalized in an Interview Summary and Amendment dated December 16, 2002. (Ex.1015.) Independent claims 1, 18 (later renumbered 17), 29 (later renumbered 28), and 33 (later renumbered 30) were replaced by proposed new claims.

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 the aforementioned Texas action their Joint Memorandum on Claim Construction ("Joint Memo") (Ex.1041) for the challenged claims of the '782 Patent and its child under the ordinary and customary meaning standard applicable in district court.

Petitioner disagrees with Patent Owner's proposed definitions and will pursue the construction Petitioner set forth in Ex.1041 in court. *See Dish Network L.L.C. v. TQ Delta LLC*, IPR 2016-01470 Institution Decision, Paper No. 14, at 6-7 (Feb. 9, 2017) and Petition, Paper No. 1, at 11 (July 20, 2016) ("fine grain parameter") (accepting Patent Owner's court construction in IPR without Petitioner acquiescing in that construction). Patent Owner's proposed constructions are

admissions against its interest and Petitioner should have the right to rely upon them in this IPR. *Cf. Aylus Networks, Inc. v. Apple Inc.*, 856 F.3d 1353, 1362 (Fed. Cir. 2017). Moreover, Patent Owner cannot argue for a narrower interpretation here as it has claimed that its constructions in the district court action allegedly represent the ordinary and customary meaning of these terms.

On May 1, 2017, Patent Owner served infringement contentions (Ex.1039), including an Exhibit 1 (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)(d)"), the following terms[1] should be given the following constructions solely for purposes of this IPR:

Term	Construction
Frame	Ex.1041 p.2 Term 3: A structure designed to shape or support Ex.1040 pp.2-4, 20-22, 35-37, 61-63, 78-79, 88-90
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, 22-23, 63-64, 78-79
Central portion located between the plurality of peripheral anchors	Ex.1041 p.2 Term 9: Any location between a plurality of peripheral anchors Ex.1040 pp.5-6, 64-65, 93
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 pp.7-8, 23-25, 46-48, 67-68
First band	Ex.1041 pp.2-3 Term 10: A circular strip or ring including a ring of elements or of fabric or tissue; *see* "band" above ** Ex.1040 pp.37-39, 90-92.
Second band	*See* "band" above ** Ex.1040 p.39, 92
Flexible valve element	Ex.1041 p.3 Term 12: A flexible part of the valve Ex.1040 pp.8-9, 25-26, 40-41, 48-49, 68-69, 81-82, 93-94

[1] The Joint Memo (Ex. 1041) includes additional terms not provided in the chart. 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
U-shaped elements / U-shaped frame elements	Ex.1041 p.3 Terms 14 and 15: Parts (of the frame) that are generally shaped like a "U" Ex.1040 pp.18, 32-33, 45-46, 78
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, 20-22, 35-37, 61-63, 78-79, 88-90
Junction	Ex.1041 p.4 Term 24: A structure where the elements (frame elements) come together *See also* U-shaped elements above
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.26-28, 40-41, 48-49, 81-82
Concave downstream side	Ex.1041 p.4 Term 27: A valve element having a downstream side that bulges away from the downstream direction *See also* Convex upstream side above

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

The challenged claims are anticipated and/or rendered obvious if Patent Owner's Definitions are applied. But, as described in Ground 3, the claims are obvious even if Petitioner's district court claim construction is applied. (Ex.1041.)

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

A. Anticipation

1. Ground 1: Claims 1, 2, 4-8, 10-13, 17-19, 21, 22, And 25-30 Are Anticipated By Leonhardt

Based on the claims construed in light of Patent Owner's Definitions (Exs.1040-1041), the challenged claims are anticipated by Leonhardt (Ex.1017). The '782 Patent issued April 1, 2003, and claims benefit of an 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. Leonhardt was filed on May 1, 1997, and issued on September 28, 1999. It is therefore prior art pursuant to 35 U.S.C. § 102(e) (and also § 102(a).) Leonhardt was not of record. As further illustrated in Claim Chart 1, Leonhardt anticipates because, under Patent Owner's Definitions, it teaches each element of the challenged claims as arranged in the claims. *In re Gleave*, 560 F.3d 1331, 1334 (Fed. Cir. 2009).

a. A Valve For Repairing A Damaged Heart Valve

Leonhardt describes a percutaneously delivered self-expanding heart valve. Valve stent 20 can be positioned within the native aortic or mitral valve, *i.e.*, between upstream and downstream regions. (Exs.1017 cols.3:57-59, 4:14-15, 5:40-52, 9:63-67; 1003 ¶54.)

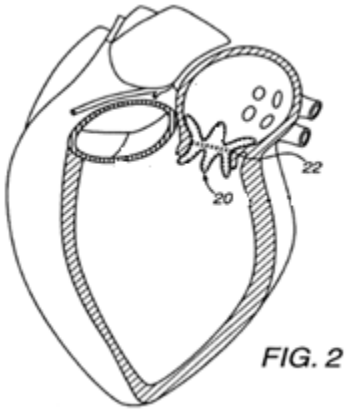


FIG. 2

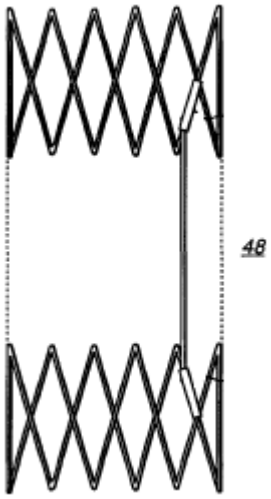
b. Flexibly Resilient Frame

Based on Patent Owner's Definitions, the claimed flexibly resilient frame encompasses any structure able to spring back to its original shape after being compressed and designed to shape or support, presumably, a FVE. (Ex.1041 p.2 Term 3, p.4 Term 23.) The Leonhardt stent is self-expanding and biases its proximal and distal ends into a fixed engagement with the tissue of the valve or annulus. (Ex.1017 cols.3:33-45, 4:53-5:33, 5:45-52.) It can be made of nitinol. (*Id.* 5:11.) Leonhardt's stent is a flexibly resilient frame as Defined. (*See* Claim Chart 1 Leonhardt "Frame-Flexibly Resilient"; Ex.1003 ¶55.) And as shown in the figures, the frame and FVE are sized and shaped to be positioned between upstream and downstream regions in a native valve annulus. (Ex.1017 col.9:49-11:68, FIGS.2, 9A-9D.)

Claims 1, 10, and 28-29 require that the frame include a plurality of peripheral anchors. Patent Owner's Definition encompasses frame elements found virtually anywhere in the stent. (*See, e.g.*, Ex.1040 pp.4-5.)

Claims 1, 28, and 30 also require a "central portion" which Patent Owner's Contentions identify as merely a region located between peripheral anchors.

FIG. 1B



The Leonhardt stent illustrated above includes two cylindrical portions disposed at each end of the stent. Each cylindrical portion is located above or below the other and spaced apart from each other by a predetermined distance by a connecting bar. (Ex.1017 cols.4:23-40, 4:53-5:52, FIGS.1B-1C, 4.) These cylindrical portions are made of frame elements which are "peripheral anchors" as Defined to the same extent as the accused frame elements of the device in Patent Owner's Contentions. (Exs.1003 ¶58; *see also* 1040 pp.4-5.) Moreover, Leonhardt discloses that the stent can "flair at one or both ends as is shown in FIG.2."

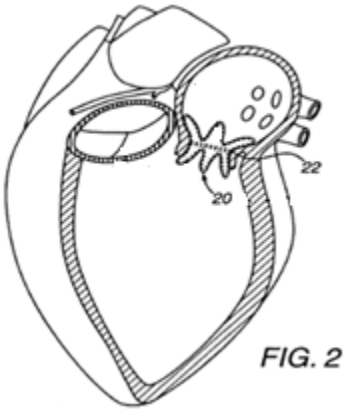


FIG. 2

(Ex.1017 col.6:9-22.) These flared portions also constitute peripheral anchors as Defined. (*See* Claim Chart 1 Leonhardt "Peripheral Anchors.") Stent 26 also contains a central portion (as Defined) located between the cylindrical portions. (Ex.1017 col.5:22-33, FIGS.1B, 4.) And, the entirety of the FVE is disposed between these peripheral anchors (as Defined) — within the "central portion" 22 in FIG.4. (*See* Claim Chart 1 Leonhardt "Central Portion"; Ex.1003 ¶¶57, 59.)

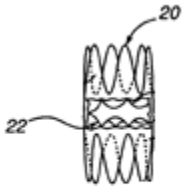


FIG. 4

Claims 18 and 29 require a plurality of "U-shaped" frame elements having opposite ends and being joined together generally midway between respective ends. (*See* Claim Chart 1 "Frame-U-Shaped Elements.") These elements are sized and shaped to fit in a native annulus. As Defined, these frame elements are

generally U-shaped. Patent Owner's Contentions merely point to a collection of struts over which a "U" can be drawn. (Ex.1040 pp.45-46, 78.)

Leonhardt's frame includes a plurality of "U-shaped" members as Defined and to the same extent as the accused structures illustrated in the Contentions — indeed more so. Those members are joined to each other along the zig-zag or "wavy form" at respective points 40 illustrated in FIGS.1A, 1B. (Exs.1017 cols.4:35-40, 4:53-5:22, 5:40-52; 1003 ¶¶60-62.) These zig-zags or waves have a predetermined radius to maximize bias and prevent sharp transitions. (Ex.1017 col.5:23-27.) Thus, while Leonhardt illustrates sharp zig-zags, it also teaches curved apices which are both "U-shaped" as Defined.

Indeed, adjacent apices are attached at a point which is midway between their respective ends as demonstrated below in FIGS.E and F. (*Id.*; *see also* FIG.1B; Ex.1003 ¶¶63-64.) U-shaped members are indicated in red or yellow and with an "A" and the junction midway between respective ends is indicated in green or blue and with a "B." And, as shown in FIGS.2, 3, and 9, the Leonhardt device is sized and shaped to be placed in a native annulus.

FIG.E

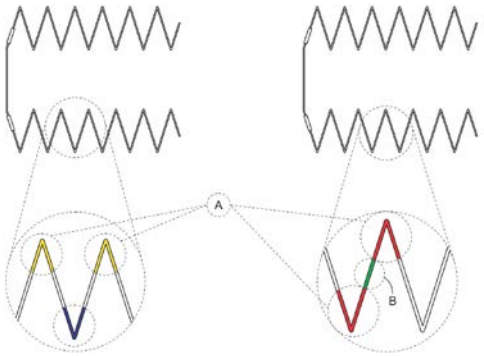
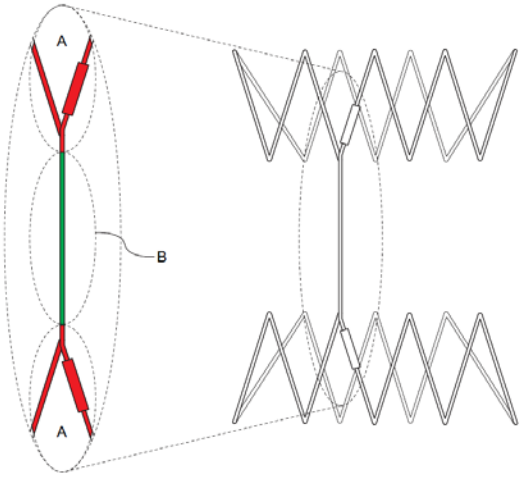


FIG.F



Finally, claims 28-29 require that the frame be collapsible to a maximum width less than about 18mm. Leonhardt teaches that its valve may be collapsed to sizes between 12 FR and 20 FR. (Ex.1017 col.6:54-65.) As explained by Dr. Dasi, the abbreviations "F" and "FR" in this context stand for "French." (Exs.1009 p.15:10-18; 1003 ¶65.) A stent that is 12 FR is 4mm in diameter and one that is 20 FR is 6.67mm in diameter. (*Id.*) Thus the range Leonhardt describes falls within the 18mm or less range claimed.

c. Bands

Claims 1, 18, and 28, require a "band" and claims 17 and 30 require a "first band," surrounding and/or attached to the frame. Patent Owner's Definition of band is a structure generally in the shape of a circular strip or ring; a band can be integrated with the frame.

Both cylindrical portions of Leonhardt's stent are circumferential rings of frame elements and therefore a band/first band as Defined. (Ex.1017 cols.4:52-65, 5:23-35, 5:45-48, FIG.1B.) Leonhardt's graft material, which surrounds the frame, is also a band/first band as Defined. Stent 26 is sutured within graft material. (*Id.* 5:45-48, 5:61-63, 6:9-13, 6:23-34, FIGS.2, 4; *see also* Claim Chart 1 Leonhardt "Band/First Band"; Ex.1003 ¶¶66-67.)

Claim 10 requires that the band be an "internal strip." The valve of Leonhardt is preferably a native porcine valve. (*Id.* 6:23-34.) To a POSA, a surgically harvested porcine valve that has been treated for human use and includes commissural points as described would necessarily require "root" tissue from the original annulus. (Ex.1003 ¶¶68-69.) This tissue is a band attached to the interior of the frame. (*Id*.) Leonhardt therefore teaches the claimed internal band as Defined.

Claims 1, 10, 18, and 28 further require that the band limit spacing between adjacent peripheral anchors. The graft material of Leonhardt restricts the expansion

of the self-expanding frame, as confirmed by Leonhardt's instruction to "cut out" the graft material to allow further outward expansion to form "distensible fingers." (Ex.1017 col.6:9-22.) The uncut graft material limits spacing as claimed. (Ex.1003 ¶70; *see also* Claim Chart 1 Leonhardt "Band/First Band.")

Claims 17 and 30 also require a second band surrounding and attached to the frame. The second band is Defined and illustrated in the Contentions as a circumferential row of frame elements or cells disposed downstream of the first band. (*See, e.g.*, Ex.1040 p.39.) Leonhardt's stent arrangement includes two spaced-apart cylindrical portions of frame elements. (Ex.1017 cols.4:26-65, 5:23-37, FIG.1B.) When deployed as part of stent valve 20 in a native annulus, one of these cylindrical portions is necessarily upstream and the other downstream (Ex.1003 ¶¶71-74) and they therefore are first and second bands as Defined. (*See* Claim Chart 1 Leonhardt "Second Band.")

d. Flexible Valve Element

All of the challenged claims require a "flexible valve element" attached to the frame or to a central portion thereof. The Patent Owner's Definitions indicate that this term encompasses any valve, and indeed any flexible part of a valve. (Ex.1041 p.3 Term 12.) Leonhardt uses a biological valve which is preferably an intact tricuspid porcine valve, which a POSA knows to be flexible. (Exs.1017 col.6:23-34; 1003 ¶¶75-76.) Biological valve 22 is presized to fit within the middle

of cylinder 48 formed by stent 26. (Ex.1017 col.6:28-31.) Such a valve includes plural leaflets and is attached to the central portion of the frame and adjacent the band as Defined (graft material 24, which extends along the entire stent length). (Exs.1017 cols.3:33-45, 5:40-52, 6:23-32, FIG.4; 1003 ¶77.) Thus Leonhardt teaches a FVE attached to the frame/central portion and adjacent a band as Defined. (*See* Claim Chart 1 Leonhardt under "Flexible Valve Element.")

Claims 1, 28, and 30, require a valve element having upstream and downstream sides facing the upstream and downstream regions, respectively. This limitation as Defined is met by the tricuspid porcine 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 ¶78; *see also* Claim Chart 1 Leonhardt "Upstream/Downstream Sides.")

Claims 10, 17, 18, and 29 further characterize 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. According to Patent Owner's Definitions, including the Contentions (Ex.1041 p.4 Terms 26, 27; *see*, *e.g.*, 1040 pp.26-28), these limitations are met by a FVE having the general structure of a native tricuspid heart valve. As Dr. Dasi explains, the FVE identified in the Contentions has the overall construction of both native human and porcine valves. (Ex.1003 ¶79.) Therefore, to the extent that the

FVE in the Contentions has convex upstream and concave downstream sides, the biological valve of Leonhardt does as well. (Exs.1017 col.6:23-34; 1003 ¶79; *see also* Claim Chart 1 Leonhardt "Convex Upstream/Concave Downstream Sides.")

Finally, claims 1, 28, and 30 require attaching the FVE to the central portion and adjacent a band, and claims 1 and 28 further require that the attachment be substantially free of connections to the frame except at the central portion and adjacent the band. As noted previously when discussing the frame and the attachment of the FVE to the frame, biological valve 22 of Leonhardt is attached to the frame and disposed within its central portion as Defined. (Exs.1017 cols.5:45-48, 6:23-32, FIG.4; 1003 ¶ 80.) Graft material 24 runs the full length of the stent so every point of the attachment of valve 22 to the frame is necessarily adjacent a band as Defined. (Ex.1017 col.5:52-6:28.) And for that very reason, this attachment is also substantially free of other connections which are not adjacent the band. (*See* Claim Chart 1 Leonhardt "Attached to a Central Portion/Substantially Connected to Central Portion.")

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

Claims 1, 17, 18, 28, 29, and 30 each include lengthy recitations merely describing the function of virtually any one-way (or check) valve, including the native heart valve and replacement valves, which were known *per se*. (Ex.1003 ¶¶81-82.) These functions were admittedly known to POSAs at the time through, if

nothing else, the articles and patents cited in the Background of the '782 Patent dating back more than 50 years. (Exs.1001 col.1:42-2:19; 1003 ¶¶81, 82.)

Patent Owner contends 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. (*See, e.g.*, Exs.1040 pp.11-12; 1003 ¶82.) Leonhardt's porcine valve functions the same way as the tricuspid valve cited in Patentee's Contentions. Leonhardt therefore meets these recitations to the same extent as asserted by Patent Owner. (Exs.1017 cols.1:10-21, 3:33-45, 5:50-52, 6:23-34; 1003 ¶82; *see also* Claim Chart 1 Leonhardt "Valve Movement Language.")

Claim 10 instead specifies that the convex side of the FVE engages the internal strip of the band to block reverse flow — to close the valve. Nonetheless, Patent Owner has taken the position that a valve having the structure of a native valve literally meets this limitation. (Ex.1040 pp.28-30.) Thus, Patent Owner admits that this element is met by the operation of a native valve and the preferred porcine valve of Leonhardt. (Exs.1017 cols.1:10-21, 3:33-44, 5:50-52, 6:23-34; 1003 ¶83.)

f. <u>Delivery Device Limitations</u>

Claims 28 and 29 additionally require a delivery device or "instrument" comprising a holder having a hollow interior for holding the valve, an elongated

manipulator attached to the holder for manipulating the holder and an ejector mounted within the holder for ejecting the valve from the holder. (Ex.1001 cols.14:47-56, 15:34-16:2.) Leonhardt describes just such an instrument. (Ex.1017 *see generally* col.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, 7:16-21.) 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 "ejector." (*Id.* 6:34-49, 8:23-42; Ex.1003 ¶84.) Because Leonhardt meets all of the limitations of the independent claims of Snyders (as Defined), those claims are anticipated.

Claim Chart 1 below reflects the recitations of the challenged independent claims reorganized such that common elements are grouped together. These citations supplement those in the above text. The numbers/letters beginning each entry (*e.g.*, "1(p)") correspond to claim numbers from which each entry originated and the breakdown provided in the Contentions (Ex.1040). Claim Chart 1 identifies where the claimed elements as Defined by Patent Owner can be found in Ground 1 (indicated as "Leonhardt"). Citations for Ground 2 include those for Leonhardt and Andersen. The citations for Ground 3 include those for Leonhardt as well as for Johnson and Imachi.

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: 10(p). *see* 1(p) 17(p). *see* 1(p) 18(p). *see* 1(p) 28(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: 29(p). *see* 28(p) 30(p). *see* 1(p)	**Cls.1, 10, 17, 18, 28, 29, 30** Leonhardt: Ex.1017 cols.3:15-45, 9:50-11:36, 11:59-12:5, FIGS.2, 3, 9A-9D. Ex.1003 ¶54. Andersen: Exs.1006 cols.2:21-68, 3:1-15, 3:37-42, FIG.2; 1003 ¶92. Johnson: Exs.1021 cols.2:62-3:19, 6:8-19, FIG.8; 1003 ¶¶121-122. **Additional "instrument" recitations for cls.28, 29** Leonhardt: Exs.1017 cols.4:14-19; 6:34-54; FIGS.5, 7, 9A-9D (artificial valve placed by deployment catheter 100); 1003 ¶84. Andersen: Exs.1006 cols.5:40-6:44, 7:17-55, FIGS.3-7; 1003 ¶99.
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, 10(a). *see* 1(a) 17(a). *see* 1(a) 28(a). an artificial valve including a	**Cls.1, 10, 17, 28, 30** Leonhardt: Exs.1017 cols.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 ¶55. Andersen: Exs.1006 cols.2:39-42, 2:45-52, 2:60-64, 3:15-17, 6:66-7:12, 7:17-23, FIGS.1, 2; 1003 ¶93.

Claim Language	Citation
flexibly resilient frame sized and shaped for insertion between the upstream region and the downstream region, 30(a). *see* 1(a)	Johnson: Exs.1021 cols.2:43-50, 4:10-48, 5:20-36, 6:2-7, FIGS.1, 2, 7; 1003 ¶¶123-125.
Frame – U-Shaped Elements 18(a). a plurality of U-shaped frame elements sized and shaped for insertion in the heart in a position between the upstream region and the downstream region, each of said plurality of frame elements having opposite ends, said elements being joined together generally midway between their respective ends at a junction of the elements; 29(a). an artificial valve including a plurality of flexibly resilient U-shaped frame elements sized and shaped for insertion between the upstream region and the downstream region, each of said plurality of frame elements having opposite ends, said elements being joined together generally midway between their respective ends	**Cls.18, 29** Leonhardt: Exs.1017 cols.3:33-45, 4:35-5:30, in particular 4:65-5:2, 5:40-52, 9:63-10:21 (aortic), 10:22-42 (mitral), FIGS.1A-1B, 2, 3, 9A-9D; 1003 ¶¶60-64. Andersen: Exs.1006 col.5:9-28, FIGS.1, 2; 1003 ¶93. Johnson: Exs.1021 cols.4:10-15, 4:35-48, 5:20-36, FIGS.1, 2, 7; 1003 ¶¶129-131.
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 10(b). *see* 1(b) 28(b). the frame having a plurality of peripheral anchors for anchoring the frame between the upstream region and the downstream region	**Cls.1, 10, 28, 29** Leonhardt: Exs.1017 cols.3:33-45, 4:14-5:52, 5:53-56, 6:9-22, 8:42-9:5; FIGS.1B-1C, 2-4, 9A-9D; 1003 ¶¶56, 58. Andersen: Exs.1006 cols.5:33-35, 6:54-63, FIGS.1, 2, 8, 9; 1003 ¶94.

Claim Language	Citation
29(b). thereby forming a frame having a plurality of peripheral anchors for anchoring the frame between the upstream region and the downstream region,	
Central Portion 1(c). and a central portion located between the plurality of peripheral anchors; 28(c). *see* 1(c) 30(d). attached to a central portion of the frame	**Cls.1, 28, 30** Leonhardt: Exs.1017 cols.5:22-35, 6:9-13 ("plurality of distensible fingers 46"), 6:23-34, FIGS.1B, 1C, 2, 4; 1003 ¶¶57, 59. Andersen: Exs.1006 cols.5:33-35, 6:54-63, FIGS.1, 2, 8-9; 1003 ¶94, 97. Johnson: Exs.1021 cols.2:47-51, 4:10-15, 4:49-68, FIGS.1, 2; 1003 ¶¶127-128.
Band/First Band 1(d). a band attached to the frame limiting spacing between adjacent anchors of said plurality of peripheral anchors; 10(c). a band comprising an internal strip positioned inside and attached to the frame limiting spacing between adjacent anchors of said plurality of peripheral anchors; 17(b). a first band surrounding and attached to the frame; 18(b). a band surrounding the frame and extending between adjacent elements of said plurality of frame elements to limit	**Cls.1, 10, 17, 18, 28, 30** Leonhardt: Exs.1017 if defined as a row of frame elements – cols.3:33-45, 4:52-65, 5:23-35, 5:45-48, FIG.1B, if defined as a cuff – cols.5:45-48, 5:53-63, 6:9-13, 6:23-34, FIGS. 1C, 2, 4; 1003 ¶¶66-70. Andersen: Exs.1006 cols.5:9-39, 6:54-62, FIG.1; 1003 ¶¶96-97. **Additional "limiting spacing" citations for cls.1, 10, 18, 28** Leonhardt: Exs.1017 col.6:9-22; 1003 ¶70. Andersen: Exs.1006 cols.5:9-39,

Claim Language	Citation
spacing between said adjacent elements; 28(e). a band attached to the frame limiting spacing between adjacent anchors of said plurality of peripheral anchors, and 30(b). a first band surrounding the frame;	6:54-62, FIG.1; 1003 ¶¶96-97. **Additional "internal strip" citations for cl.10** Leonhardt: Exs.1017 cols.5:45-52, 6:23-34 (biological porcine valve), FIG.4; 1003 ¶68. Andersen: Exs.1006 cols.5:9-39, 6:54-62, FIG.1; 1003 ¶¶96-97. Johnson: Exs.1021 cols.5:54-6:14, FIGS.6, 7; 1003 ¶134.
Second Band 17(c). a second band surrounding and attached to the frame downstream from said first band for supporting tissue defining said downstream region to reinforce said tissue and prevent distention thereof; 30(c). a second band surrounding the frame downstream from said first band for supporting tissue defining said downstream region to reinforce said tissue and prevent distention thereof; and	**Cls.17, 30** Leonhardt: Exs.1017 cols.4:26-65; 4:66-5:10; 5:23-37, 5:40-52; FIGS.1A, 1B; 1003 ¶¶71-74. Andersen: Exs.1006 cols.5:9-39, 6:54-62, FIG.1; 1003 ¶¶96-97.
Flexible Valve Element 1(e). and a flexible valve element attached to the central portion of the frame and adjacent the band, 10(d). and a flexible valve element positioned inside the band and attached to the frame, 17(d). and a flexible valve element attached to the frame	**All challenged claims** Leonhardt: Exs.1017 cols.3:33-45; 5:23-52; 6:23-34; FIGS.1B, 1C, 2, 4; 1003 ¶¶75-77, 80. Andersen: Exs.1006 cols.2:34-36, 5:11-17, 5:31-35, 7:12-16, FIGS.1, 2; 1003 ¶¶95-96.

Claim Language	Citation
18(c). and a flexible valve element attached to the junction of the frame elements 28(f). a flexible valve element attached to the central portion of the frame and adjacent the band, 29(d). and a flexible valve element attached to the frame 30(d). a flexible valve element attached to a central portion of the frame	Johnson: Exs.1021 cols.2:43-50, 4:49-68, 5:35-53, 6:2-8, FIGS.2, 4, 5; 1003 ¶¶139-141.
Upstream/Downstream Sides 1(g). said valve element 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, 28(h). said valve 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 downstream region when the frame is anchored between the upstream region and the downstream region, 30(d). a flexible valve element attached to a central portion of the frame having	**Cls.1, 28, 30** Leonhardt: Exs.1017 cols.5:40-52; 6:23-34; 9:63-10:21; 10:22-43, FIGS.2, 3, 4, 9A-9D; 1003 ¶78. Andersen: Exs.1006 cols.5:9-39, FIG.1; 1003 ¶92. Johnson: Exs.1021 cols.5:37-53, 6:14-19, FIGS.4, 5, 8; 1003 ¶141.

Claim Language	Citation
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,	
Convex Upstream/Concave Downstream Sides 10(e). said valve 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, 17(d). *see* 10(e) 18(c). having a convex upstream side facing said upstream region when said plurality of frame elements is inserted 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 said plurality of frame elements is inserted in the position between the upstream region and the downstream region, 29(d). a convex upstream side facing said	**Cls.10, 17, 18, 29** Leonhardt: Exs.1017 col.6:23-34 biologic porcine valve; 1003 ¶79. Andersen: Exs.1006 col.5:9-39, FIG.1; 1003 ¶¶97-98. Johnson: Exs.1021 cols.2:54-61, 4:49-68, 5:37-45, FIGS.2, 7, 8; 1003 ¶151.

Claim Language	Citation
upstream region when the frame is anchored 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 between the upstream region and the downstream region,	
Attached To A Central Portion/Substantially Connected To Central Portion 1(f). said valve element being substantially free of connections to the frame except at the central portion of the frame and adjacent the band, 28(g). said valve element being substantially free of connections to the frame except at the central portion of the frame and adjacent the band, 30(d). a flexible valve element attached to a central portion	**Cls.1, 28, 30** *See also* Central Portion above. Leonhardt: Exs.1017 cols.3:39-45, 5:45-48, 5:52-6:32, 6:23-34 ("Biological valve 22 is attached to stent 26, to the graft material 24 or both . . . Attachment is along biological valve's 22 commissural points 68 and around its base."), FIGS.1B, 4; 1003 ¶77, 80. Andersen: Exs.1006 cols.5:11-17, 5:29-35, FIGS.1, 2; 1003 ¶100. Johnson: Exs.1021 cols.4:57-68, 5:42-45; 1003 ¶¶142-150. Imachi: Ex.1020 cols.3:49-4:30, FIGS.2A-3C
Collapsed Width 28(d). the frame being collapsible to a configuration having a maximum width less than about 18 mm, 29(c). the frame being collapsible to a configuration having a maximum width less than about 18 mm,	**Cls.28, 29** Leonhardt: Exs.1017 col.6:54-65; 1003 ¶65. Andersen: Exs.1006 col.6:23-30; 1003 ¶98.

Claim Language	Citation
Valve Movement Language 1(h). said 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 element permits downstream flow between said upstream region and said downstream region and a closed position in which the element blocks flow reversal from said downstream region to said upstream region, wherein the 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 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. 17(e). valve movement limitations — *see* claim 1(h) 18(d). valve movement limitations — *see* claim 1(h) 28(i). valve movement limitations — *see* claim 1(h) 29(e). valve movement limitations — *see* claim 1(h)	**Cls.1, 17, 18, 28, 29, 30** Leonhardt: Exs.1017 cols.1:5-21, 3:33-45, 6:23-34, FIGS.2, 3, 4, 9B,5:50-52; 1003 ¶¶81-82. Andersen: Exs.1006 cols.2:22-26, 3:13-16, 3:37-42, 5:31-39, FIGS.7, 10; 1003 ¶¶95-96, 100. Johnson: Exs.1021 cols.3:26-47, 5:37-53, FIGS.4, 5; 1003 ¶¶152-153.

Claim Language	Citation
30(e). valve movement limitations — *see* claim 1(h)	
Valve Movement Language 10(f). said 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 element permits downstream flow between said upstream region and said downstream region and a closed position in which **the convex side of the element engages the internal strip of the band <u>so the element blocks flow reversal from said downstream region to said upstream region</u>**, wherein the 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 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.	**Cl.10** <u>Leonhardt</u>: Exs.1017. *See* Valve Movement language (claim 1(h)) above; 1003 ¶83. <u>Andersen</u>: Ex.1006 *see* 1(h) above. <u>Johnson</u>: Ex.1021 *see* 1(h) above.
Holder 28(j). an instrument including a holder having a hollow interior sized for holding the artificial valve when the frame is in the collapsed configuration; 29(f). *see* 28(j)	**Cls.28, 30** <u>Leonhardt</u>: Exs.1017 cols.6:55-61, 7:16-21, FIGS.5-7, 9A-9D;1003 ¶84. <u>Andersen</u>: Exs.1006 cols.2:45-52, 5:40-45, 7:30-55 (protection cap), FIG.3; 1003 ¶99.

Claim Language	Citation
Manipulator 28(k). an elongate manipulator attached to the holder for manipulating the holder into position between the upstream region and the downstream region; 29(g). *see* 28(k)	**Cls.28, 30** Leonhardt: Exs.1017 cols.6:34-7:10, 7:21-8:22, FIGS.5-7, 9A-9D; 1003 ¶84. Andersen: Exs.1006 cols.5:40-56, 7:44-48, FIG.3 (proximal end of balloon catheter); 1003 ¶99.
Ejector 28(l). and an ejector mounted in the hollow interior of the holder for ejecting the artificial heart valve from the hollow interior of the holder into position between the upstream region and the downstream region. 29(h). *see* 28(l)	**Cls.28, 30** Leonhardt: Exs.1017) 6:34-49, 8:23-41, FIGS.5-7, 9A-9D; 1003 ¶84. Andersen: Exs.1006 cols.5:40-45, 7:44-48 (balloon means pushed out), FIG.3; 1003 ¶99.

g. Dependent Claims

Dependent claims 2, 4-5, 11-12, and 21-22 require the frame to be collapsible to a specified maximum width. In claims 2, 11, and 21 the width is less than 18mm. This limitation is met for the reasons previously discussed in connection with claims 28 and 29. (Exs.1017 col.6:54-65 (12 and 20 FR ("French") are less than 18mm); 1003 ¶¶65, 85.) Dependent claims 4, 12, and 22 limit the maximum width when collapsed to less than 6mm. In claim 5, the maximum width is between about 4mm and about 6mm. 12FR taught by Leonhardt is 4mm which falls within these claimed ranges. (*Id.*.)

Claim 6 requires that the FVE be attached to the frame substantially centered between the plurality of peripheral anchors. This was discussed previously and is clearly illustrated in Leonhardt in, *inter alia*, FIG.4, element 22, as Defined. (Exs.1017 cols.5:40-52, 6:23-34, FIG.4; 1003 ¶¶77, 80, 86.)

Claim 7 specifies that the FVE is attached to the frame at a plurality of points around the frame, thereby forming flaps extending between adjacent attachment points and each at least partially defining a valve opening during fluid flow. Patent Owner Contends that this limitation encompasses the commissures of a traditional tricuspid valve that are attached to a stent and the leaflets emanating therefrom. (Ex.1040 p.17.) The biological valve of Leonhardt has two or more commissural points and "[a]ttachment is along biological valve's 22 commissural points 68 and around its base." (Ex.1017 col.6:23-32.) This is a disclosure of attachment creating flaps to the same degree as the accused valve cited in Patent Owner's Contentions. (Ex.1003 ¶87.) Thus, Leonhardt anticipates claim 7 as Defined.

Claims 8 and 13 require that the stent comprise a plurality of "U-shaped" elements joined together at a junction of the elements. This was already discussed in connection with independent claims 18 and 29 and these dependent claims are anticipated for the same reasons. (Exs.1017 col.4:26-40, FIGS.1A, 1B; 1003 ¶¶60-64, 88.)

Claim 19 requires that each end of each frame element includes an anchor. According to Patent Owner, this is met by the ends of a "U-shaped" element, which, in other claims, are identified as peripheral anchors. (Ex.1040 p.-52.) This recitation as Defined is met by the alternating apices of the zig-zag 40 or waves of stent 26 of Leonhardt at the upstream and downstream ends of the stent. (Exs.1017 cols.3:33-44, 4:53-5:22, 5:40-52, FIG.1B; 1003 ¶89.)

Claims 25 and 26 require that the distance between the opposite ends of frame elements be between 3-5cm or 2-3cm respectively. According to the Contentions, this is the diameter of the stent when expanded, which is consistent with the specification. (Ex.1001 col.5:51-63.) Diameters identified in the Contentions for the aortic annulus range from 19mm to 27mm (Ex.1040 pp.54-56). A POSA would generally recognize these as the aortic annulus sizes of most human adults. (Ex.1003 ¶90.) Leonhardt describes the diameter of its device as "pre-sized" to be "approximately thirty percent (30%) larger in diameter than the largest diameter of the tissue against which the valve stent 20 (FIG.3) will seal." (Ex.1017 col.4:66-5:5.) Adding 30% to the standard aortic annulus sizes reflected in the Contentions results in a diameter range of 2.47-3.51cm, the first endpoint falling within the range of claim 26 and the second within the range of claim 25. (Ex.1003 ¶90.)

Claim 27, which depends from claim 18, identifies the band claimed therein as being a first band, and further requires a second band. Leonhardt describes using a first and a second band, as Defined, as discussed previously in connection with independent claims 17 and 30, which also require both bands, and is anticipated for the same reasons. (Ex.1003 ¶91.)

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

B. Obviousness

To the extent one were to argue that one or more of the claimed elements was not exactly shown in Leonhardt in the same manner as claimed, the differences would be obvious to a POSA based on the following combinations. The various claimed elements were all known in the field of collapsible heart valves and interchanging known elements, each having a known function, yielding only expected and predictable results, is "the work of the skillful mechanic, not that of the inventor." *Sundance, Inc. v. Demonte Fabricating Ltd.*, 550 F.3d 1356, 1367 (Fed. Cir. 2008) (quoting *Sakraida v. Ag Pro, Inc.*, 425 U.S. 273, 282 (1976)). As the Supreme Court has stated:

> [A] "patent for a combination which only unites old elements with no change in their respective functions . . . obviously withdraws what already is known into the field of monopoly and diminishes the resources available to skillful

> men.' . . . The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.

KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 415-16 (2007) (quoting *Great Atl. & Pac. Tea Co. v. Supermarket Equip. Corp.*, 340 U.S. 147, 152-53 (1950)).

By the filing date, there were already patents and publications describing collapsible heart valves comprised of a stent, a band, and a valve, all as Defined. (Exs.1003 ¶¶27-33; 1006-1009, 1017, 1022-1024.)

And the functions of each of these elements were known. Letac, for example, memorialized the known danger of stent movement after implantation, which it termed "catastrophic." (Exs.1009 p.5:28-30; 1003 ¶103.) Letac also proposed specific structure to mitigate this problem (Ex.1009 p.15:3-9, FIGS.3a-3b) as did Andersen and Bessler (Exs.1006 col.6:54-62; 1008 cols.4:12-26, 5:67-6:2, FIGS.6, 7; 1003 ¶¶103-104).

Given the limited amount of closely related art, all made using the same types of components, organized and operating in the same way, and in view of the breadth of these claims, swapping one stent for another, one band for another, one FVE for another, is the application of routine engineering, which is characteristic of obviousness; nothing more. (Ex.1003 ¶¶102, 104-106.) And no independent motivation to do so is needed.

In the alternative, it would be obvious to try various combinations of these known elements from the limited pool of collapsible artificial heart valves. As the Supreme Court held in *KSR*, an invention can be obvious to try when there are "a finite number of identified, predictable solutions" a POSA has good reason to pursue the known options within his or her technical grasp. *KSR*, 550 U.S. at 421.

1. Ground 2: Claims 1, 2, 4-8, 10-13, 17-19, 21, 22, And 25-30 Are Obvious Over Leonhardt In View Of Andersen

Leonhardt's applicability to these claims was extensively discussed in Ground 1 and Claim Chart 1. It is equally applicable here.

Andersen (Ex.1006) issued in 1995 and is therefore prior art pursuant to 35 U.S.C. § 102(b). Andersen was of record, but was not applied. Like the Leonhardt valve discussed in Ground 1, Andersen's valve comprises a stent and a biological cardiac valve and band mounted inside, which can be placed transluminally into a patient to define upstream and downstream regions. (Exs.1006 cols.2:34-68, 3:1-4, 3:37-42, 5:9-39, 6:3-44, FIGS.1, 2, 8-10; 1003 ¶¶92-100.)

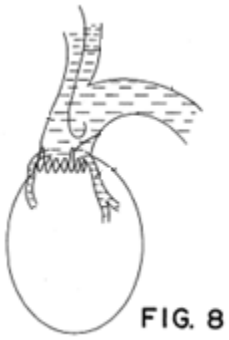


FIG. 8

Andersen's stent is a flexibly resilient frame. (*Id.* cols.2:39-42, 2:45-52, 2:60-64, 3:16-17, 6:66-7:12, 7:17-23; Ex.1003 ¶93.) It can include two or more rings (7, 8) as shown in FIGS.1 and 2, which are placed on top of each other and they are mutually secured by means of a number of sutures (not shown). (Ex.1006 col.5:9-28.)

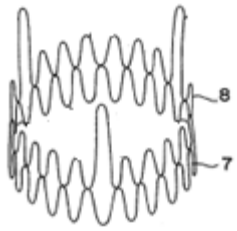
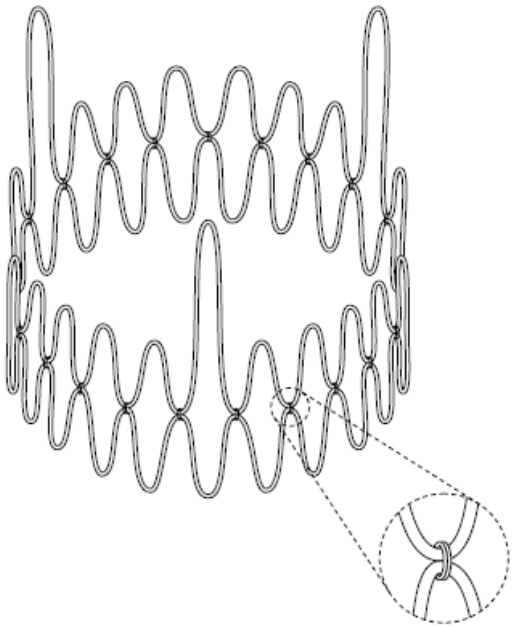


FIG. 1

As illustrated in Andersen's FIG.1, the stent has "U-shaped" members joined together at junctions midway between their respective ends (via the sutures not shown in the patent, but illustrated in FIG.G) as Defined. (*Id.* col.5:9-28, FIGS.1, 2; Ex.1003 ¶93.)

FIG.G



The upstream and downstream extremities of these rings can be peripheral anchors for the reasons discussed for Leonhardt in Ground 1 as Patent Owner Defined, and the region between these peripheral anchors, where rings 7 and 8 are attached together, is a central portion as Defined. (*Id.* cols.5:33-35, 6:54-63, FIGS.1, 2, 8, 9; Ex.1003 ¶94.)

Like Leonhardt, Andersen uses a biological valve as the FVE, which is obtained from a slaughtered pig (Ex.1006 col.5:29-39) attached to the stent with sutures to form a prosthetic valve as Defined (*id.* cols.2:34-36, 5:11-17, 5:31-35, 7:12-16). Accordingly, Andersen discloses a band of root tissue (as Defined) attached within the stent. (Ex.1003 ¶¶95-96.)

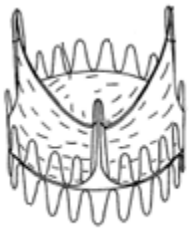


FIG. 2

It would have been obvious to interchange elements of Andersen for those of Leonhardt even without specific motive. *See Sundance,* 550 F.3d at 1367; *KSR*, 550 U.S. at 417. Both are replacement valves produced from a collapsible and expandable stent, a band, and a porcine valve for transcatheter implantation, all as Defined. (Ex.1003 ¶¶92-102.) That said, motivation exists. Their FVEs are already the same. And both have bands, whether Defined as circumferential rows of frame elements or the root tissue of the porcine valve. (*Id.* ¶¶102, 105-107.) Andersen teaches a structure for directly attaching the biological valve's commissures to a collapsible stent and using a stent that can be extended by additional rings so that it extends farther into the vasculature which also can help prevent migration. (Exs.1006 cols.5:11-14, 6:54-63; 1003 ¶¶103-104.) The flexibility this offers in terms of stent design is motive to use Andersen's stent even though no motivation should be needed. (Ex.1003 ¶¶109-110.) Andersen also provides an alternative stent structure which includes U-shaped elements including peripheral anchors as Defined that, like the ends of the Leonhardt stent, can flare out to engage an internal structure. (Ex.1006 FIGS.8, 9.) So a POSA would have reason to consider

using the Andersen stent, or aspects of it, in place of the Leonhardt stent. And given their similarity in structure and function, and that both are U.S. patents and presumed enabling, a POSA would have a reasonable expectation of success from any such combination.

For the reasons stated above, Leonhardt in combination with Andersen meets all of the limitations of the independent claims of the ’782 Patent.

Leonhardt’s disclosure of a delivery device of claims 28 and 29 (*see* Part IX.A.1.f., *supra*) can be substituted with those of Andersen (Ex.1006 cols.2:44-52 (stent is compressed and inserted into an insertion or protection cap from which the stent is dispensed), 2:64-68 (a catheter is contracted and removed from the channel), 5:40-6:44, FIGS.3-7).

As to claim 10, the convex upstream side of a porcine valve, if indeed it can be called convex as Defined, does not engage an inner surface of a stent, band, or annulus to prevent blood flow. Only the downstream side of the valve engages the inner surface of the stent or annulus, and it does so only when the valve is open to permit blood flow. (Ex.1003 ¶83.) However, Patent Owner’s Contention (Ex.1040 pp.28-30) is, at least, an admission that the claim is met by a traditional tricuspid valve as described in both Leonhardt and Andersen. Thus, claim 10 is obvious. (*See* Claim Chart 1 Leonhardt and Andersen.)

The dependent claims are obvious for the reasons discussed in Ground 1. Claims 8 and 13 are obvious based on Leonhardt, but also because of the "U-shaped" elements of Andersen as noted above. Claims 6 and 7 are obvious over Leonhardt, but also based on Andersen. (Exs.1006 col.5:9-39, FIG.2; 1003 ¶93.)

Claims 2, 4-5, 11-12, and 21-22 are obvious in view of Leonhardt, but also in view of Andersen's teaching that the collapsed valve can be 10mm and also that the valve needs to be collapsible to a diameter which allows it to be inserted through the vasculature. (Exs.1006 cols.6:23-30, 2:44-55; 3:1-7; 1003 ¶¶100-101.)

Claim 19 is obvious as both Leonhardt and Andersen disclose peripheral anchors (as Defined) and claims 25 and 26 are obvious in view of Leonhardt as discussed in Ground 1 and Andersen's disclosure of a diameter of 3cm. (Ex.1006 col.6:29-31.) Finally, claim 27 is obvious as both references teach first and second bands, at least to the same extent as Defined. (Ex.1003 ¶101.)

2. Ground 3: Claims 1, 2, 4-8, 10-13, 17-19, 21, 22, And 25-30 Are Obvious Over Leonhardt In View Of Johnson And Imachi

Leonhardt's applicability was discussed in Ground 1 and Claim Chart 1. It is equally applicable here.

Johnson (Ex.1021, issued 1982) and Imachi (Ex.1020, issued 1995) are both prior art pursuant to 35 U.S.C. § 102(b). Johnson was considered during

prosecution of the ’782 Patent as a primary reference. (*See* Part VI.B, *supra.*) Imachi was cited but not considered. Leonhardt was not of record.

No motivation should be needed to substitute known equivalents for the reasons discussed previously. However, a POSA would have been motivated to substitute a funnel valve and cage structure taught in Johnson in place of Leonhardt’s biological valve. Leonhardt provides an express teaching to substitute mechanical and synthetic valves for its biological valve (Ex.1017 col.6:31-34) and Johnson provides motive for Leonhardt to make this substitution.

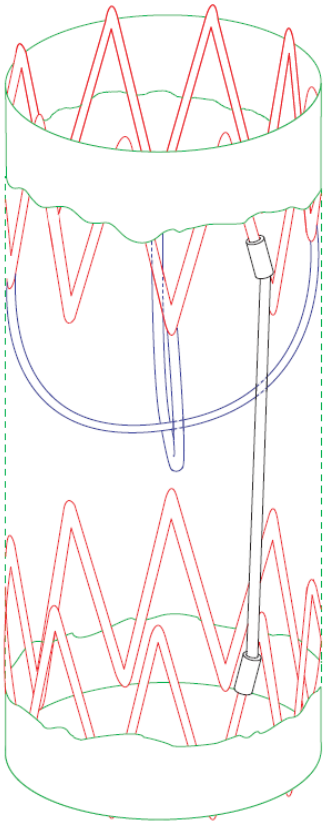
A POSA would know that the patients most in need of transcatheter procedures are the frailest and that subsequent procedures, beyond the initial valve implantation, should be avoided. (Ex.1003 ¶¶39, 117, 156-158.) So a POSA would be very interested in durable solutions. One seeking a durable transcatheter valve would realize that Johnson’s valve teaches that very thing. (Ex.1021 cols.2:39-42, 3:37-47.) A POSA would also recognize that Johnson’s valve could be made in a collapsible form out of “springy” material. (*Id.* 4:22-25; Ex.1003 ¶¶119, 124.)

In the combined structure, the Leonhardt tubular structure (stent and graft) 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 biological valve of Leonhardt, allowing downstream flow but

blocking upstream flow. And because one known FVE is merely substituted for another, there would be a reasonable expectation of success. (Ex.1003 ¶¶117-120, 156-159.)

This resulting structure is schematically depicted in FIG.H below, with portions of the Leonhardt graft 24 and the FVE removed for clarity of illustration:

FIG.H



The birdcage-like frame of Johnson acts as a "seat" to attach the apex of the funnel valve to a central portion of the frame, just as the apex of the funnel valve of the '782 Patent is attached to its central portion 36/junction 32. And so configured, the combination would be collapsible. (Ex.1003 ¶¶118-119.)

To block upstream flow of blood, the valve element 30 balloons outwardly so that its downstream edges 32, 34, and 36 seat against the surrounding annulus 41. (Ex.1021 col.5:37-53, FIGS.2, 4-5.) To allow downstream flow, portions of the valve element 30 between the struts (*e.g.*, the reversing cusps) collapse inwardly, toward the central axis of the cage and valve element, just as occurs in the '782 Patent. (*Id.*; Ex.1003 ¶120.)

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

As described in Ground 1, Leonhardt describes a percutaneously delivered self-expanding heart valve which can be disposed within the native aortic and mitral valve. (Ex.1017 cols.3:57-58, 4:14-15, 5:40-52, 9:63-65.)

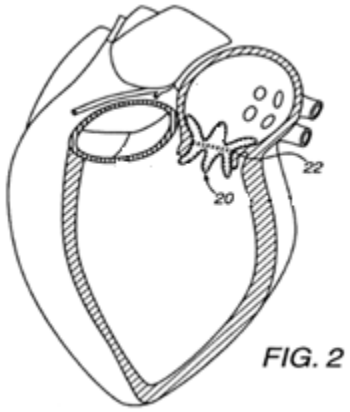
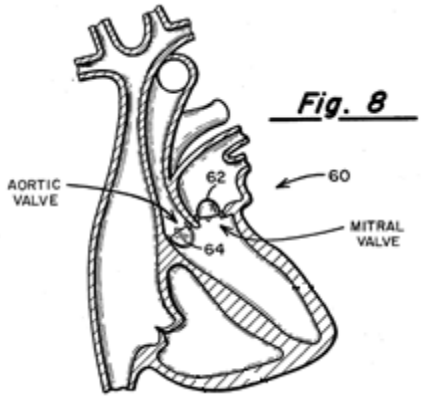


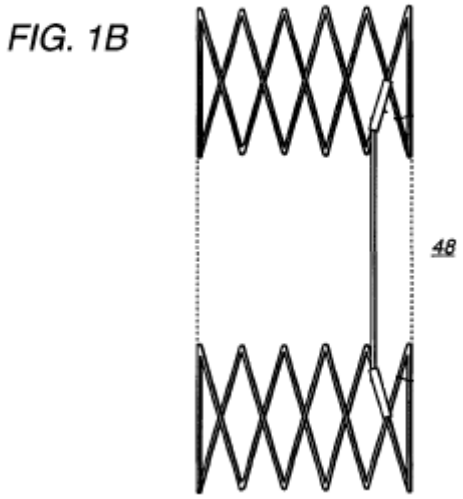
FIG. 2

The same is true for the valve of Johnson. (Exs.1021 cols.2:62-3:6, 6:14-19, FIG.8; 1003 ¶¶121-122; *see also* Claim Chart 1 Leonhardt and Johnson "Preamble.")



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

As explained in Ground 1, the cylindrical, self-expanding stent of Leonhardt biases the proximal and distal ends of the stent valve into fixed engagement with the tissue of the valve or annulus. (Exs.1017 cols.3:33-44, 4:53-5:33, 5:45-52, FIG.1B; 1003 ¶123.)



Leonhardt's stent is therefore a flexibly resilient frame as Defined. And, as discussed in Ground 1, Leonhardt's valve is also sized and shaped to be positioned between an upstream and downstream region as claimed. (*Id.* 5:45-52, 9:49-11:68, FIGS.2, 9A-9D.)

Johnson also describes a flexibly resilient frame as Patent Owner Defines it — a structure designed to shape or support and able to spring back to its original shape on its own after being compressed. (Ex.1021 cols.2:43-50, 4:10-48, 5:20-36, 6:2-7, FIGS.1, 2, 7.) The framework may be made of resilient or springy material such as titanium or polytetrafluoroethylene (PTFE) or Teflon® polymer and is acknowledged as flexible. (*Id.* 2:43-50, 4:22-25; Ex.1003 ¶124.)

In the alternative, Petitioner's construction of frame is "a conical geodesic birdcage-shaped wire structure." (Ex.1041 p.2 Term 3) This interpretation is based on statements made by the inventor (Ex.1011 App.B pp.B-5:12-18, B-6:2-5, B-7:7-16, B-9:17-19), which match exactly the only structure described and shown in the figures of both the provisional and nonprovisional applications. Johnson's framework is a flexibly resilient frame under that definition based on the passages of Johnson already cited. (Exs.1021 cols.4:10-48, 5:20-36, 6:2-7, FIGS.1, 2, 7; 1003 ¶125; *see also* Claim Chart 1 Leonhardt and Johnson "Frame-Flexibly Resilient.")

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

Claims 1, 10, and 28-29 require that the frame include a plurality of peripheral anchors and a central portion. As described in Ground 1, Leonhardt discloses "peripheral anchors" as Patent Owner Defines. Both the frame elements themselves and the fact that the stent can "flair at one or both ends as is shown in

FIG.2," meet this limitation as Defined. (Exs.1017 cols.6:9-22, 4:23-40, 4:53-5:52, FIGS.1B-1C; 1003 ¶¶126-128.)

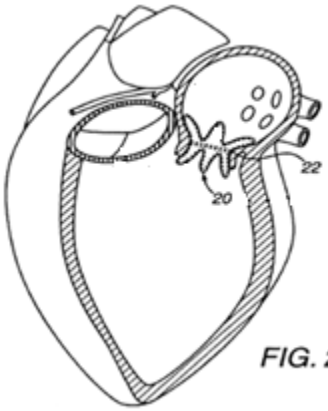


FIG. 2

Leonhardt's "flared" structure would even constitute peripheral anchors if Petitioner's construction of "distinct structures formed outside of the general shape of the frame and used to attach the frame to the native anatomy" were applied. (*See also* Claim Chart 1 Leonhardt "Peripheral Anchors.")

And, the entirety of the valve 22 is depicted in FIG.4 between the spaced apart cylindrical portions of Leonhardt's stent, and thus between the peripheral anchors — *i.e.,* in the "central portion" of Leonhardt (as Defined). (Ex.1003 ¶¶57, 59, 77, 80, 126; *see also* Claim Chart 1 Leonhardt "Central Portion.")

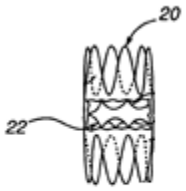


FIG. 4

On the other hand, if one adopts Petitioner's proposed construction of "central portion," namely an "apex of the frame located along the central axis of the valve" (Ex.1041 p.2 Term 7), that is found in Johnson. The apex of the funnel-shaped valve element or "membrane" 30 of Johnson is attached to the apex of the birdcage-like structure at the point of joinder 16 between the respective ends of the frame members. (Ex.1021 cols.2:47-51, 4:10-15, 4:49-68, FIGS.1, 2.) This is a "central portion" according to Petitioner's Definition. And this central portion is disposed between the peripheral anchors of Leonhardt, both longitudinally and radially, as it is mounted in the center of the Leonhardt stent. (*See* FIG.H, *supra*.) This common point of joinder 16 of Johnson is the same structure as shown as the central portion 36/junction 32 of the '782 Patent. (Exs.1001 col.7:1-10, FIGS.2, 3; 1003 ¶¶127-128; *see also* Claim Chart 1 Johnson "Central Portion.")

d. "U-Shaped" Anchor

Claims 18 and 29 require a plurality of "U-shaped" frame elements having opposite ends and being joined together generally midway between respective ends. Patent Owner's Definition of this term is "parts of the frame that are generally shaped like a 'U.'" Petitioner instead characterizes this term as "distinct components of the frame in the shape of the letter U." (Ex.1041 p.3 Terms 14, 15.) Leonhardt's frame includes a plurality of generally "U-shaped" members as

explained in Ground 1, at least under Patent Owner's Definition. (*See* Claim Chart 1 Frame-U-Shaped Elements.)

But Johnson's frame is composed of "U-shaped elements" joined midway between their ends under either construction. (Exs.1021 cols.4:10-15, 4:35-48, 5:20-36, FIGS.1, 2, 7; 1003 ¶¶130-131.)

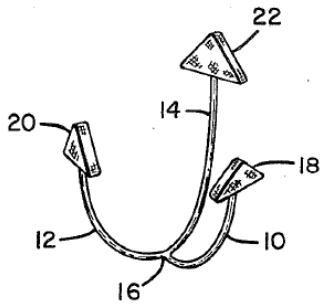


Fig. 1

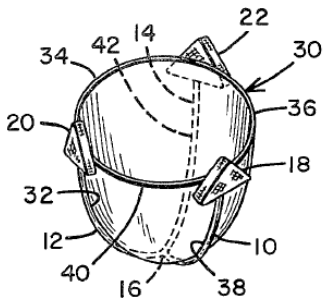
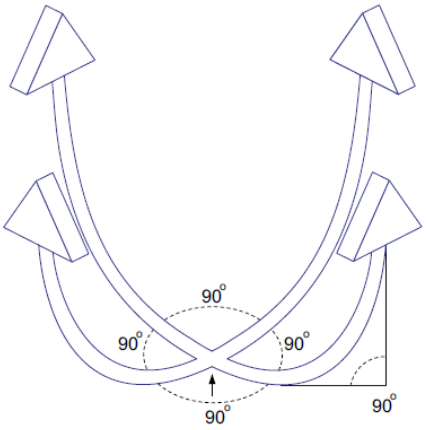


Fig. 2

During prosecution, the applicant incorrectly argued that Johnson did not teach "U-shaped" frame elements because there were only three struts. (*See* Part VI.B, *supra*.) However, Johnson teaches that it may include four struts "joined at the point of joinder 16 so that the struts radially extend at 90° from one another." (Ex.1021 col.5:23-28.) While not pictorially illustrated in the patent, the four-strut structure is depicted in FIG.I below:

FIG.I



The framework illustrated in FIG.I includes at least two "U"-shaped elements, each extending along a single plane and intersecting one another at a point of joinder. Thus, Johnson teaches U-shaped frame elements joined midway between their respective ends as claimed under both proposed constructions. (*See* Claim Chart 1 Leonhardt and Johnson "Frame-U-Shaped Elements"; Ex.1003 ¶¶48-49, 112-113, 131.)

Claims 28-29 require that the frame be collapsible to a maximum width less than about 18mm. Leonhardt teaches that its valve may be collapsed to sizes between 12 FR and 20 FR, which fall within this range. (Exs.1017 col.6:54-65; 1003 ¶¶65, 132; *see also* Claim Chart 1 Leonhardt "Collapsed Width.")

e. Bands

Claims 1, 18, and 28, require a "band" and claims 17 and 30 require a "first band," surrounding and/or attached to the frame. Patent Owner's Definition of a band is a structure in the shape of a circular strip or ring. Patent Owner's

Definition makes clear that a band is satisfied by either a ring of frame elements or a cuff or strip of material. (*See*, *e.g.*, Ex.1040 pp.7-8.) As explained in Ground 1, Leonhardt, having both rings of frame elements and graft 24, includes a band/first band under this Definition. (*See* Claim Chart 1 Leonhardt "Band/First Band.") (Ex.1003 ¶¶66-74, 133.)

Claim 10 requires that the band be an "internal strip." Johnson teaches a soft "reconstruction ring 50" for sealing engagement with the valve element to which the frame can be attached. (Ex.1021 col.5:54-6:14, FIGS.6, 7.) While this ring was sewn to the anatomy in Johnson, its goal was to provide a better surface for attachment — moot in this combination — and for coaptation with the free edges of the flap. A POSA would realize that this second goal is best satisfied by disposing the ring 50 inside of the stent of Leonhardt. (Ex.1003 ¶134.) Johnson meets the internal band limitation of claim 10. (*See* Claim Chart 1 Johnson "Band/First Band.")

Claims 1, 10, 18, and 28 further require that the band limit spacing between adjacent peripheral anchors. The graft material of Leonhardt restricts the expansion of the self-expanding frame, as confirmed by Leonhardt's instruction to "cut out" the graft material to allow further outward expansion to form "distensible fingers." (Exs.1017 col.6:9-13; 1003 ¶¶70, 136.) The uncut graft material limits spacing as claimed. (*See* Claim Chart 1 Leonhardt "Band/First Band.")

Petitioner's claim construction of "band" requires a "tissue or material that encircles the frame and binds the frame elements." (Ex.1041 pp.2-3 Term 10.) This would read on the rings of tissue/material taught by both Leonhardt and Johnson (graft material 24 and/or reconstruction ring 50). (Ex.1003 ¶135.)

Claims 17 and 30 also require a second band surrounding and attached to the frame. If a second band is a row of frame elements (*see, e.g.,* Ex.1040 p.39) as Patent Owner Defined and illustrated in its Contentions, this element is met by a ring of frame elements of Leonhardt downstream of the valve (Ex.1003 ¶71-74, 138; *see also* Claim Chart 1 Leonhardt "Second Band.").

Under Petitioner's alternative definition, a "band" is a material or tissue which encircles and binds the frame elements. (Ex.1041 pp.2-3 Term 10.) Leonhardt's extended graft material runs the full length of the external surface of the stent, meeting both requirements. A POSA would consider the downstream end of graft material 24 to be a second band, or to render one obvious, as this portion of the graft material is both external and would prevent distention. (Exs.1017 col.6:1-8 (graft material substantially preventing contact between stent 26 and living tissue); 1003 ¶¶72-73, 138.)

f. <u>Flexible Valve Element</u>

All of the challenged claims require a "flexible valve element" attached to the frame or to a central portion thereof. (*See* Claim Chart 1 "Flexible Valve

Element.") According to Patent Owner's Definition, this envisions any flexible valve, including a tricuspid valve. Indeed, it allegedly encompasses any flexible part of a valve. In contrast, according to Petitioner, a FVE is a unitary piece of tissue or material that collapses inwardly away from the frame to allow forward fluid flow between the frame and the unitary piece of tissue or material. (Ex.1041 p.3 Term 12.) This is based on the inventor's repeated statements that the FVE is, and indeed must be, a single unitary funnel matching the shape of the birdcage-like stent and attached inside thereof. The apex of the FVE must be attached to central portion of the stent. And the downstream edge of the flap is attached to the frame elements and/or band at discreet positions forming reversing flaps. (*See* Part VI.A, *supra*; Ex.1011 App.A pp.A-1:5-8, A-3:17-26, A-4:10-15, App.B pp.B-4:3-5, B-5:12-18, B-6:31 to B-7:3, B-7:20-27, B-8:13-30, B-9:17-24.)

The FVE of Leonhardt meets Patent Owner's Definition for the reasons discussed in Ground 1. (Ex.1003 ¶¶75-77, 139-140.) The FVE of Johnson meets both parties' definitions. It is funnel or bowl shaped, its apex is attached to the central portion (apex) of a correspondingly cage-shaped frame and the downstream edge is attached to the frame to produce flaps. (Ex.1021 cols.2:43-50, 4:49-68, 5:35-36, 6:2-8.) To block upstream flow of blood, the valve element balloons outwardly so that that its downstream edges seat against the surrounding annulus. (*Id.* 5:37-53, FIGS.2, 4, 5.) To allow downstream flow, portions of the valve

element 30 between the struts (*e.g.*, the reversing cusps) collapse inwardly, toward the central axis of the cage and valve element, just as occurs in the '782 Patent. (*Id.*) It is clearly a part of the valve and is flexible. (Ex.1003 ¶140.)

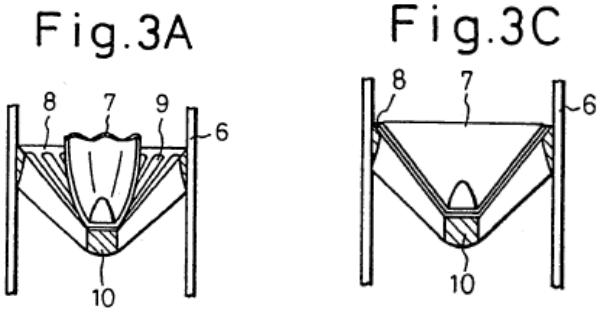
As for attachment, a POSA would know that the apex of the FVE must be attached to a central apex of the frame. This is a simple engineering exercise which has been practiced in many different analogous situations. (*Id.* ¶143.) But Johnson conveniently provides a structure that already can be used to provide that attachment — its framework. As shown in FIG.H, the Johnson framework could be formed as a part of Leonhardt's frame or Johnson's framework could be secured to the tubular stent of Leonhardt by sewing pads 18, 20, 22 or by other means known to a POSA. (*Id.* ¶¶144-145.) The FVE is then attached as described in Johnson as noted above. The result is that the FVE of Johnson is attached to a central portion under either Patent Owner's or Petitioner's definitions. And, as the graft material of Leonhardt can run the length of the stent, the attachment of the Johnson valve would necessarily be adjacent a band. (Exs.1017 col.5:31-52; 1021 col.4:57-68; *see also* Claim Chart 1 Leonhardt and Johnson "Flexible Valve Element.")

Claims 1, 28, and 30 also require attaching the FVE to the central portion and adjacent a band, which are discussed immediately above, and claims 1 and 28 further require that the attachment be substantially free of connections to the frame except at the central portion and adjacent the band. (*See* Claim Chart 1 Leonhardt

and Johnson "Attached to a Central Portion/Substantially Connected to Central Portion.")

As to the added requirement of claims 1 and 28 that attachment be substantially only at the central portion and adjacent the band, the requirement is obvious over the attached of Johnson's valve substantially only within the central interior of Leonhardt's stent as shown in FIG.H. (Ex.1003 ¶¶77, 80, 145.)

Alternatively, Imachi teaches a funnel valve for use with blood in an artificial heart. (Ex.1020 col.3:49-4:30.) This valve includes a supporting structure or "seat" 8, which is secured inside a tubular structure 6, and a funnel-shaped valve element or "membrane" 7 is secured to the seat at its apex. (*Id.* FIGS.2A-3C.) Thus, the seat is attached within a tube to retain the apex of a flexible valve just as the framework of Johnson.



Johnson attaches the downstream edge of the funnel valve to spaced apart locations to form flaps with "free edges" extending between these locations. (Ex.1021 col.4:61-68.) Additionally, Johnson attaches the funnel valve to the frame at locations intermediate the upstream and downstream ends. (*Id.*) However,

a POSA would appreciate from Imachi that the funnel valve would also operate without intermediate attachment taught by Johnson. (Ex.1003 ¶¶146-149.) Stated another way, the art as a whole teaches a limited menu of attachments for FVEs, from (a) apex-only; (b) to apex, intermediate and downstream edge; and (c) apex and downstream edge. Selection of any one of these is the routine work of a POSA and any degree of attached is a matter of routine design choice. (*Id.* ¶ 149.)

Further, Johnson's express teaching is that it is the "edges 32, 34, 36" of the leaflets at the downstream end of the flap that contact the surrounding structure or "tissue annulus" and form the seal when reverse flow occurs. (Ex.1021 col.5:42-45). A POSA therefore would understand that the attachment of the downstream edge to the frame would keep the edges in position and facilitate sealing. By contrast, Johnson attributes no function to the attachment of intermediate portions of the funnel valve to the frame. And while the applicant noted the degree of attachment of the flap in distinguishing these claims over Johnson during prosecution (*see* Part VI.B, *supra*), it placed no significance on that distinction. A POSA would understand fully that the intermediate attachments could be omitted with no loss of function. (Ex.1003 ¶150.) The claims are obvious from this combination. (*See* Claim Chart 1 "Attached to a Central Portion/Substantially Connected to Central Portion.")

The independent claims and, in particular, claims 1, 28, and 30, require a FVE having upstream and downstream sides facing the upstream and downstream regions, respectively. This limitation is met by the valve of Leonhardt/Johnson mounted in the aortic or mitral position. (Exs.1017 cols.5:40-52, 6:13-19, 6:23-34, 9:63-10:21, 10:22-42, FIGS.2, 3, 8, 9D; 1021 cols.5:37-53, 6:14-19, FIGS.4, 5, 8; 1003 ¶141; *see also* Claim Chart 1 Leonhardt and Johnson "Upstream/Downstream Sides.")

Claims 10, 17, 18, and 29 further characterize the "upstream" and "downstream" sides of the FVE as a "convex" upstream side facing the upstream region and a "concave" downstream side opposite the upstream side facing the downstream region. (*See also* Claim Chart 1 Leonhardt and Johnson "Convex Upstream/Concave Downstream Sides.") These limitations as Defined are met by Leonhardt as described in Ground 1 and by Johnson as well. (Exs.1021 cols.2:54-61, 4:49-68, 5:37-45, FIGS.2, 7, 8; 1003 ¶¶79, 151.)

g. Valve Movement Limitations

The independent claims include a lengthy recitation which describes the general operation of virtually any one-way (or check) valve, including the native heart valve and replacement valves, all of which were known *per se*. (Ex.1003 ¶¶81-83, 152-153.) These features were known to POSAs at the time as discussed in Ground 1.

These limitations are obvious in view of Leonhardt for the reasons described in Ground 1. Moreover, as explained in Johnson, the flexible valve membrane is attached to the flexible framework in such a manner that the membrane segments freely open inwardly to allow unimpeded forward blood flow through the valve. When the cardiac cycle reverses, leaflets bellow outwardly and effect closure against the tissue annulus. (Ex.1021 col.3:26-47, 5:37-53, FIGS.4, 5; *see also* Claim Chart 1 Leonhardt and Johnson "Valve Movement Language.") This meets the claimed language as well.

h. <u>Delivery Device Limitations</u>

Claims 28 and 29 additionally require a delivery device or "instrument" comprising a holder having a hollow interior for holding the valve, an elongated manipulator attached to the holder for manipulating the holder and an ejector mounted within the holder for ejecting the valve from the holder. Leonhardt describes just such an instrument as previously discussed in Ground 1. (Exs.1017 col.6:34-8:42, FIGS.5-7A, 9A-9C; 1003 ¶84; Claim Chart 1 Leonhardt "Holder," "Manipulator," "Ejector.")

Claim Chart 1 provides citations that supplement those in the above text. It contains citations to Leonhardt, Johnson, and Imachi reflected in Ground 3.

i. Motivation And Reasonable Expectation Of Success

As suggested previously, no motivation should be required to substitute equivalent known elements in this way from among the known technology. And, Leonhardt provided motivation for the combination by teaching that mechanical valves and the like could be used in place of the biological valve exemplified. (Exs.1017 col.6:31-34; 1003 ¶155.)

Additional motivation to consider the Johnson valve is provided by Johnson itself. Indeed, Johnson discloses that tissue valves, such as those preferred in Leonhardt, have had durability problems resulting from, *inter alia*, the fact that the leaflets are attached to a rigid or semirigid fixation ring around the perimeter. "By using a central attachment without an outer fixation ring, the dynamic annulus valve effects closure by leaflet coaptation with the natural or reconstructed tissue annulus. This closing method as well as the flexibility of the structural frame should avoid localized stress points on the leaflets and result in extreme durability." (Exs.1021 cols. 3:37-47, 2:39-42; 1003 ¶156.)

A POSA would be motivated to try the construction of the Johnson valve to replace a native tissue valve of Leonhardt in hopes of obtaining a more durable valve. This is particularly important here since transcatheter valves were designed for elderly and weak patients who could not survive open chest surgery. (Ex.1003

¶158.) Durability, which reduces the potential need for further procedures in such patients, is of particular import.

A POSA would also have a reasonable expectation of success from this combination. All of the elements are disclosed in issued U.S. patents, which are presumed enabling. And all use the same basic elements (stent, band, valve), arranged in generally the same way, used for the same purpose. Given the similarity of structure and function, a POSA would reasonably expect that this combination would work. (*Id.* ¶158.)

j. Dependent Claims

Dependent claims 2, 4-5, 11-12, and 21-22 require the frame to be collapsible to a configuration having a specified maximum width. In claims 2, 11, and 21 the width is less than 18mm. This limitation was previously discussed in connection with claims 28 and 29 and is met for the reasons previously discussed. (Ex.1017 col.6:54-65 (12 and 20 FR ("French") are less than 18mm).) Dependent claims 4, 12, and 22 are similar, but limit the maximum width when collapsed to less than 6mm. In claim 5, the maximum width is between about 4mm and about 6mm. 12 FR taught by Leonhardt is 4mm, which falls within the claimed ranges of claims 4, 5, 12, and 22. (Exs.1017 col.6:54-57; 1003 ¶¶65, 132, 159.)

Claim 6 specifies that the FVE, which is attached to the central portion of the frame, be attached substantially centered between the plurality of peripheral

anchors. This is clearly illustrated in the rendition of the combination of Leonhardt and Johnson of FIG.H, *supra*. The valve would sit exactly where the valve of Leonhardt would sit, which is between the two rings of its frame. (Ex.1017 cols.5:40-52, 6:23-34, FIG.4; FIG.H; 1003 ¶¶80, 142-150, 160.)

Claim 7 specifies that the FVE is attached to the frame at a plurality of points around the frame, thereby forming flaps extending between adjacent attachment points and each at least partially defining a valve opening during fluid flow. The funnel valve of Johnson is attached to the U-shaped frame so as to form flaps or reversing cusps between attachment points just as claimed. (Exs.1021 cols.2:54-61, 3:26-35, 4:57-68, 5:37-53, FIGS.2, 4, 5, 7; 1003 ¶¶87, 161.)

Claims 8 and 13 require that the stent comprise a plurality of "U-shaped" elements joined together at a junction of the elements. This element was already discussed in connection with independent claims 18 and 29 and these dependent claims are disclosed for the same reasons. (Ex.1003 ¶¶60-64, 129-131, 162.)

Claim 19 requires that each end of each frame element includes an anchor. As discussed above in connection with peripheral anchors (*see* Part IX.A.1.g, *supra*), Leonhardt meets this limitation as Defined (Ex.1003 ¶¶56, 58, 90, 163).

Claims 25 and 26 require that the distance between the opposite ends of frame elements be between 3-5cm or 2-3cm, respectively. This is consistent with the teaching of the specification. (Ex.1001 col.5:51-63.) A POSA would know that

the generally recognized aortic annulus sizes of most human adults range from about 19mm to about 27mm. (Ex.1003 ¶164.) Leonhardt describes the diameter of its device as "pre-sized" to be "approximately thirty percent (30%) larger in diameter than the largest diameter of the tissue against which the valve stent 20 (FIG.3) will seal." (Ex.1017 col.4:66-5:5.) Adding 30% to the standard aortic annulus sizes reflected in the Contentions results in a diameter range of 2.47-3.51cm, the first end point falling within the range of claim 26 and the second within the range of claim 25. (Ex.1003 ¶¶90, 164.)

Finally, claim 27, which depends from claim 18, identifies the band claimed therein as being a first band, and further requires a second band. Leonhardt describes using a first and a second band as Defined as discussed previously in connection with independent claims 17 and 30, which also require both bands, and is obvious for the same reasons. (Ex.1003 ¶¶66-69, 91, 165.)

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 '782 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 '782 Patent for purposes of suing industry participants nor settlement of a similar lawsuit brought against Medtronic Corporation, *Snyders Heart Valve LLC v. Medtronic, Inc.*, No. 16-cv-00813 (E.D. Tex. Oct. 25, 2016), constitute such evidence. The terms of the settlement are not publicly available and the settlement could as easily have resulted from the more important business priorities of Medtronic as from a recognition of this technology.

Even if secondary evidence exists, however, it is not relevant to the question of anticipation, is not commensurate, and cannot overbalance the strong showing of *prima facie* obviousness reflected in Grounds 2 and 3 of this petition.

XI. CONCLUSION

For the foregoing reasons, Petitioner requests that *inter partes* review be instituted for claims 1, 2, 4-8, 10-13, 17-19, 21, 22, and 25-30 of the '782 Patent and that those claims be held unpatentable over each of the grounds discussed hereof.

Dated: October 23, 2017 By: s/Michael H. Teschner/
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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 13,521. 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, 2, 4-8, 10-13, 17-19, 21, 22, AND 25-30 OF U.S. PATENT NO. 6,540,782**, together with all exhibits, the Power of Attorney, and all other papers issued therewith was served on October 23, 2017, as follows.

VIA FEDEX

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