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. IPR2018-00106

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) ("Child Application")
1017	U.S. Patent No. 5,957,949 (issued Sept. 28, 1999) ("Leonhardt")
1018	Final Rejection, U.S. Serial No. 10/135,746, Feb. 11, 2004
1019	Supplemental Amendment, U.S. Serial No. 10/135,746, July 9, 2004
1020	U.S. Patent No. 5,413,599 (issued May 9, 1995) ("Imachi)
1021	U.S. Patent No. 4,339,831 (issued July 20, 1982) ("Johnson")
1022	U.S. Patent No. 5,397,351 (issued Mar. 14, 1995) ("Pavcnik")
1023	U.S. Patent No. 3,657,744 (issued Apr. 25, 1972) ("Ersek")
1024	U.S. Patent No. 6,458,153 (issued Oct. 1, 2002) ("Bailey")
1025	Jerald L. Cohen *et al.*, *Two-dimensional echocardiographic preoperative prediction of prosthetic aortic valve size*, 107(1) Am. Heart J. (Jan. 1984), at 108-112

Exhibit #	Reference
1026	John A. Ormiston *et al., Size and Motion of the Mitral Valve Annulus in Man:I.A Two-dimensional Echocardiographic Method and Findings in Normal Subjects,* 64(1) Circulation (July 1981), at 113-120
1027	Thomas Sandgren *et al., The diameter of the common femoral artery in healthy human: Influence of sex, age, and body size,* 29 J. Vasc. Surg. (Mar. 1999), at 503-510
1028	John O. Burris *et al., Pathophysiological Considerations In Aortic Valve Disease,* 147(18) Annals New York Academy Scis. (Oct. 30, 1969), at 716-724
1029	Lieutenant Richard Gorlin (MC) USNR & Robert B. Case, M.D., *Clinical Diagnosis of Aortic-Valve Disease,* 255(8) New England J. Med. (Aug. 23, 1956), at 368-373
1030	Blase A. Carabello, *Mitral Valve Disease,* 18 Curr Probl Cardiol (July 1993), at 425-478
1031	Kenneth V. Iserson MD, FACEP, *J.-F.-B. Charrière: The Man Behind The "French" Gauge,* 5 J. Emerg. Med. (1987), at 545-548
1032	Kenneth V. Iserson MD, FACEP, *The Origins Of The Gauge System For Medical Equipment,* 5 J. Emerg. Med. (1987), at 45-48
1033	Robert V. Snyders, M.D.
1034	Marc Bessler, M.D.
1035	Prof. Alain Cribier, M.D.
1036	Howard J. Leonhardt, Honorary Ph.D.
1037	Kou Imachi, Ph.D.
1038	Spyridon D. Moulopoulos, Ph.D., M.D.
1039	Disclosure of Asserted Claims and Infringement Contentions ("Contentions"), *Snyders Heart Valve LLC v. St. Jude Med. S.C., Inc. et al.*, Civil Action No. 4:16-cv-00812 (E.D. Tex. Sherman Div. May 1, 2017)
1040	Disclosure of Asserted Claims and Infringement Contentions ("Contentions") Exhibit 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 (the "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 Oct. 25, 2016 in the Eastern District of Texas, Sherman Division (Civil Action No. 4:16-cv-00812), alleging infringement of the challenged claims of the '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-002. Two others are being filed 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. § 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 Bessler.

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

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

Ground 4. Claims 1, 2, 4-8, 10-13, 17-19, 21, 22, and 25-30 are obvious over Bessler 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

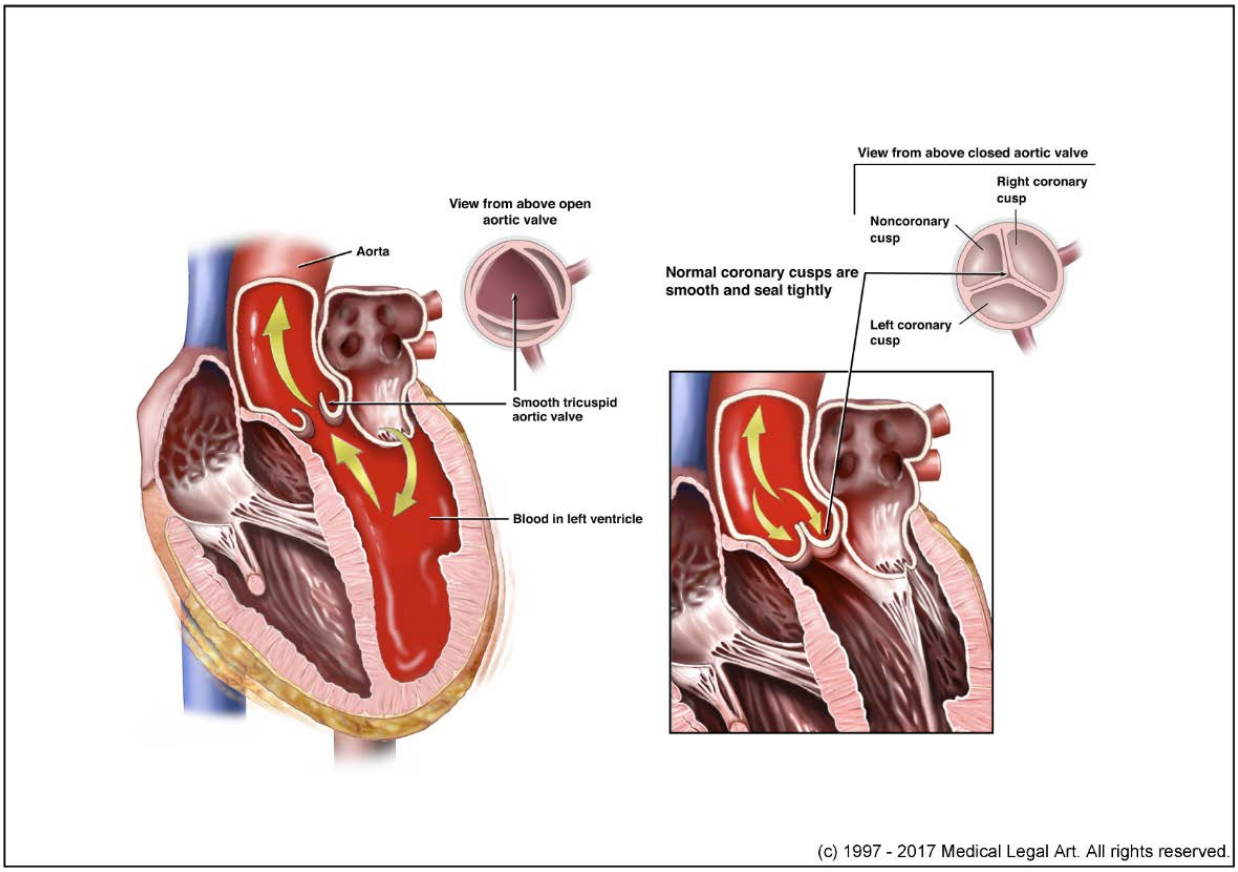
Some artificial heart valves can be collapsed, inserted into the heart, and expanded in the annulus of a defective native valve to take over that valve's function. These collapsible valves are implanted much like cardiac stents, through the patient's vasculature, avoiding invasive open chest surgery. 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 ¶25.) 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 disadvantages of open surgical intervention by the time this patent was filed. (Exs.1001 col.1:62-2:19; 1003 ¶25.)

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

FIG.A



(Ex.1044, with redactions.)

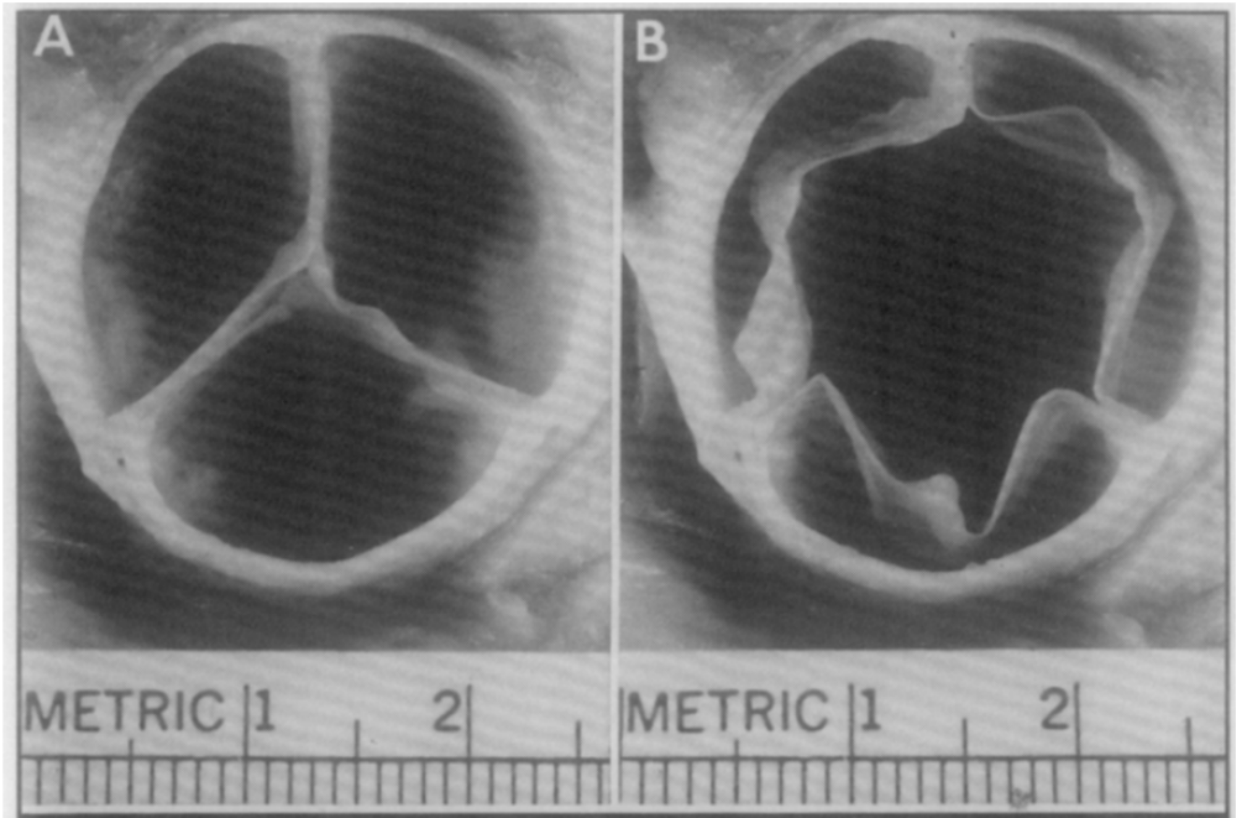
The aortic valve shown in FIG.A is referred to as a "tricuspid" valve because the valve element comprises three separate leaflets or "cusps," which cooperate to control blood flow. Other valves, like the mitral valve, have two leaflets. In FIG.A, when the left ventricle contracts, the resulting pressure 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 ¶23.) 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.* ¶24.)

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.* ¶¶27-29.) Indeed, two of the valves cited in the '782 Patent's Background and one reference cited during prosecution include porcine valves which have the native architecture. (*Id.*) They all include a flexible valve element ("FVE") and a band mounted to a generally tubular shaped stent.

FIG.B

Native valve



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

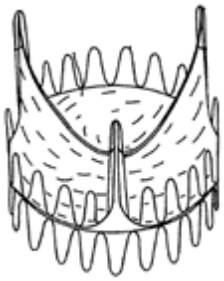


FIG. 2

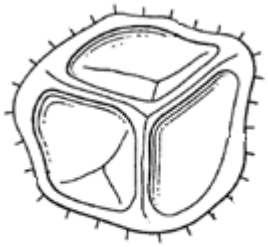


FIG. 12

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 ¶30.) Still others suggested a single flap or inverted funnel shaped valve element. (*Id.* ¶¶31-34.)

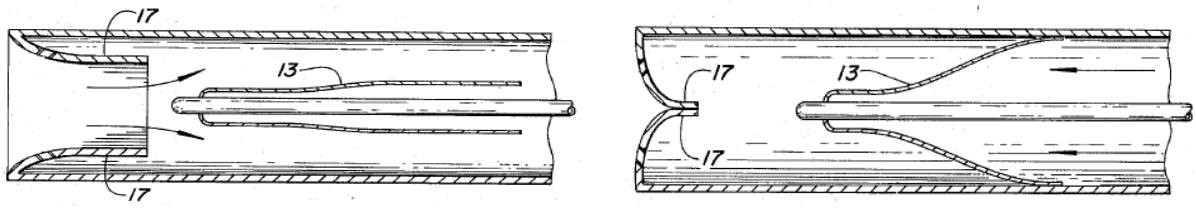


FIG 2A FIG 2B

(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.)

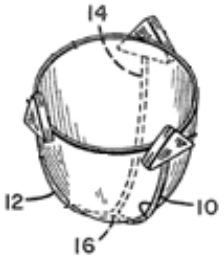


Fig. 2

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, 9:2-15, 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 thereof, looking down into the valve, from the aorta, showing blood flow up out of the page around the unitary flap.

FIG.C

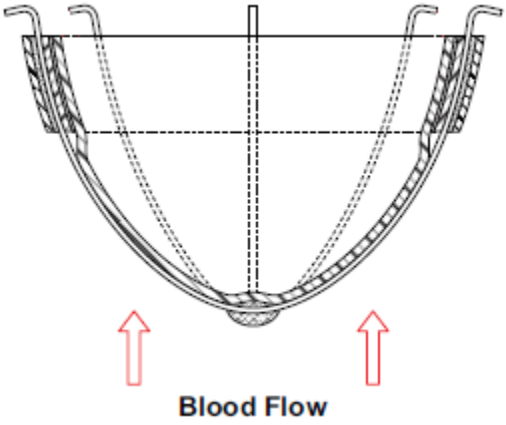
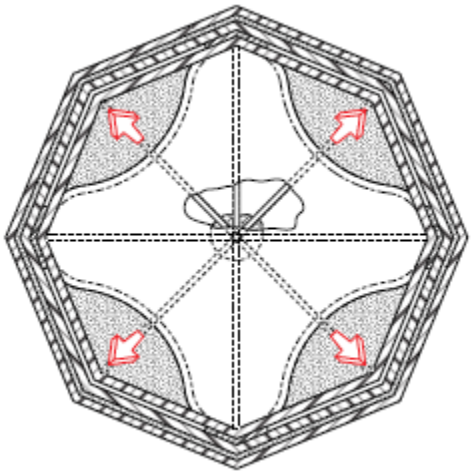


FIG.D



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 ¶¶43-47.)

The inventor discussed Bessler (Ex.1008) extensively in the appendices of the provisional application and also in the nonprovisional application. He 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.)

Moreover, Bessler is criticized as not describing the specific construction of the valve and requiring a surgical procedure to remove the native valve leaflets.

(Ex.1001 col.2:14-19.) The first criticism is addressed in Ground 1. As to the second, the challenged claims are device claims so such criticism is inapposite. Moreover, a POSA knew that a collapsible valve could be implanted without removal of the leaflets. (Exs.1007 col.9:45-53; 1003 ¶44.)

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.* p.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, and 14) along their entire lengths. (*Id.* p.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 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. (*See* Ex.1003 ¶¶48-54.)

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)(ed)"), 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	Ex.1041 p.2 Term 9: Any location between a plurality of peripheral anchors**

[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.

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 pp.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
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 construction 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 Grounds 3 and 4, the claims are also obvious 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 Bessler

Based on the claims construed in light of Patent Owner's Definitions (Exs.1040, 1041), the challenged claims are anticipated by Bessler (Ex.1008). 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. Bessler issued on January 5, 1999. It is therefore prior art pursuant to 35 U.S.C. § 102(b). Bessler was of record but was not applied by the Examiner. (*See* Part VI.B, *supra*.) As further illustrated in Claim Chart 1, Bessler anticipates the challenged claims because, under Patent Owner's Definitions, it teaches each element of the challenged claims arranged as in the claims. *In re Gleave*, 560 F.3d 1331, 1334 (Fed. Cir. 2009).

a. A Valve For Repairing A Damaged Heart Valve

Bessler describes a valve for replacement of a diseased or defective heart valve comprised of a frame, a band, and a FVE to be disposed in a native valve annulus between upstream and downstream regions, all as Defined. (Exs.1008 cols.2:25-28, 2:57-62, 3:46-4:21, 7:26-67, FIGS.1-7, 14, 15; 1003 ¶56.)

b. Flexibly Resilient Frame

As Defined by Patent Owner, the claimed flexibly resilient frame is met by any structure able to spring back to its original shape after being compressed and designed to shape or support, presumably the FVE. (Ex.1041 p.2 Term 3; p.4, Term 23.) Bessler teaches a self-expanding stent, which biases the valve into engagement with the surrounding tissue. (Ex.1008 cols.2:60-62, 3:51-55, 4:63-5:14, 5:19-21, 5:31-35, 5:43-6:18, 7:26-67, FIGS.1-7, 14-15.) It can be made of nitinol. (*Id.* 6:5.) And, as shown in these same passages, and in particular, cols.2:25-28, 2:57-62, 4:53-5:3, and 7:26-67, the valve, including its frame and FVE, is sized and shaped for insertion or placement between upstream and downstream regions. It is therefore a flexibly resilient frame as Defined. (Ex.1003 ¶57; *see also* Claim Chart 1 Bessler "Frame-Flexibly Resilient.")

c. Frame's Peripheral Anchors/Central Portion

Claims 1, 10, and 28-29 require that the frame include a plurality of peripheral anchors, which Patent Owner Defines as merely a peripheral structure that secures or stabilizes something in place. (Ex.1041 p.2 Term 5.)

Claims 1, 28, and 30 also require a "central portion," which Patent Owner's Contentions identify as merely a region located between peripheral anchors. (*Id.* Term 9; *see also, e.g.*, Ex.1040 pp.5-6.)

A number of Bessler's structures can be considered peripheral anchors as Defined.

FIG.4

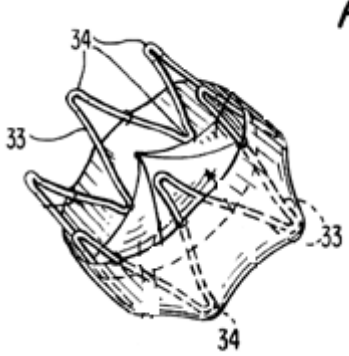
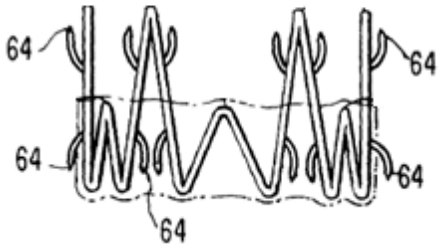


FIG.7



The barbs that Bessler locates upstream and downstream to maintain implantation are peripheral anchors as Defined. (Exs.1008 cols.4:12-21, 5:67-6:2, 7:26-67, FIG.7; 1003 ¶¶60-61.) Moreover, as illustrated in FIG.4, the frame can have a zig-zag or sine wave structure of straight 33 and bend sections 34. These bends 34 can also be peripheral anchors as Defined. (Exs.1008 cols.5:19-21,

5:28-35, 5:51-60, 6:7-11, FIGS.1-4; 1003 ¶¶60-61; *see* Claim Chart 1 "Peripheral Anchors.")

The central portion as Defined would be the straight sections 33, 53 between the bends 34, 54 (Ex.1008 cols.5:28-35, 5:55-60, FIGS.1, 4, 6) or the portions of the stent disposed between the first and second circles of barbs (*id.* 4:12-21, 5:60-6:2, 7:43-67, FIGS.6-7, 14, 15; Ex.1003 ¶¶59-62; *see* Claim Chart 1 Bessler under "Central Portion").

d. "U-Shaped" Elements

Claims 18 and 29 require a plurality of "U-shaped" frame elements having opposite ends and being joined together generally midway between respective ends. These elements are sized and shaped to fit in a native annulus. As Defined, any strut or group of struts having a "general" "U" shape qualifies. (Ex.1041 p.3 Term 15.)

Bends 34, 54 are joined to each other by the straight sections 33, 53 midway between the ends of successive "U"s and these are "U-shaped" members as Defined. (Exs.1008 cols.5:28-35, 5:51-60, FIGS.1-7; 1003 ¶64.)

FIGS.E and F show U-shaped elements of Bessler (shown in red or yellow designated with an "A") and junctions midway between respective ends (shown in green and blue and designated with a "B").

FIG.E

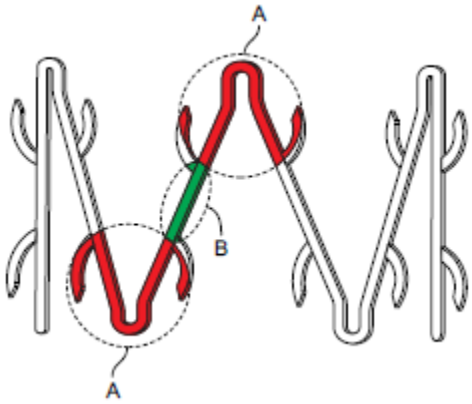
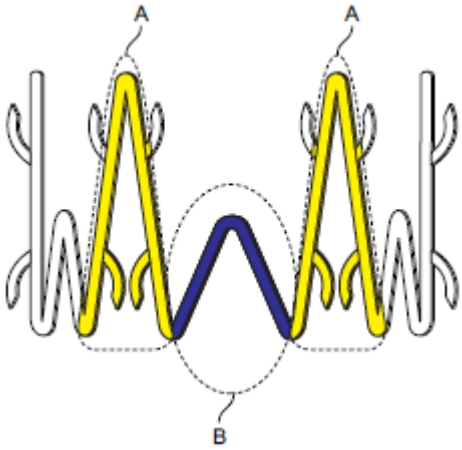


FIG.F



The Bessler device is sized and shaped to be placed in a native annulus as noted earlier. (*See* Claim Chart 1 Bessler "Frame-U-Shaped Elements"; Ex.1003 ¶64.)

e. Collapsible Stent

Claims 28-29 require that the frame be collapsible to a maximum width less than about 18mm. Bessler discloses that the diameter of the noncollapsed stent member ranges from 1.5cm (15mm) to 3.5cm (35mm). And Bessler teaches that the stent must be collapsed further to be inserted. (Ex.1008 cols.3:51-55, 4:53-66, 6:14-18, 7:21-67.) Since the expanded configuration of the stent can be 15mm,

which is already less than 18mm, its compressed state must necessarily fall within the range claimed. (Ex.1003 ¶65.)

f. Bands

Claims 1, 10, 18, and 28, require a "band" and claims 17 and 30 require a "first band," surrounding and/or attached to the frame. Patent Owner Defines band as a structure generally in the shape of a circular strip or ring, which can be a portion of the frame. (Ex.1041 pp.2-3 Term 10.)

Bessler has bands/first bands as Defined, for example the upstream, inflow portion of the stent. (Ex.1008 cols.4:12-21, 5:15-27, 5:51-6:2, FIGS.1-5, 7.) The "band" as Defined can also be the cuff. (*Id.* 3:54-64, 4:4-11, 5:24-27, FIGS.1-5, 7.) While depicted as surrounding the frame (*id.*), Bessler contemplates a cuff disposed in the interior of the stent as well, an arrangement as claimed in claim 10 (*id.* 4:6-9 ("In some of the preferred embodiments . . . the cuff portion of the valve means extends on only one side of the circular portion of the stent member."); Ex.1003 ¶¶66-67).

Alternatively, the valve of Bessler can be porcine. (Ex.1008 col.6:19-24.) To a POSA, a surgically harvested porcine valve would necessarily require root tissue from the original annulus. This tissue is a ring and qualifies as a band attached to the interior surface of the stent as Defined. (Ex.1003 ¶¶68-69.) This is also a

band/first band as Defined. (*See* Bessler in Claim Chart 1 under "Band/First Band.")

Claims 1, 10, 18, and 28 further require that the band limit spacing between adjacent peripheral anchors. (*See* Claim Chart 1 "Band/First Band.") The cuff of Bessler is shown as being tight against the self-expanding stent. (Ex.1008 col.5:15-27, 40-43, FIGS.1, 4.) This cuff would restrict the expansion of the self-expanding frame. (Ex.1003 ¶70.)

Claims 17 and 30 require a second band surrounding and attached to the frame. The Contentions illustrate this as a circumferential row of frame elements disposed downstream of the first band. (Ex.1040 pp.39, 92.) Bessler describes a downstream portion, which is uncovered by the cuff, which is a second band as Defined. (Ex.1008 FIGS.1-5; *see* Claim Chart 1 Bessler "Second Band"; Ex.1003 ¶71.)

g. Flexible Valve Element

All of the challenged claims require a "flexible valve element" attached to the frame or to a central portion thereof. Patent Owner Defines this as encompassing any flexible part of a valve. (Ex.1041 p.3 Term 12.) According to Bessler "[t]he valve member is flexible, compressible, host-compatible, and non-thrombogenic." (Ex.1008 col.6:19-20 (emphasis added).) It can be porcine or synthetic. (*Id.* 6:20-31.) Bessler also teaches that the valve is mounted to the

central portion of the frame — "central portion" having been discussed in connection with the flexibly resilient frame above. Indeed, as illustrated in FIG.7, FVE 63 can be disposed centrally and attached to "crowns" or the tops of "smaller waves" 61. (*Id.* 5:60-6:2, FIG.7.) Thus Bessler teaches a FVE attached to the frame and in particular to a central portion thereof as Defined. (*See* Claim Chart 1 Bessler "Flexible Valve Element"; Ex.1003 ¶¶72, 75.)

Claims 1, 28, and 30, require a valve element having upstream and downstream sides facing the upstream and downstream regions. Bessler notes that its valve device has upstream and downstream sides corresponding to inflow and outflow ends. (Ex.1008 col.4:12-21 (barbs facing upstream and downstream directions on the inflow and outflow sides of the valve).) And its valve is a replacement valve to be disposed in a native annulus. (Exs.1008 cols.3:55-4:3, 4:63-5:14, 5:20-27, 5:43-51, 7:26-67, FIGS.1, 4; 1003 ¶73.) Thus, the FVE has sides facing upstream and downstream. (*See* Claim Chart 1 Bessler "Upstream/Downstream Sides.") Indeed, this is necessarily met by any prosthetic heart valve.

Claims 10, 17, 18, and 29 further characterize these upstream and downstream sides as a "convex" and "concave" respectively. As Defined, these are elements that bulge in a recited direction. (Ex.1041 p.4 Terms 26, 27.) According to Patent Owner's Contentions, a native tricuspid heart valve meets this Definition.

As Dr. Dasi explains, the valve identified in these Contentions mimics the overall construction of both native human and porcine valves. (Ex.1003 ¶74.) Therefore, to the extent that the FVE in the Contentions has convex upstream and concave downstream sides, the valve of Bessler does as well. (Exs.1008 col.6:19-24; 1003 ¶74.) Moreover, Bessler describes its valve as "arcuate" illustrating it forming a generally concave downstream side. (Exs.1008 cols.3:54-64, 5:20-27, 5:36-42, FIG.4; 1003 ¶74.) This necessarily means that Bessler's valve has a complementary convex upstream side. (*See* Claim Chart 1 "Convex Upstream/Concave Downstream Sides.")

Finally, claims 1, 28, and 30 require the FVE be attached to the central portion and adjacent the 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. Bessler describes its FVE as being disposed within the cylindrical stent member with the arcuate portion transverse of and at some acute angle relative to the stent walls. (Ex.1008 col.3:54-64.) The cuff extends from the periphery and is attached to the stent. (Exs.1008 col.5:36-42, FIG.4.) This discloses the claimed limitation as Defined. Moreover, Bessler describes that the FVE can be secured to the crowns of the "small waves" of the stent which, as shown in FIG. 7, are substantially centered longitudinally. (Ex.1008 col.5:60-6:2, FIG.7.) So the FVE is mounted in the central portion adjacent the band and is

substantially free of other connections. (*See* Claim Chart 1 Bessler "Attached to a Central Portion/Substantially Connected to Central Portion"; Ex.1003 ¶¶72, 75.)

h. Valve Movement Limitations

The independent claims each include lengthy recitations merely describing the general operation of native and replacement valves, which were known *per se*. Indeed, if nothing else, the articles and patents cited in the Background of the '782 Patent dating back more than 50 years convey this information. (Exs.1001 col.1:42-2:19; 1003 ¶76.)

Patent Owner contends that these recitations, all beginning with "said valve element moving" (the "valve movement language") are met by the operation of the tri-leaflet valve identified in the Contentions. (*See, e.g.,* Ex.1040 pp.11-12.) Bessler's FVE functions the same way as the tricuspid valve cited in Patentee's Contentions. Bessler therefore meets these recitations as Defined. (Exs.1008 cols.3:65-4:3, 4:63-5:14, 5:36-43, 6:19-24, FIG.4; 1003 ¶77; *see* Claim Chart 1 Bessler "Valve Movement Language.")

Claim 10 additionally specifies that the convex side of the FVE engages an internal 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.) "That which would literally infringe if later in time anticipates if earlier . . . ." *See Lewmar,* 827 F.2d at 747.

Thus Patent Owner admits that this element is met by the operation of a native valve and the valve of Bessler. (Ex.1003 ¶78.)

i. Delivery Device Limitations

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. (Ex.1001 cols.14:47-56, 15:34-16:2.) Bessler describes just such an instrument. Bessler's hollow distal end of its flexible catheter which can be inserted into a vessel is the "holder." (Ex.1008 cols.4:53-58 ("The distal end of the catheter, which is hollow and carries the artificial heart valve . . . in its collapsed configuration"), 7:26-67, FIGS.12-15.) The proximal end of the catheter, element 91 in FIGS. 12-15, is the manipulator which is used to position the distal holder. (*Id.* 4:63-5:1, 7:26-67, FIGS.12-15.) Finally, Bessler describes a pusher member 93 disposed within the catheter to push the valve from the holder. (*Id.* cols.4:60-66, 5:3-14, 7:26-67, FIGS.12-15; Ex.1003 ¶79.) 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 the claim number from which each entry

originated and the breakdown provided in the Contentions. (Ex.1040.) Claim Chart 1 identifies where the claimed elements as Defined by Patent Owner can be found in Ground 1 (indicated as "Bessler"). Citations to "Andersen" in combination with Bessler are used for Ground 2 and "Johnson" and "Imachi" are used in combination with Bessler in Grounds 3 and 4.

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** Bessler: Exs.1008 cols.2:25-28, 2:57-67, 3:46-4:21, 7:26-67, FIGS.1-7; 1003 ¶56. Andersen: Exs.1006 cols.2:21-26, 3:1-15; 1003 ¶89. Johnson: Exs.1021 cols.2:62-3:19, 6:8-19, FIGS.7, 8; 1003 ¶113. **Additional "instrument" recitations for cls.28 and 29** Bessler: Exs.1008 cols.4:53-5:14, 7:26-67, FIGS.11-15; 1003 ¶79. Andersen: Exs.1006 cols.2:34-68, 3:1-42, 5:40-6:44, FIGS.3-7; 1003 ¶98.

Claim Language	Citation
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 flexibly resilient frame sized and shaped for insertion between the upstream region and the downstream region, 30(a). *see* 1(a)	**Cls.1, 10, 17, 28, 30** Bessler: Exs.1008 cols.2:60-63, 3:51-55, 4:63-5:14, 5:19-21, 5:31-35, 5:43-6:18, 7:26-67, FIGS.1-7, 14, 15; 1003 ¶57. Andersen: Exs.1006 cols.2:39-41, 2:46-51, 2:59-63, 3:15-17, 6:66-7:12, 7:17-23, FIGS.1, 2; 1003 ¶90. Johnson: Exs.1021 cols.2:43-50, 4:10-48, 5:20-36, 6:2-7, FIGS.1, 2, 7; 1003 ¶¶114-115.
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** Bessler: Exs.1008 cols.2:60-63, 3:51-55, 4:63-5:14, 5:19-21, 5:28-35, 5:43-6:21, , 7:25-67, FIGS.1-7, 14, 15; 1003 ¶¶64-65. Andersen: Exs.1006 col.5:9-28, FIGS.1, 2; 1003 ¶90. Johnson: Exs.1021 cols.4:10-15, 4:35-48, 5:20-36,, FIGS.1, 2, 7; 1003 ¶¶120-121.
Peripheral Anchors 1(b). the frame having a plurality of	**Cls.1, 10, 28, 29** Bessler: Exs.1008

Claim Language	Citation
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 29(b). thereby forming a frame having a plurality of peripheral anchors for anchoring the frame between the upstream region and the downstream region,	cols.4:12-21, 5:19-21, 5:28-35, 5:51-60, 5:67-6:2, 6:7-11, 7:25-67, FIGS.1-7, 14, 15; 1003 ¶¶60-61. Andersen: Exs.1006 cols.5:33-35, 6:54-63, FIGS.1, 2, 8, 9; 1003 ¶90.
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** Bessler: Exs.1008 cols.4:12-21, 5:28-35, 5:51-6:2, 7:43-67, FIGS.6-7, 14, 15; 1003 ¶¶59, 62. Andersen: Exs.1006 cols.5:33-35, 6:54-63, FIGS.1, 2; 1003 ¶90. Johnson: Exs.1021 cols.4:10-15, 4:35-48, 4:61-63, FIG.1; 1003 ¶¶118-119, 132-134.
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;	**Cls.1, 10, 17, 18, 28, 29, 30** Bessler: Exs.1008 cols.3:54-64, 4:4-21, 5:15-27, 5:40-43, 5:51-6:2, 6:19-24, FIGS.1-5, 7; 1003 ¶¶68-70. Andersen: Exs.1006 cols.5:9-35, 6:54-62, FIG.1; 1003 ¶91.

Claim Language	Citation
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 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;	Johnson: Exs.1021 cols.5:54-6:14, FIGS.6, 7; 1003 ¶¶123-126. **Additional "limiting spacing" citations for cls. 1, 18, 28** Bessler: Exs.1008 col.5:15-27, 5:40-43, FIGS.1, 4; 1003 ¶70.
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** Bessler: Exs.1008 col.4:-9, FIGS.1-5; 1003 ¶71. Andersen: Exs.1006 cols.5:9-35, 6:54-62, FIG.1; 1003 ¶92. Johnson: Exs.1021 cols.5:54-6:14, FIGS.6, 7; 1003 ¶¶127-128.
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	**Cls.1, 10, 17, 18, 28, 29, 30** Bessler: Exs.1008 cols.3:54-4:3, 5:20-51, 5:60-6:2, 6:19-31, FIGS.1-4, 7; 1003 ¶¶72-75. Andersen: Exs.1006 cols.2:34-36, 5:11-17, 5:31-35, 7:12-16, FIGS.1, 2; 1003 ¶¶91-93.

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 ¶¶129-134. Imachi: Exs.1020 cols.3:49-4:30, FIGS.2A-3C; 1003 ¶136. *See also* "Attached To A Central Portion," *infra*
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 an	**Cls.1, 28, 30** Bessler: Exs.1008 cols.3:54-4:3, 4:63-5:14, 5:20-27, 5:36-38, 5:43-51, 7:26-67, FIGS.1, 4; 1003 ¶73. Andersen: Exs.1006 cols.5:9-34, FIG.1; 1003 ¶91. Johnson: Exs.1021 col.6:14-19, FIG.8; 1003 ¶131.

Claim Language	Citation
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 upstream region when the frame is anchored between the upstream region and	**Cls.10, 17, 18, 29** Bessler: Exs.1008 cols.3:54-64, 5:20-27, 5:36-42, 6:19-24, FIG.4; 1003 ¶74. Andersen: Exs.1006 cols.5:9-34, FIG.1; 1003 ¶99. Johnson: Exs.1021 cols.2:45-61, 4:49-68, 5:37-45, FIGS.2, 7, 8; 1003 ¶139.

Claim Language	Citation
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** Bessler: Exs.1008 cols.3:54-4:3, 5:20-28, 5:34-42, 5:60-6:2, 6:19-31, FIGS.1-4, 7; 1003 ¶75. Andersen: Exs.1006 cols.5:11-17, 5:29-34, FIGS.1, 2; 1003 ¶92. Johnson: Exs.1021 cols.4:49-68, 5:35-53, 6:2-8, FIGS.2, 7; 1003 ¶¶118-119, 132-138. Imachi: Exs.1020 cols.3:49-4:30, FIGS.2A-3C; 1003 ¶136. *See also* "Central Portion," *supra.*
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** Bessler: Exs.1008 cols.3:51-55, 4:53-66, 6:14-18, 7:21-67, FIG.5; 1003 ¶65. Andersen: Ex.1006 col.6:26-28.
Valve Movement Language 1(h). said valve element moving in response to a difference between fluid pressure in said upstream region and fluid	**Cls.1, 17, 18, 28, 29, 30** Bessler: Exs.1008 cols.3:65-4:3, 4:63-5:14, 5:36-43, 6:19-24, FIG.4; 1003

Claim Language	Citation
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) 30(e). valve movement limitations — *see* claim 1(h)	¶¶76-77. Andersen: Exs.1006 cols.3:13-21, 3:37-42, 6:45-65. Johnson: Exs.1021 cols.3:26-47, 5:37-53, FIGS.4, 5; 1003 ¶¶140-141.
Valve Movement Language 10(f). said valve element moving in response to a difference between fluid pressure in said upstream region and fluid	**Cl.10** Bessler: *See* 1(h) above. (Ex.1003 ¶78.)

Claim Language	Citation
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 so 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.	Andersen: Exs.1006 cols.3:13-21, 3:37-42, 6:45-65; 1003 ¶99. Johnson: *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, 29** Bessler: Exs.1008 cols.4:53-58, 7:26-67, FIGS.12-15; 1003 ¶79. Andersen: Exs.1006 cols.2:46-50, 5:40-45, 7:30-55 (protective cap), FIG.3; 1003 ¶98.

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* 29(k)	**Cls.28, 29** Bessler: Exs.1008 cols.4:63-5:1, 7:26-67, FIGS.12-15 (element 91) — the proximal portion of the catheter; 1003 ¶79. Andersen: Exs.1006 cols.5:40-56, 7:44-48, FIG.3 (proximal end of balloon catheter); 1003 ¶98.
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* 29(l)	**Cls.28, 29** Bessler: Exs.1008 cols.4:60-66, 5:3-14, 7:26-67, FIGS.12-15; 1003 ¶79. Andersen: Exs.1006 cols.5:40-45, 7:44-48 (balloon means pushed out), FIG.3; 1003 ¶98.

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. 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. Bessler does not expressly identify size for the collapsed valve. However, Bessler teaches that the valve is collapsed and delivered to the implantation site

percutaneously. (Ex.1008 cols.2:65-67, 4:53-60, 7:26-67.) Bessler also specifically describes standard techniques that include access through the femoral artery. (*Id.* 8:7-15, 8:48-50.) A POSA would know as of February 1, 2000, that a device suitable for such a procedure would generally require a compressed diameter of about 6mm or less. (Ex.1003 ¶¶65, 80-81.) The ranges claimed are obvious in view of this teaching.

Claim 6 specifies that the FVE is attached to the frame substantially centered between the plurality of peripheral anchors. (*See* Claim Chart 1 Bessler "Attached to a Central Portion/Substantially Connection to Central Portion.") This element has already been discussed in connection with claims 1, 28, and 30, and, as Defined, is clearly illustrated in Bessler in connection with, *inter alia*, FIG.4, valve member 35, and FIG.7, valve member 63 attached to frame member 61. (Ex.1008 col.5:28-43, 5:60-6:2, FIGS.4, 7; 1003 ¶¶72, 82.)

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 at least partially defining a valve opening. Patent Owner Contends that this limitation is met by the commissures of a traditional tricuspid valve. (Exs.1040 p.17; 1008 col.6:18-24; 1003 ¶83.) Bessler's valve, when attached to its stent, meets this limitation to the same extent as the valve that is subject to the Patent Owner's Contentions. (Ex.1003 ¶83.)

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.1008 col.5:51-60, FIGS.1-7; 1003 ¶¶63-64, 84; *see also* Claim Chart 1 Bessler "Frame U-Shaped Elements.")

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 pp.4-5, 52.) As Defined, this recitation is met by the upstream and downstream facing barbs of Bessler. (Exs.1008 cols.4:12-20, 5:6-6:2, 7:26-67, FIGS.6, 7, 14, 15; 1003 ¶85.)

Claims 25 and 26 require that the distance between the opposite ends of frame elements be between 3-5cm or 2-3cm respectively. The Contentions suggest that this limitation means the diameter of the stent when expanded. (Ex.1040 pp.55-56.) The specification suggests the same thing. (Ex.1001 col.5:55-63.) Bessler describes the diameter of its device as ranging from about 1.5cm to 3.5cm, preferably 1.75cm to 3.0cm. 3cm anticipates both claims as Defined. (Exs.1008 col.6:14-16; 1003 ¶86.)

Claim 27 depends from claim 18, and identifies the band as being a first band, and further requires a second band. Bessler describes using both bands as discussed previously in connection with independent claims 17 and 30, which also

require both bands, and is anticipated for the same reasons. (*See* Claim Chart 1 "Band/First Band," "Second Band"; Ex.1003 ¶¶66-71, 87.)

B. Obviousness

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

The challenged claims are invalid as obvious over Bessler (Ex.1008) in view of Andersen (Ex.1006). Andersen issued in 1995 and qualifies as prior art pursuant to 35 U.S.C. § 102(b). It was of record and is identified in the Background, but not applied. As noted in Ground 1 and Claim Chart 1, Bessler contains all of the elements cited in the challenged claims based on the Patent Owner's Definitions. (Ex.1003 ¶¶35-42.)

To the extent one were to argue that Bessler's elements were not exactly shown in the same manner claimed, the differences would be obvious to a POSA in view of Andersen. 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) (citing *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).

In this case, given this art's use of the same types of components, organized and operating in the same way, and in view of the scope of these claims as Defined, swapping one stent, one band, or one FVE for another, is the application of routine engineering, characteristic of obviousness; nothing more. (Ex.1003 ¶¶35-42, 93-96.) It would also be obvious to try various combinations of these known elements as 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.

Like the Bessler valve, Andersen's valve comprises a stent and a valve and band mounted within, which can be placed transluminally into a heart annulus defining 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 ¶89.)

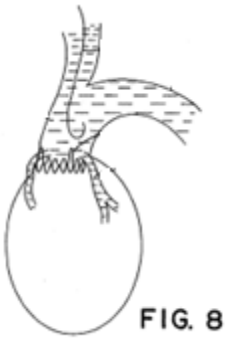
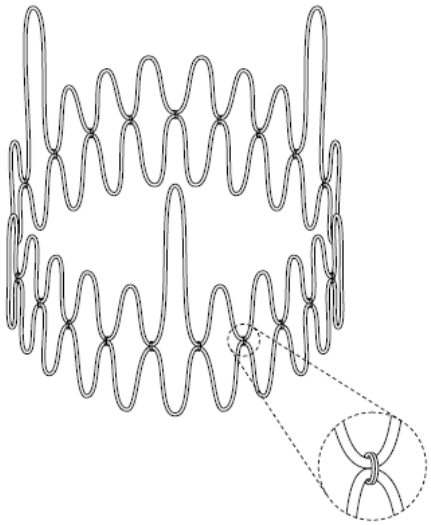


FIG. 8

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.) It can include two or more rings (7, 8) composed of "U-shaped" members as shown in FIGS.1 and 2, which are placed on top of each other and they are mutually secured together at junctions midway between their respective ends by means of a number of sutures (not shown in the patent, but illustrated in FIG.G). (Ex.1006 col.5:9-28, FIGS.1, 2; Ex.1003 ¶90.)

FIG.G



The upstream and downstream extremities of these rings are peripheral anchors as Defined for the reasons discussed for Bessler in Ground 1. 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, 6:54-64, FIGS.1, 2, 8, 9; Ex.1003 ¶90.)

Andersen uses a biological valve as the FVE, which is obtained from a slaughtered pig (Ex.1006 col.5:29-39) and is attached to the stent with sutures to form a prosthetic valve (*id.* cols.2:34-37, 5:11-17, 5:31-35, 7:12-16). The root

tissue of the biological valve is a band that is attached within the stent. (Ex.1003 ¶91.)

It would have been obvious to interchange elements of Andersen for those of Bessler 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 FVE, which can be a porcine valve. That said, motivation does exist. (Ex.1003 ¶¶93-96.)

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 of "U-shaped" elements so that it extends farther into the vasculature which also can help prevent migration. (Ex.1006 cols.5:11-14, 6:54-63.) The flexibility this offers in terms of a stent design and reducing the risk of migration is motive to use Andersen's stent. (Ex.1003 ¶95.) So a POSA would have reason to consider using the Andersen stent, or aspects of it, in place of the Bessler stent.

Both of their FVEs can be porcine valves. And both have bands, whether Defined as a cuff, circumferential rows of frame elements or the root tissue of the porcine valve. (Ex.1003 ¶96.) Indeed, to the extent that the cuff of Bessler did not explicitly disclose limiting spacing of anchors (cls.1, 10, 18, 28), there are limited options of forming Bessler's cuff. Bessler's cuff extends along the outer periphery

of the circular portion of the stent, and is attached thereto. (Ex.1008 col.5:24-42, FIG.4.) The only options for such a cuff would be a greater, lesser or equal circumference compared to the stent. The use of a cuff having a circumference smaller than the circumference of a stent would necessarily limit spacing. (Ex.1003 ¶70.) Thus, including a band limiting spacing would at least be obvious to try. *See KSR* 550 U.S. at 421 ("When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp.").

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. (Ex.1003 ¶96.)

For the reasons stated above, Bessler in combination with Andersen teaches all of the limitations of the independent claims.

Bessler's disclosure of a delivery device of claims 28 and 29 (*see* Part IX.A.1.i, *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; Ex.1003 ¶¶79, 98.).

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 ¶99.) However, Patent Owner's Contention (Ex.1040 pp.28-30) is, at least, an admission that this element is obvious over the traditional tricuspid valve described in both Bessler and Andersen. Thus, claim 10 is obvious. (*See also* the entries for both Claim Chart 1 Bessler and Andersen.)

The dependent claims are obvious for the reasons discussed in Ground 1. Claims 8 and 13 are obvious based on Bessler, but also because of the "U-shaped" elements of Andersen as noted above. Claims 6 and 7 are obvious over Bessler, but also based on Andersen. (Exs.1006 col.5:9-39, FIG.2; 1003 ¶100.)

Claims 2, 4-5, 11-12, and 21-22 are obvious in view of Bessler. Andersen also teaches 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 6:23-30, 2:44-55; 3:1-7; 1003 ¶101.)

Claim 19 is obvious as both Bessler and Andersen disclose peripheral anchors (as Defined) and claims 25 and 26 are obvious in view of Bessler as discussed in Ground 1 and Andersen's disclosure of a diameter of 3cm. (Exs.1006

col.6:29-31; 1003 ¶102.) Finally, claim 27 is obvious as both references teach first and second bands, at least to the same extent as Defined. (*Id*.)

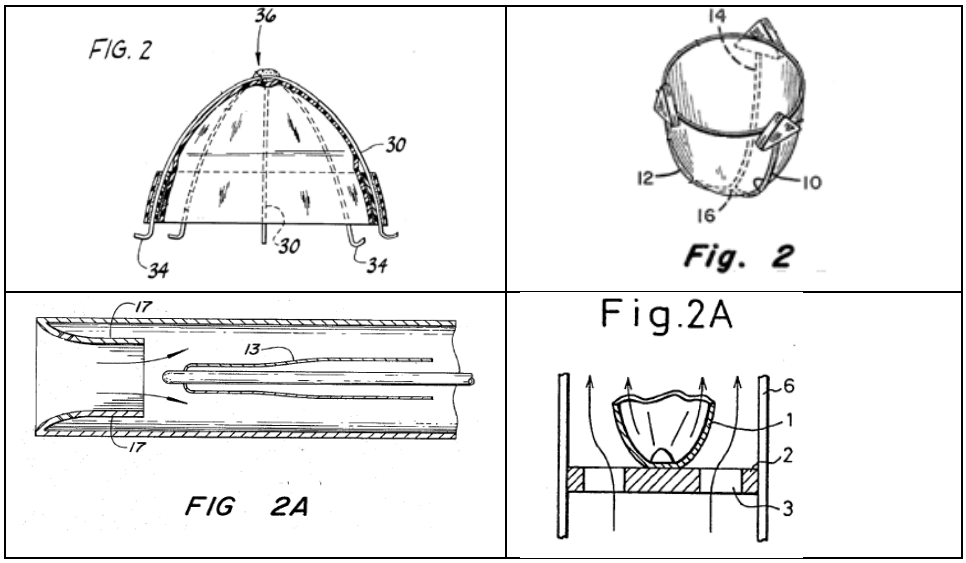
2. Ground 3: Claims 1, 2, 4-8, 10-13, 17-19, 21, 22, And 25-30 Are Obvious Over Johnson In View Of Bessler And Imachi

Johnson (Ex.1021) and Imachi (Ex.1020) issued in 1982 and 1995 respectively and both qualify as prior art pursuant to 35 U.S.C. § 102(b). Both were of record and Johnson was applied as a primary reference. (*See* Part VI.B, *supra*.) Neither was combined with Bessler.

As noted in the ’782 Patent’s Background, the use of surgically implanted artificial heart valves dates back decades. But by the time the ’782 Patent was filed, there was already a movement toward transcatheter heart valves to avoid invasive open chest surgery. (Part V, *supra*; Ex.1003 ¶¶25, 105.) The existence of the problem of invasive surgery supplied the motivation for the solution of transcatheter replacement valves. *KSR*, 550 U.S. at 420. Indeed, at least three patented transcatheter valves were already cited by the inventor. (Ex.1001 col.2:6-19.)

None of those patents, however, employed a funnel shaped valve even though such valves were known. (*See* FIG.J.)

FIG.J



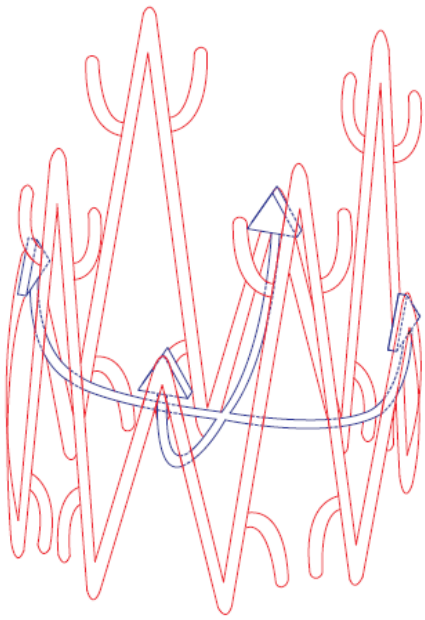
(Exs.1001 FIG.2 (prior art — 1021 FIG.2; 1010 FIG.2A; 1020 FIG.2A).)

A POSA would know that the patients most in need of transcatheter procedures are the frailest. Not only is open chest surgery to be avoided, but even subsequent transcatheter procedures should be avoided where possible. (Ex.1003 ¶107.) Johnson's valve is collapsible and durable, which makes it a likely candidate. (Exs.1021 cols.2:39-42, 3:37-47, 4:22-25; 1003 ¶107.)

However, Johnson only disclosed sutures for fixation, which means surgical intervention. But, by the relevant time, using stents for fixation of a transcatheter-deliverable replacement valve was readily known. Indeed, this was the advance of Andersen, Stevens, Letac, Leonhardt, and the like. (Exs.1006; 1007; 1009; 1013; 1017; 1024; 1003 ¶108.) One particularly useful stent that would be apparent to a POSA for this purpose is that of Bessler. Bessler recognizes that

securely holding a valve in place in a heart annulus can be accomplished with a self-expanding stent including upstream and downstream facing barbs. A representation of the combination is shown below in FIG.H.

FIG.H



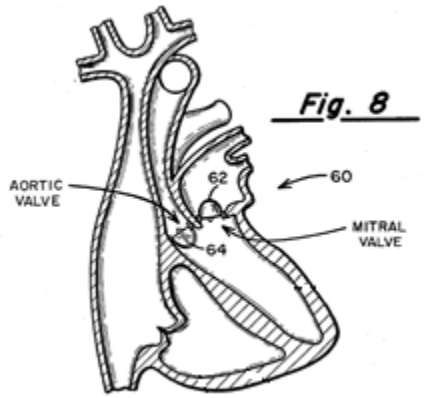
Bessler's "optimal" valve, like the valve of Johnson, was made from a synthetic material. Indeed, both identify polytetrafluoroethylene (PTFE) as a material useful for making their respective valves. (Exs.1008 col.6:23-31; 1021 col.4:49-57.) And Johnson suggests durability improvements over tricuspid valves such as those preferred in Bessler. (Exs.1008 col.2:11-12; 1021 cols.2:39-42, 3:37-47.) Thus there is reason to mount a durable synthetic funnel valve of Johnson within the stent of Bessler to produce a durable, collapsible, transcatheter replacement heart valve. (Ex.1003 ¶¶108-112.)

In the combined structure, the Bessler tubular structure (stent and cuff) performs its known function of holding the entire structure within the anatomy, whereas the Johnson valve performs its known function and, indeed the same function as the valve of Bessler. A POSA would know that to use a funnel valve, the apex of the FVE must be attached to somewhere near the central axis of the frame. This is a simple engineering exercise which has been practiced in many different analogous situations. (*Id.* ¶111.) An accommodating structure could be added to, or integrally formed as part of, the Bessler stent. That said, a POSA here would recognize that Johnson provides a structure that already can be used to provide that attachment — its framework. The framework of Johnson acts as a seat or central portion to allow attachment of the FVE's apex. (*Id.* ¶112.)

a. A Valve For Repairing A Damaged Heart Valve

In this Ground, and Ground 4, Patent Owner's Definitions are applied. However, as discussed herein, these grounds are equally applicable under Petitioner's proposed construction in the aforementioned district court action. (Ex.1041.) As discussed in Ground 1, Bessler describes replacement valves comprised of a frame, a band, and a FVE, to be disposed in a native valve annulus between upstream and downstream regions, all as Defined. (Ex.1008 cols.2:25-28, 2:55-60, 3:46-64, 7:26-67, 8:46-49.) Johnson similarly teaches a replacement valve including a frame, a band, and a FVE, for placement in a native valve annulus as

claimed. Johnson clearly shows disposing the valve in the mitral or aortic heart annulus. (Exs.1021 cols.2:62-3:19, 6:14-19, FIG.8; 1003 ¶113.)



b. Flexibly Resilient Frame

Five of the challenged independent claims require a flexibly resilient frame. Johnson teaches a flexibly resilient frame as Patent Owner Defines it — a structure designed to shape or support and able to spring back to its original shape on its own after being compressed. (Exs.1021 cols.4:10-48, 5:20-36, 6:2-7, FIGS.1, 2, 7; 1041 p.2 Term 3.) Indeed, Johnson's framework may be made of resilient or "springy" material such as titanium, PTFE, or Teflon® polymer and is acknowledged as flexible. (Ex.1021 cols.2:43-50, 4:22-25.) And, as shown in, *inter alia*, FIG.8, the valve, including the frame and FVE, is sized and shaped for insertion or placement between upstream and downstream regions. (Ex.1003 ¶114.) Bessler's stent also meets Patent Owner's Definition as discussed in Ground 1. (Exs.1008 cols.2:60-62, 3:51-55, 4:63-5:14, 5:19-21, 5:31-36, 5:43-6:18, 7:26-67, FIGS.1-7, 13-14; 1003 ¶57.)

It is Petitioner's position that the flexibly resilient frame of the '782 Patent is "a conical geodesic birdcage-shaped wire structure" which was identified by the inventor as part of the "fundamental design" of his stented funnel valve. (Exs.1041 p.2 Term 3; 1011 App.B, p.B-5:12-18, B-6:2-5, B-7:7-16, B-9:17-19.) Johnson's structure meets this definition as it is a flexible, conical, birdcage structure. (Ex.1021 cols.4:10-48, 5:20-36, 6:2-7, FIGS.1, 7; *see also* Claim Chart 1 Bessler and Johnson "Frame-Flexibly Resilient"; Ex.1003 ¶115.)

c. Frame's Peripheral Anchors/Central Portion

Claims 1, 10, and 28-29 require that the frame include a plurality of peripheral anchors. Claims 1, 28, and 30 also require a "central portion."

Bessler's stent includes peripheral anchors under either party's definition. (*See* Ex.1041 p.2 Term 5.) As discussed in Ground 1, either the barbs that Bessler locates upstream and downstream, or the curved sections of Bessler's frame, are peripheral anchors as Defined. (*See* Claim Chart 1 Bessler "Peripheral Anchors"; Ex.1003 ¶ 117.)

As discussed in Ground 1, Patent Owner's Definition of the "central portion" is essentially anywhere between peripheral anchors. (Exs.1040 pp.5-6, 64-65, 93; 1041 p.2 Term 9.) According to Petitioner, the central portion is an apex of the frame. (Ex.1041 p.2 Term 9.) Johnson's teaching meets both. The "central portion" of Johnson is the junction or point of joinder 16 of its framework.

(Ex.1021 cols.4:10-15, 4:35-48, FIG.1.) The apex of the valve is mounted to this framework's apex. (*Id.* 4:61-63.) And the stent of Johnson could be mounted or formed centrally between the first and second circles of barbs in Bessler, both radially and longitudinally — located in a central portion as Patent Owner Defines. (Ex.1008 cols.4:12-21, 5:60-6:2, 7:43-67, FIGS.6, 7, 14, 15; *see* FIG.H, *supra*.) Thus, both references teach a central portion as Defined by Patent Owner. Johnson meets Petitioner's definition as well. (*See also* Claim Chart 1 Bessler and Johnson "Central Portion"; Ex.1003 ¶¶118-119.)

d. "U-Shaped" Frame Elements

Claims 18 and 29 require a plurality of "U-shaped" frame elements having opposite ends and being joined together generally midway between respective ends that fit in a native annulus. Johnson's frame is composed of "U-shaped elements" joined midway between their ends under both Patent Owner's Definition and Petitioner's. (Exs.1021 cols.4:10-15, 4:35-48, 5:20-36, FIGS.1, 2, 7; 1041 p.3 Terms 14, 15.)

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*.)

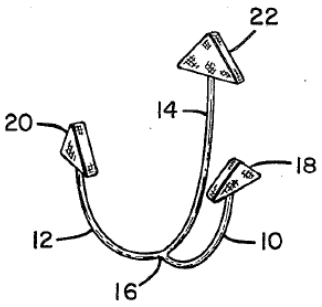


Fig. 1

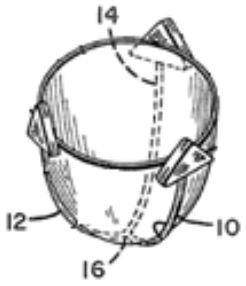
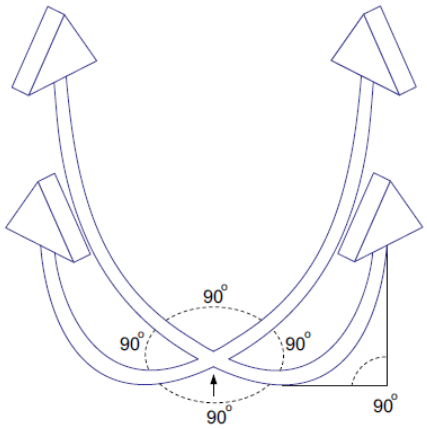


Fig. 2

However, Johnson actually teaches that its framework may include four struts wherein "the struts would be 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 framework is illustrated 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. Accordingly, Johnson teaches U-shaped elements joined midway between their respective ends under both proposed constructions. (*See also* Claim Chart 1

Bessler and Johnson "Frame-U-Shaped Elements"; Ex.1003 ¶¶50-51, 63-64, 120-121.)

e. Collapsible Frame

Claims 28-29 require that the frame be collapsible to a maximum width less than about 18mm. As discussed in Ground 1, Bessler discloses that the diameter of the non-collapsed stent member ranges from 15mm to 35mm and that the stent must be collapsed to be inserted. Bessler's compressed state therefore falls within the range claimed. (Ex.1003 ¶122; *see also* Claim Chart 1 Bessler "Collapsed Width.")

f. 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. Claim 10 requires an internal strip. Both Patent Owner and Petitioner acknowledge that "band" can be satisfied by a ring of tissue or material. (Ex.1041 pp.2-3 Term 10.) However, according to Patent Owner, a ring of frame elements can also be a band. (*Id.*)

As noted in Ground 1, Bessler has bands/first bands. Bessler discloses a cuff 25. (Ex.1008 cols.3:54-64, 4:4-11, 5:24-27, FIGS.1-5, 7.) While depicted as surrounding the frame and attached to it (*id.*), Bessler contemplates a cuff disposed in the interior of the stent as well, an arrangement as claimed in claim 10. (*Id.* 4:6-9; Ex.1003 ¶¶66-70.) Johnson teaches a band attached to the frame as well.

Specifically, Johnson teaches a soft "reconstruction ring" for sealing engagement with the valve element to which the frame can be attached. (Ex.1021 col.5:54-6:14, FIGS.6, 7.) This suggests adding Johnson's band externally of Johnson's frame, but within the frame of Bessler, an "internal strip" or band for coaptation with the free edges of the flap. (Ex.1003 ¶¶123-125; *see also* Claim Chart 1 Bessler and Johnson "Band/First Band.")

Claims 1, 10, 18, and 28 further require that the band limit spacing between adjacent peripheral anchors. The cuff of Bessler is shown as being tight against the self-expanding stent. (Ex.1008 col.5:15-27, 5:40-42, FIGS.1, 4.) A POSA would expect the cuff to restrict the expansion of the self-expanding frame. (Ex.1003 ¶¶70, 126; *see also* Claim Chart 1 Bessler "Band/First Band.") Alternatively, it would be obvious to try a band that restricted expansion of the frame as discussed in Ground 2.

Claims 17 and 30 also require a second band surrounding and attached to the frame. Under Patent Owner's Definition, this second band can be a ring of frame elements. (Exs.1040 pp.39, 92; 1041 pp.2-3 Term 10.) Bessler meets this with the frame elements exposed (downstream) of the cuff as discussed in Ground 1. (Ex.1003 ¶¶71, 127; *see also* Claim Chart 1 Bessler "Second Band.")

Petitioner's definition of second band would not include frame elements. (Ex.1041 pp.2-3 Term 10.) The claims would still be obvious, however, because as

discussed above, the cuff of Bessler can extend over any portion of the interior or exterior of the frame (Ex.1008 col.4:6-9) and therefore can cover a region of the stent downstream of that portion adjacent to where the FVE is attached. A POSA would appreciate that this extended downstream portion of the cuff meets the claims criteria: it is downstream; it surrounds the frame; and it prevents distention. (Ex.1003 ¶128.)

g. Flexible Valve Element

All of the challenged claims require a "flexible valve element" attached to the frame or to a central portion thereof. A FVE according to Patent Owner is any flexible part of a valve. (Ex.1041 p.3 Term 12.) On the other hand, a FVE according to Petitioner 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. (*Id*.) As explained in the provisional application, the FVE is similar in shape to the birdcage-like stent and is congruently attached inside thereof. The apex of the FVE is attached to the central portion of the stent. And the downstream edge is attached to the frame elements and/or band at discreet positions forming reversing cusps. (*See* Part VI.A, *supra*; Exs.1011 App.A pp.A-1:5-8, A-3:17-26, A-4:10-15, 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; 1003 ¶129.)

The FVE of Johnson meets both Patent Owner's Definition and Petitioner's requirements. It is a flexible funnel, which meets Patent Owner's Definition. Its apex is attached to the central portion of a correspondingly birdcage-shaped framework of Johnson. (Ex.1021 cols.2:43-50, 4:49-68.) And the FVE's downstream edge is attached to the framework at discrete locations to produce flaps adjacent Bessler's band. (*Id.* cols.4:49-68, 5:35-36, 6:2-8.) The FVE blocks flow in the upstream direction. (*Id.* 5:37-53, FIGS.2, 4, 5.) Thus, Johnson discloses a FVE as defined by Petitioner as well. (*See* Claim Chart 1 Bessler and Johnson "Flexible Valve Element"; Ex.1003 ¶130.)

Claims 1, 28, and 30 also require the FVE be attached to the central portion and adjacent the 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. Bessler's FVE is disposed within the cylindrical stent member transverse of, and at some acute angle relative to, the stent walls. (Ex.1008 col.3:54-60.) Bessler's cuff extends from the periphery of the FVE and is attached to the stent as well. Moreover, Bessler explains that the valve member can be secured to the "crowns" of the "small waves" 61 of the stent which, as shown in FIG.7, is substantially centered in the stent. (*Id.* 5:60-67, FIG.7.) So the FVE of Bessler is substantially only mounted in the central portion, adjacent the band. (*Id.*

col.5:36-43, FIG.4; Ex.1003 ¶¶75, 132.) Replacing it with Johnson's FVE would yield the same result. (*See* FIG.H.)

As noted previously, a POSA would appreciate that the apex of the funnel of the FVE would need to be attached centrally. (Ex.1003 ¶¶109-112, 132-138.) And a POSA would realize that the framework of Johnson could itself provide the needed structural support and attachment point for the FVE's apex.. (*Id.*) As shown in FIG.H, the framework of the Johnson valve could be attached using sewing pads 18, 20, and 22, or by other means known to a POSA. (*Id.*) Bessler's stent could also be modified to provide the necessary central apex for attachment.

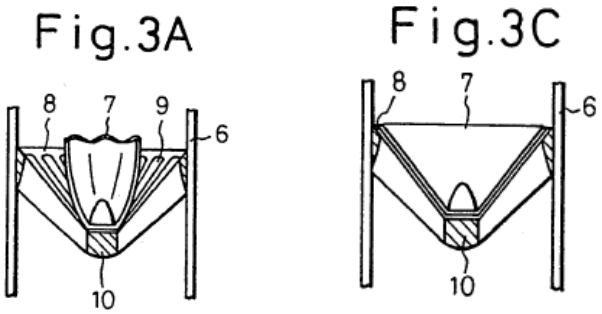
Indeed, replacing the FVE of Johnson for that of Bessler would result in a FVE attached substantially only in the center of the Bessler stent, both longitudinally and radially. This meets these claims' requirements under either parties' definitions.

Johnson also meets the attached substantially only to the central portion requirement under Petitioner's definition because its FVE is mounted to the centralized junction of its frame and is central in terms of its position within the Bessler stent as well. (*See* Claim Chart 1 Bessler 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 attachment of Johnson's valve substantially only within the interior of Bessler's stent as shown in FIG.H. Moreover, the attachment of the FVE is always described in Bessler as being adjacent the cuff. (Ex.1008 col.5:20-27, 35-42, FIG.4.) The cuff can extend over the entire exterior of the stent (*id.* 4:4-10) so anywhere the FVE is attached can be adjacent at the band.

Patent Owner noted during prosecution that the FVE of Johnson was attached along the entire length of its supports and therefore was not attached substantially only at the central portion and adjacent the band. As explained above, that is not true for the combined device. But even if that were a difference, it is still obvious. Imachi teaches a funnel valve for use with blood in an artificial heart. (Ex.1020 col.3:49-4:30, FIGS.2A-3C.) 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 thereto at its apex. (*Id.*) The frame of Johnson serves the very same function as this seat 8.



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 Johnson, Imachi, and even Moulopoulos, that while the apex must be secured, the rest need not. Indeed, Imachi demonstrates that the funnel valve would also operate without any further attachment. (Ex.1003 ¶¶136-138.) 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 only of these is obvious and only a degree of attachment beyond the apex is a matter of routine design choice. (*Id.* ¶137.)

Johnson's express teaching is that the "edges 32, 34, 36" at the downstream end of the flap that contacts the surrounding structure forms 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 appreciate that intermediate attachment could be

omitted with no loss of function. (Ex.1003 ¶138.) Thus, for several reasons, the claims are obvious from this combination.

Claims 1, 28, and 30, require a FVE having upstream and downstream sides facing the upstream and downstream regions. This is taught in Bessler as discussed in Ground 1. Moreover, the Johnson valve mounted within Bessler's stent has upstream and downstream facing sides. (*See* FIG.C; Ex.1021 col.6:14-19, FIG.8; *see also* Claim Chart 1 Bessler and Johnson "Upstream/Downstream Sides.")

Claims 10, 17, 18, and 29 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. These limitations are met by a FVE of Johnson wherein the valve element, like the cage-like frame, is "parabolic." (Exs.1021 cols.2:45-61, 4:49-68, 5:37-45, FIGS.2, 7, 8; 1003 ¶139.)

h. Valve Movement Limitations

The independent claims include a lengthy recitation, which describes the general operation of native heart valves and replacement valves, all of which were known *per se* and is required of any such valve. (Ex.1003 ¶140.) These features were known to POSAs at the time through, if nothing else, the various articles and patents cited in the Background of the '782 Patent. (Exs.1001 col.1:42-2:19; 1003 ¶¶140-141.)

This valve movement language is met by the operation of the Johnson valve. As explained in Johnson, the flexible valve membrane is attached to the flexible framework in such a manner that the membrane segments or leaflets 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 cols.3:26-47, 5:37-53, FIGS.4, 5.) This movement meets the claims' limitations.

i. Delivery Device Limitations

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.) Bessler describes just such an instrument as previously discussed in Ground 1. (Ex.1008 cols.4:53-5:14, 7:26-67, FIGS.12-15; *see also* Claim Chart 1 Bessler "Holder, Manipulator and Ejector"; Ex.1003 ¶¶79, 142.)

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.

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. Bessler does not expressly identify size for the collapsed valve. However, Bessler teaches that the valve is collapsed and delivered to the implantation site percutaneously. (Ex.1008 cols.2:65-67, 4:53-60, 7:26-67.) Bessler also specifically describes standard techniques that include access through the femoral artery. (*Id.* 8:7-15, 8:48-50.) A POSA would know as of February 1, 2000, that a device suitable for such a procedure would require a compressed diameter of about 6mm or less. (Ex.1003 ¶¶27, 80-81, 143.) The ranges claimed are obvious in view of this teaching.

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 element has already been discussed in connection with claims 1, 28, and 30, and is clearly illustrated in Bessler in connection with, *inter alia,* FIG.7. (Ex.1008 col.5:28-43, 5:60-6:2, FIGS.4, 7.) And, as shown in FIG.H, if the Johnson valve is mounted to the "crowns" 61 of Bessler, it is disposed centrally both radially and longitudinally. And its attachment to the point of joinder 16 is also an attachment to the central portion, which is substantially centered as well. (*See* Claim Chart 1 Bessler and Johnson "Attached to a Central Portion/Substantially Connection to Central Portion"; Ex.1003 ¶¶62, 75, 82, 144.)

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 at least partially defining an opening to the valve. Johnson includes this same structure. (Exs.1021 cols.2:54-61, 3:26-35, 4:49-67, 5:20-53, FIGS.2, 4, 5, 7; 1003 ¶¶83, 145.)

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. (*See also* Claim Chart 1 Bessler and Johnson "Frame U-Shaped Elements"; Ex.1003 ¶¶63-64, 84, 146.)

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 pp.4-5, 52.) As Defined, this recitation is met by the upstream and downstream facing barbs of Bessler. (Exs.1008 cols.4:12-21, 5:6-6:2, 7:26-67, FIGS.6, 7, 14, 15; 1003 ¶¶85, 147.)

Claims 25 and 26 require that the distance between the opposite ends of frame elements be between 3-5cm or 2-3cm, respectively. Bessler describes the diameter of its device as ranging from about 1.5cm to 3.5cm, preferably 1.75cm to 3.0cm. (*Id.* 6:14-16.) 3cm thus discloses the subject matter of both claims. (Ex.1003 ¶¶65, 86, 148.)

Finally, claim 27 depends from claim 18, identifies the band claimed therein as being a first band, and further requires a second band. Bessler and Johnson describe using a first band and Bessler describes using a second band as discussed previously in connection with independent claims 17 and 30, which also require both bands. (*See* Claim Chart 1 Bessler and Johnson "Band/First Band," "Second Band"; Ex.1003 ¶149.)

k. Motivation And Reasonable Expectation Of Success

For the reasons discussed earlier, there should be no need for motivation to make this combination. Moreover, as noted at the beginning of this ground, the art recognized problems and complications of open chest surgery provided motive to seek transcatheter solutions. *KSR,* 550 U.S. at 420. But there were also specific reasons to start with the idea of converting the valve of Johnson to a transcatheter valve.

Johnson discloses that tissue valves, such as those disclosed in Bessler, and in fact synthetic valve designs, may have had durability problems resulting from, *inter alia,* the fact that the leaflets are attached to a rigid or semirigid fixation ring around the perimeter. "By using a central attachment without an outer fixation ring, the dynamic annulus valve effects closure by leaflet coaptation with the natural or reconstructed tissue annulus. This closing method as well as the flexibility of the structural frame should avoid localized stress points on the leaflets

and result in extreme durability." (Ex.1021 col.3:37-47.) Johnson further specifies that the invention "provides a dynamic annulus heart valve configuration which may effectively provide the non-thrombogenic qualities of tissue valves while not sacrificing durability or hemodynamic performance." (*Id.* 2:39-42.) But for the fact that it was a surgical valve, Johnson would be a likely candidate. Since, at the time, it was known to mount collapsible valves within a stent to provide a transcatheter solution, a POSA would be motivated to try this combination. (Ex.1003 ¶¶150-152.) Durability, which reduces the potential need for further procedures, is of particular importance in such patients. And for the reasons discussed in Ground 2 there would also be a reasonable expectation of success from such a combination.

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

The teachings of Bessler, Johnson, and Imachi, as described in Ground 3, are equally applicable here. Johnson can be used as a principal reference for the reasons discussed in Ground 3, namely converting a surgical valve with desirable properties to a transcatheter valve by mounting it in a collapsible, flexibly resilient stent already used for such purposes. However, the combination could be viewed in the opposite direction. Bessler teaches a self-expanding transcatheter valve including a frame with peripheral anchors and a cuff. The "optimal" material

useful for producing its flexible valve member would be synthetic and only two materials, polyester and PTFE, are noted. (Ex.1008 col.6:18-31.) Bessler therefore provides the motive to use synthetic FVEs. Johnson describes a flexible synthetic valve element produced from PTFE. (Ex.1021 col.4:49-56.) It therefore describes a synthetic FVE made from the "optimal" material contemplated by Bessler. (Ex.1003 ¶¶153-156.)

Johnson also discloses that leaflet valves, such as those preferred in Bessler, have had durability problems resulting from, *inter alia*, the fact that the leaflets are attached to a rigid or semirigid fixation ring around the perimeter. "By using a central attachment without an outer fixation ring, the dynamic annulus valve affects closure by leaflet coaptation with the natural or reconstructed tissue annulus. This closing method as well as the flexibility of the structural frame should avoid localized stress points on the leaflets and result in extreme durability." (Ex.1021 cols.2:39-42, 3:37-47.) Even Bessler recognized durability as an issue. (Ex.1008 col.2:11-12.)

A POSA would be motivated to try the construction of the Johnson valve to replace the synthetic valve of Bessler, which has leaflets, in hopes of obtaining a more durable solution. This is particularly important here since transcatheter valves were originally indicated for patients who are too old and weak to survive open chest surgery as noted in Ground 3.

The manner in which the elements of Bessler, Johnson, and Imachi would be combined is identical to that explained in Ground 3. So too are the reasons for a POSA to have a reasonable expectation of success from this combination. Viewed with Johnson as the primary reference (Ground 3) or Bessler (Ground 4), the combination renders the claims obvious.

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 ¶¶28-29.) 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 that settlement are not publicly available and the settlement could as easily reflect more important business priorities of Medtronic than a recognition of patentability.

Even if secondary evidence exists, however, it is not relevant to the question of anticipation, is not commensurate with the scope of these claims, and cannot overbalance the strong showing of *prima facie* obviousness reflected in Grounds 2-4 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 canceled as unpatentable over each of the grounds discussed hereof.

Dated: October 23, 2017 By: s/ Michael H. Teschner /
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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 13,831. 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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