

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

EDWARDS LIFESCIENCES CORPORATION AND EDWARDS
LIFESCIENCES LLC
Petitioners

v.

COLIBRI HEART VALVE LLC
Patent Owner

Case IPR2022-00878
Patent No. 9,737,400

PETITION FOR *INTER PARTES* REVIEW OF

U.S. PATENT NO. 9,737,400

UNDER 35 U.S.C. §§ 311-319 AND 37 C.F.R. § 42

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EX1003	U.S. Patent App. Pub. No. 2007/0043431 to Melsheimer
EX1004	PCT Publication WO 2009/042196 to Braido <i>et al.</i>
EX1005	U.S. Patent No. 6,287,334 to Moll <i>et al.</i>
EX1006	U.S. Patent App. Pub. No. 2007/023322 to Eberhardt <i>et al.</i>
EX1007	U.S. Patent App. Pub. No. 2005/0113910 to Paniagua <i>et al.</i>
EX1008	U.S. Patent App. Pub. No. 2004/0186558 to Pavcnik <i>et al.</i>
EX1009	D. Pavcnik <i>et al.</i> , “Aortic and Venous Valve for Percutaneous Insertion,” Min. Invas. Ther. & Allied Technol., 9(3/4):287-292 (2000)
EX1010	U.S. Provisional Patent App. No. 61/423,051
EX1011	U.S. Patent No. 6,730,118 to Spenser <i>et al.</i>
EX1012	U.S. Patent App. Pub. No. 2006/025913 to Nguyen <i>et al.</i>
EX1013	Steven R. Bailey, “Percutaneous Expandable Prosthetic

	Valves”, <u>Textbook of Interventional Cardiology</u> , Chapter 75 (1994)
EX1014	U.S. Patent App. Pub. No. 2002/0052651 to Myers <i>et al.</i>
EX1015	U.S. Patent No. 6,287,335 to Drasler <i>et al.</i>
EX1016	U.S. Patent App. Pub. No. 2006/0229716 to Mitrev
EX1017	H.R. Andersen <i>et al.</i> , “Transdermal Implantation of Artificial Heart Valves. Description of a New Expandable Aortic Valve and Initial Results with Implantation with Catheter Technique in Closed Chest Pigs,” <i>European Heart Journal</i> , 13:704-708 (1992)
EX1018	U.S. Patent No. 5,411,552 to Andersen <i>et al.</i>
EX1019	U.S. Patent App. Pub. No. 2002/0198594 to Schreck
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EX1022	U.S. Patent No. 6,231,598 to Berry <i>et al.</i>
EX1023	U.S. Patent No. 6,229,635 to Frantzen

EX1024	U.S. Patent No. 4,580,568 to Gianturco
EX1025	U.S. Patent App. Pub. No. 2005/0228472 to Case <i>et al.</i>
EX1026	Declaration of Jonathan Rourke
EX1027	Christopher Huber and Ted Feldman, Transcatheter Valve Therapies (2010)
EX1028	Photographs of Models of U.S. Patent App. Pub. No. 2007/0043431 to Melsheimer Figure 8 Embodiments
EX1029	D. Pavcnik <i>et al.</i> , “Percutaneous Therapy for Deep Vein Reflux,” Seminars in Interventional Radiology, Vol. 22:3, pp. 225-32 (2005)
EX1030	March 13, 2007 Information Disclosure Statement, Prosecution History of U.S. Pat. App. 11/506,459 (Melsheimer)
EX1031	D. Walker, Metals and Non-Metals (2007)
EX1032	P. Pibarot <i>et al.</i> , “Prosthetic Heart Valves: Selection of the Optimal Prosthesis and Long-Term Management,” Circulation, 119:1034-48 (2009)

I. OVERVIEW OF PETITION

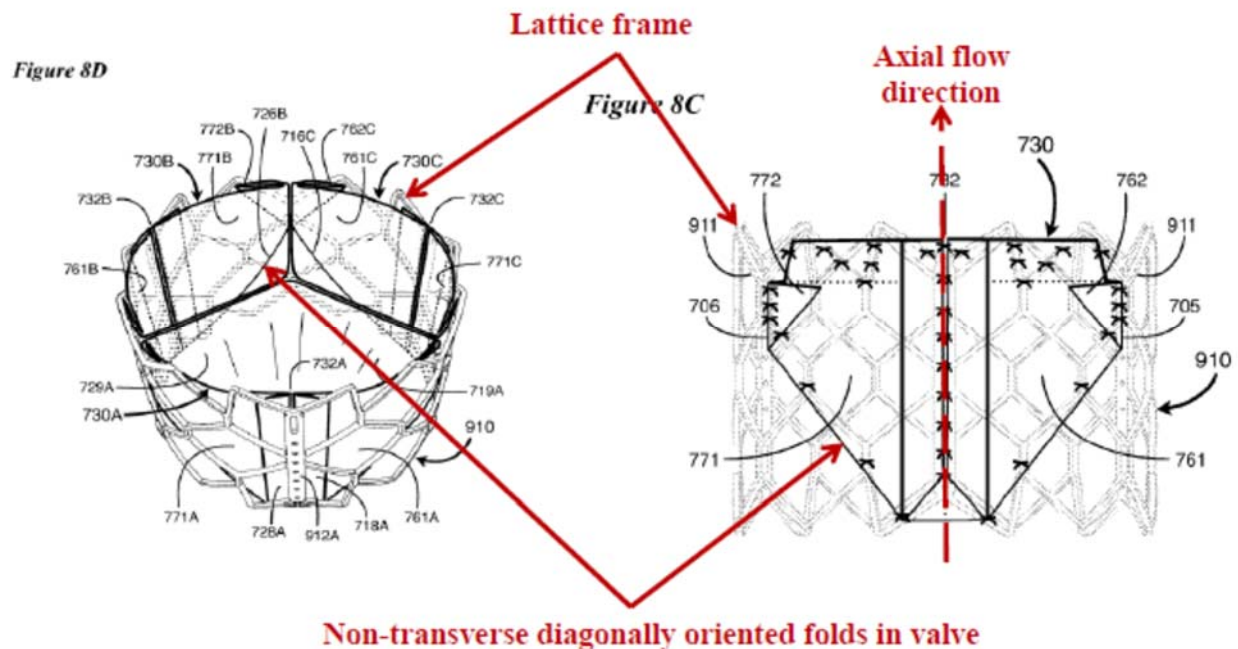
Edwards Lifesciences Corporation and Edwards Lifesciences LLC (collectively, “Edwards”) respectfully request *inter partes* review of claims 55-72, 78-80, and 83-85 (the “Challenged Claims”)¹ of U.S. Patent No. 9,737,400 (“’400 Patent,” EX1001) under 35 U.S.C. §§ 311-319 and 37 C.F.R. § 42.100 *et seq.*

This Petition is focused on overbroad claims directed to transcatheter valves, which are collapsible and expandable prosthetic valves that are implantable in a patient’s heart or elsewhere in a patient’s vasculature via a catheter. Transcatheter valve technology was far from its infancy as of the purported December 2010 priority date of the ’400 Patent.² By that time, a number of transcatheter valves had been commercially approved, a number of other valves were in the midst of the regulatory approval process, and a host of other valves had been conceptualized

¹ An element-by-element breakdown of the Challenged Claims is provided in the Appendix attached hereto.

² For purposes of this Petition only, Edwards has applied a December 14, 2010 priority date to its analysis. However, the provisional application to which the ’400 Patent claims priority does not support the entirety of the ’400 Patent’s disclosure. *Compare* EX1001 (’400 Patent) *with* EX1010 (U.S. Provisional Patent App. No. 61/423,051) (missing, *e.g.*, Figures 1C-G, 2-4, 5A-F, 6, 7A-K, 8A-D, 9A-E of the ’400 Patent and the corresponding disclosures related thereto).

and made public through patent applications and other publications. EX1026, ¶¶28-29.³ The Challenged Claims include three independent claims, each broadly directed to a “vascular system implant” with a “lattice frame” and a valve structure having “non-transverse diagonally oriented folds that are angled relative to an axial flow direction.” EX1001, Claims 55, 60, 67.



Id., Figs. 8C, 8D.⁴ None of these features were unique or non-obvious to a POSITA—either alone or in combination—as of December 2010. EX1026, ¶30.

³ This Petition is supported by the Declaration of Jonathan Rourke, a distinguished engineer who has extensive experience with stent-based devices for the repair and replacement of heart valves. EX1026, ¶¶5-17.

⁴ All annotations added unless otherwise noted.

The Challenged Claims are anticipated and/or obvious as set forth in Grounds 1-8 below.

II. BACKGROUND

A. The Beginnings of Transcatheter Valve Technology

In 1989, Andersen and his colleagues conceived of and developed prototypes of a transcatheter valve, which included a biological valve mounted on a collapsible and expandable stent. This technology provided a minimally invasive alternative to surgical valve replacement procedures. The Andersen team's work was first published in 1992 and a series of patents followed. EX1017, 1-5;⁵ EX1018. At the outset of this technology, the Andersen team recognized that a transcatheter valve could be made with a variety of different balloon-expandable and self-expanding stent structures, that the valve material could include biological or synthetic material, and that the valve structure could include various numbers of leaflets. EX1018, 2:38-68, 7:3-16. The Andersen team also recognized at the outset that transcatheter valve technology could be used to treat a number of medical problems (*e.g.*, aortic insufficiency, aortic stenosis, varicose veins, and cancerous tumors), and that such a valve could be placed in a patient's heart to

⁵ Pincite citations herein other than those to patents and patent publications are to the page number(s) identified in the exhibit stamp at the bottom of the exhibit's page.

help restore normal valve function or placed elsewhere in the patient's vasculature to function as, *e.g.*, a venous valve. *Id.*, 3:13-62; EX1026, ¶¶31-32.

In 1994, the Textbook of Interventional Cardiology recognized the Andersen team's work as "[t]he most exciting published work in this area to date," and noted that "[a]lthough the ... [Andersen] [] study presents only early data illustrating the large amount of work required before a device such as this can be used, it illustrates that such devices await only the focused evaluation and improvement of a few investigators." EX1013, 12. This textbook also recognized risks associated with prosthetic valves, and that "[t]he designer of any percutaneously placed valve" will consider, among others, the risks of thrombus formation and embolization, perivalvular leak, infection, difficulty sizing valve to annulus, valve degeneration, and pannus formation in designing a transcatheter valve. *Id.*, 7; EX1026, ¶33.

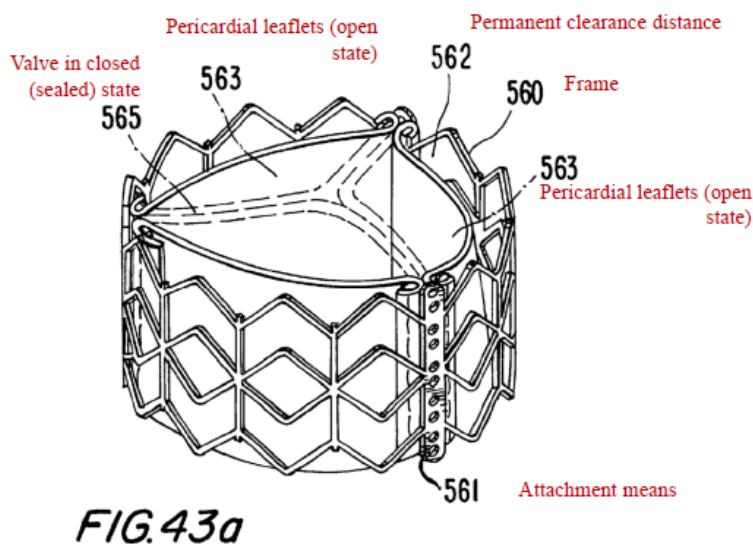
B. Commercialization of Transcatheter Valve Technology

Transcatheter valve technology was a commercial reality by the '400 Patent's December 2010 priority date, due in large part to the early work of Percutaneous Valve Technologies ("PVT"), which Edwards acquired in 2004, and CoreValve, which was acquired by Medtronic, Inc. in 2009.⁶ EX1026, ¶¶28, 35-

⁶ Medtronic's transcatheter Melody valve was also commercially available for use in the pulmonary valve as of the '400 Patent's 2010 priority date.

39, 44.

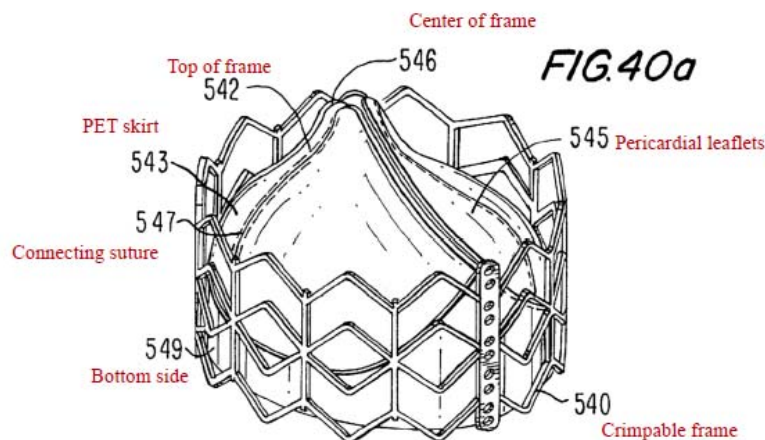
PVT commenced transcatheter valve development in 2000. PVT's work led to the first-in-human implantation of a transcatheter aortic heart valve in April 2002. *Id.*, ¶35. PVT patented its device along with a series of other transcatheter valve embodiments, which are described, for example, in U.S. Patent No. 6,730,118 to Spenser et al. ("Spenser") granted in 2004. *See* EX1011; EX1026, ¶35. A representative embodiment is pictured below:

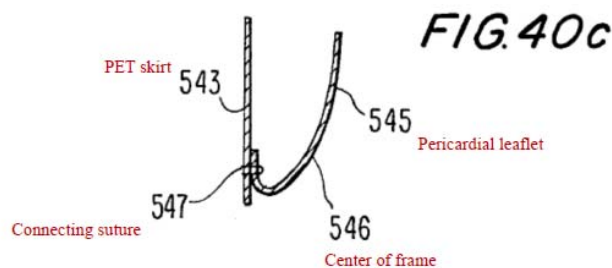
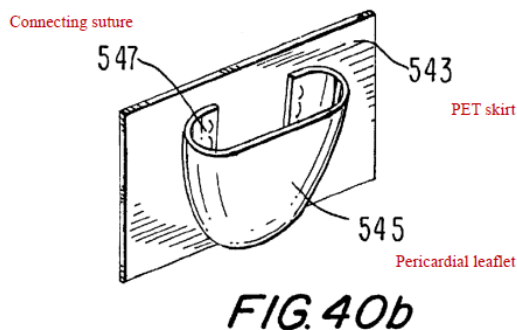


EX1011, Fig. 43a.

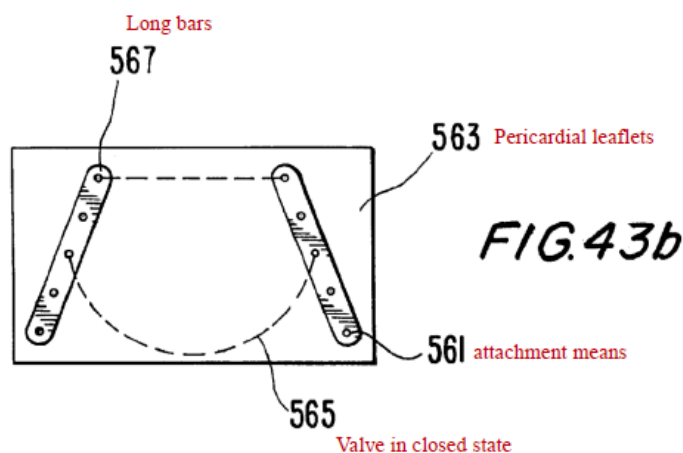
Spenser, like the early work of Andersen, recognized that a transcatheter valve could be made with a self-expanding or balloon-expandable frame, and that the valve assembly could be made from biological tissue, including pericardium, or from synthetic material. *Id.*, 12:11-49. Spenser also recognized at the outset of

transcatheter valve development the importance of stress distribution across the valve leaflets, which was a well-known design goal for valves implanted surgically (via an open-heart procedure) as well. EX1026, ¶¶36-37. “One of the main goals in valve design, in general, is to distribute the stresses in a homogeneous way in the pericardium material and the attachment areas. The design of the pericardium leaflet as a pocket assists in distributing the stresses along suture line 547 The shape of the leaflets in the valve assembly is determined by the boundary conditions, which in this case are the suture lines. The suture lines can be designed to have an optimal shape regarding the stress distribution in accordance with geometrical restrictions.” EX1011, 25:39-65.





Id., Figs. 40a-c. Moreover, as shown in Figure 43a above and Figure 43b below, it was recognized by Spenser that forming angled folds along the commissure supports of the valve leaflets help form a tapered valve structure, which “creates a permanent clearance distance 562 between the pericardial leaflets 563 and frame 560. This is of major importance in the protection of the pericardium from abrading against the frame.” *Id.*, 26:41-67; EX1026, ¶38.

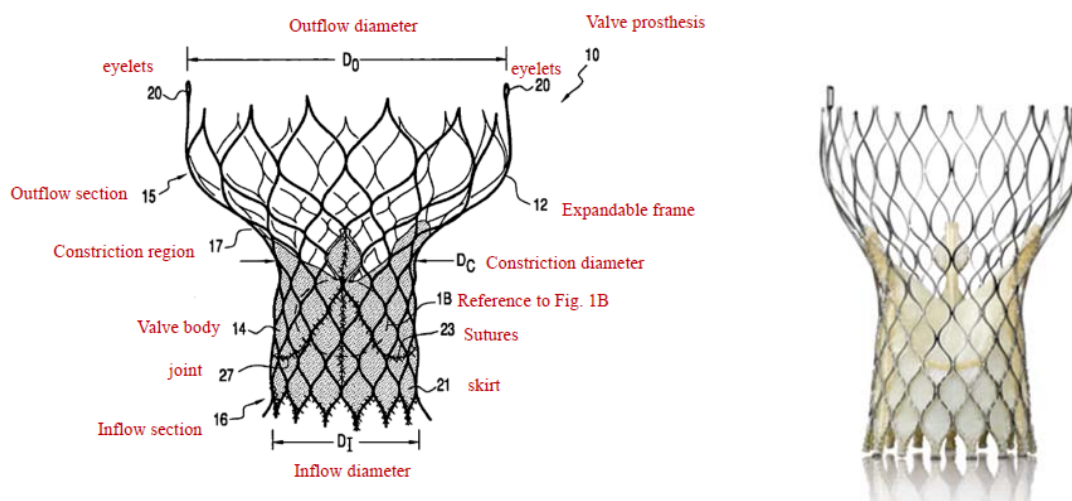


EX1011, Fig. 43b. The PVT device ultimately became Edwards’ SAPIEN valve, which received its first commercial approval in 2007:

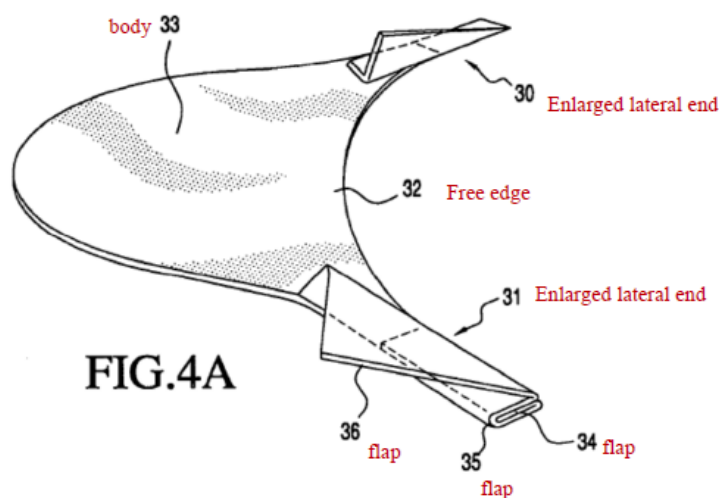
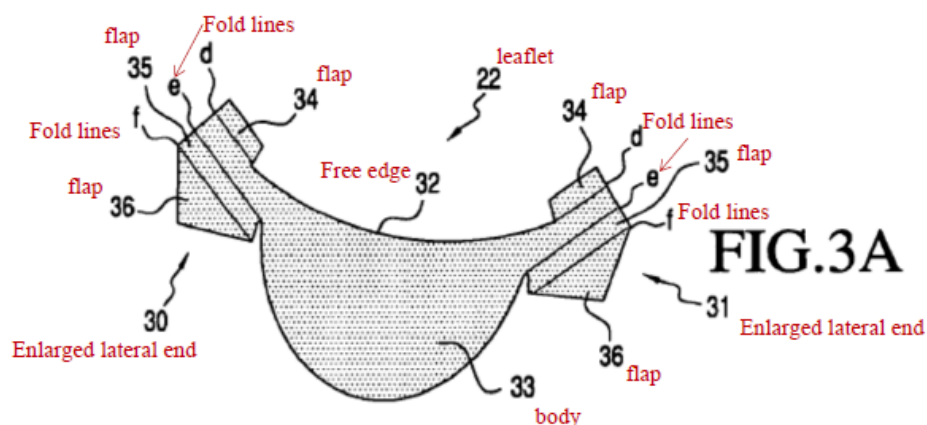


EX1027, 230; EX1026, ¶39.

As to Medtronic's CoreValve device, work that led to its commercialization (also in 2007) was detailed in, *e.g.*, U.S. Patent Application Publication No. 2006/0259136 ("Nguyen"):



EX1012. Fig. 1A; EX1027, 233 (commercial embodiment). As with Spenser, the Nguyen application also recognized that the design of the valve leaflets should aid in stress distribution, and it describes a valve leaflet structure with angled folds intended to help uniformly distribute the load when the valve is closed:



EX1012, ¶[0050], Figs. 3A, 4A; EX1026, ¶44.

C. Other Known Transcatheter Valve Designs Comprising the Primary Features of the Challenged Claims As of the '400 Patent's Priority Date

As of December 2010, a number of other transcatheter valve designs also embodied a “vascular system implant” with a “lattice frame” and a valve structure having “non-transverse diagonally oriented folds that are angled relative to an axial

flow direction.”

1. Prior Art Identified in Foreign Search Reports Not Applied by the Examiner

A number of designs were identified as the closest prior art in foreign patent office search reports examining foreign counterparts to the '400 Patent. Three of these references form the basis of a number of Petitioner's grounds of invalidity, none of which were substantively relied upon by the Examiner during prosecution: U.S. Patent Application Publication No. 2007/0043431 (“Melsheimer”, EX1003), PCT Publication WO 2009/042196 (“Braido”, EX1004), and U.S. Patent Application Publication No. 2007/0233228 (“Eberhardt”, EX1006). *See* EX1002, 2116, 3268, 3309, 3525, 3618. These references are discussed in detail in the grounds for invalidity, *infra* Sections V.C.-D.; a brief summary is provided below.

First, Melsheimer discloses a transcatheter valve having a frame and folded leaflet structure:

Implanted Transcatheter Valve

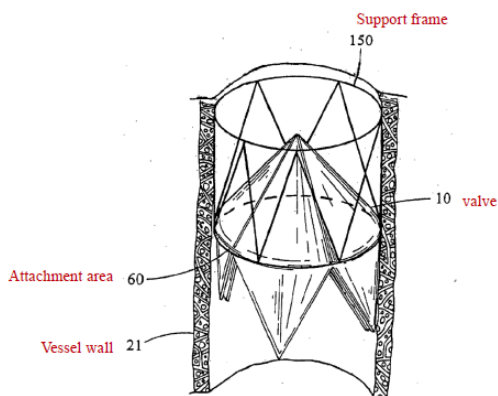


Fig. 6

Folded Leaflet Structures

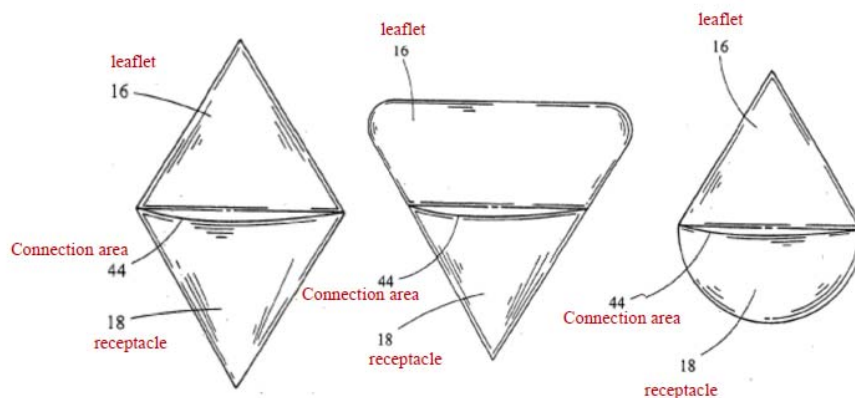


Fig. 4A

Fig. 4B

Fig. 4C

EX1003, Figs. 4A-4C, 6; *id.*, ¶[0041] (“As shown in FIGS. 4A-C, the shape of the leaflets 16 and chambers 18 may be triangular, curvilinear, or any shape that will allow the leaflets 16 to form a contact region and the receptacle 18 to form a pocket for receiving fluid in the second direction 22.”); EX1026, ¶¶48-50.

Second, Braido likewise discloses a transcatheter valve structure having a

frame and folded leaflet structure:

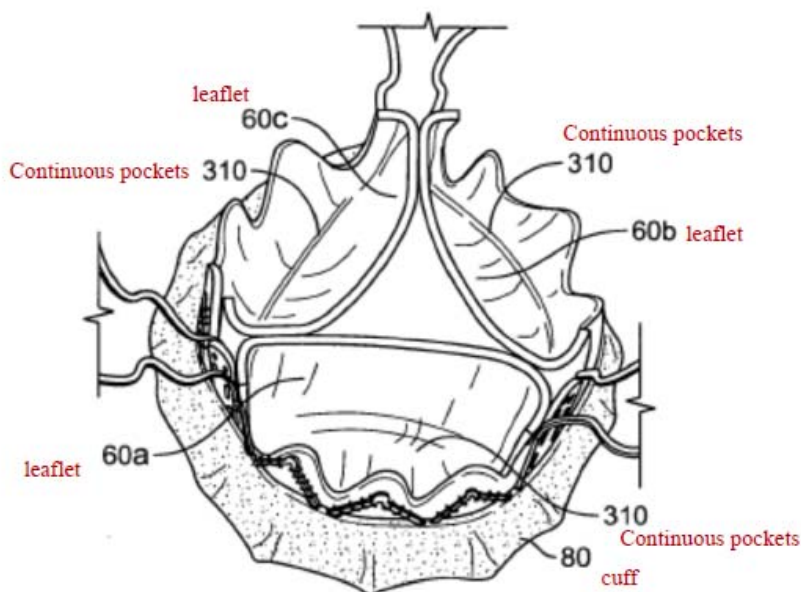


FIG. 59

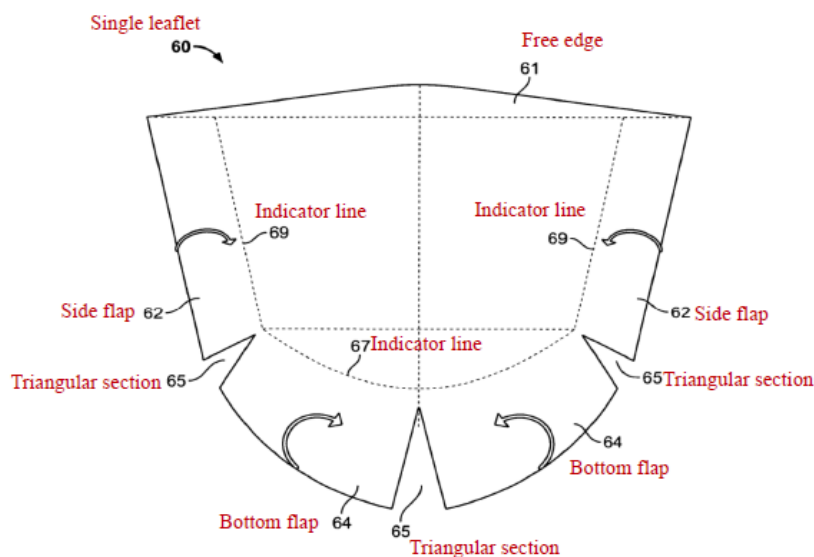
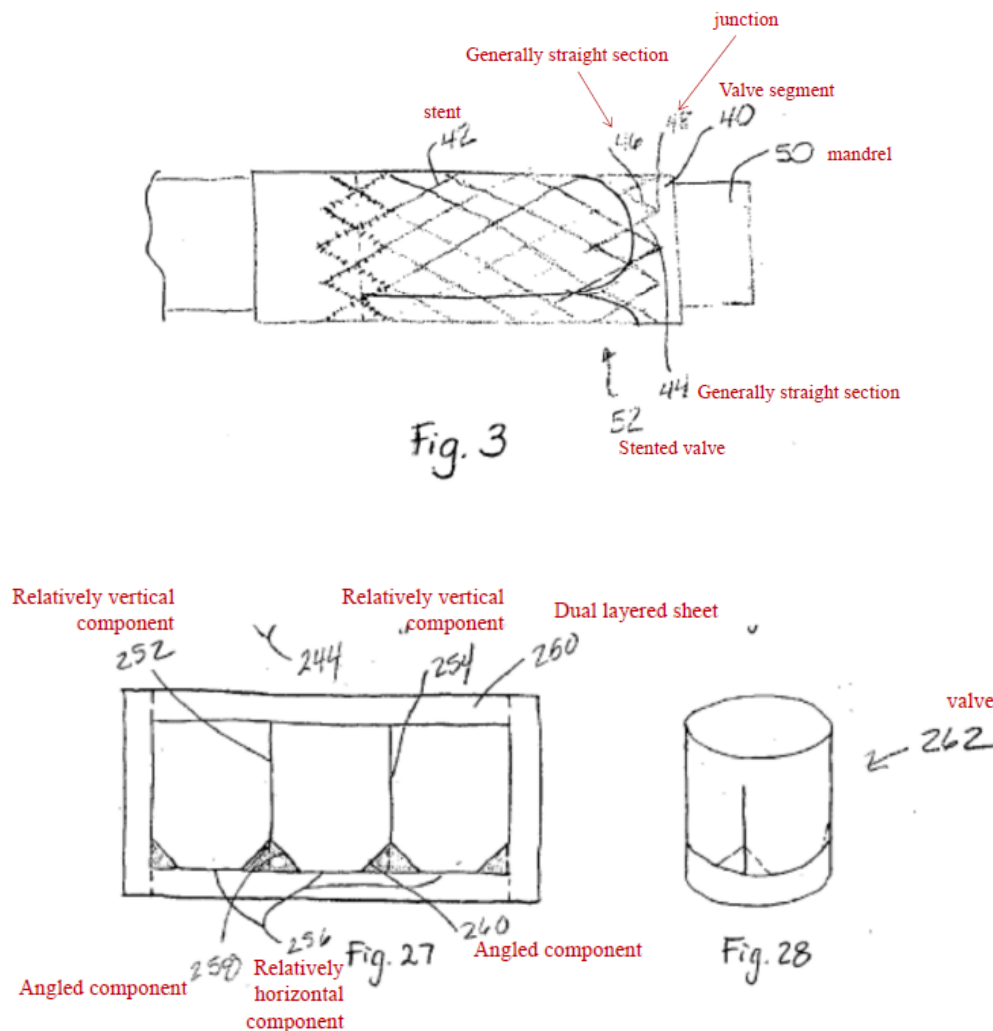


FIG. 19

EX1004, Figs. 19, 59; *Id.*, ¶¶[0120], [0129] (Fig. 19: “this design forms a pocket under back-pressure, with no seams along the suture line. ... Since these flaps are folded back up against the leaflet OD, when the leaflet opens, the flaps 64 actually

form a buffer between the upper base stent portion 40 and the leaflet.”); EX1026, ¶¶51-57.

Third, Eberhardt also discloses a transcatheter valve structure having a frame and folded leaflet structure:



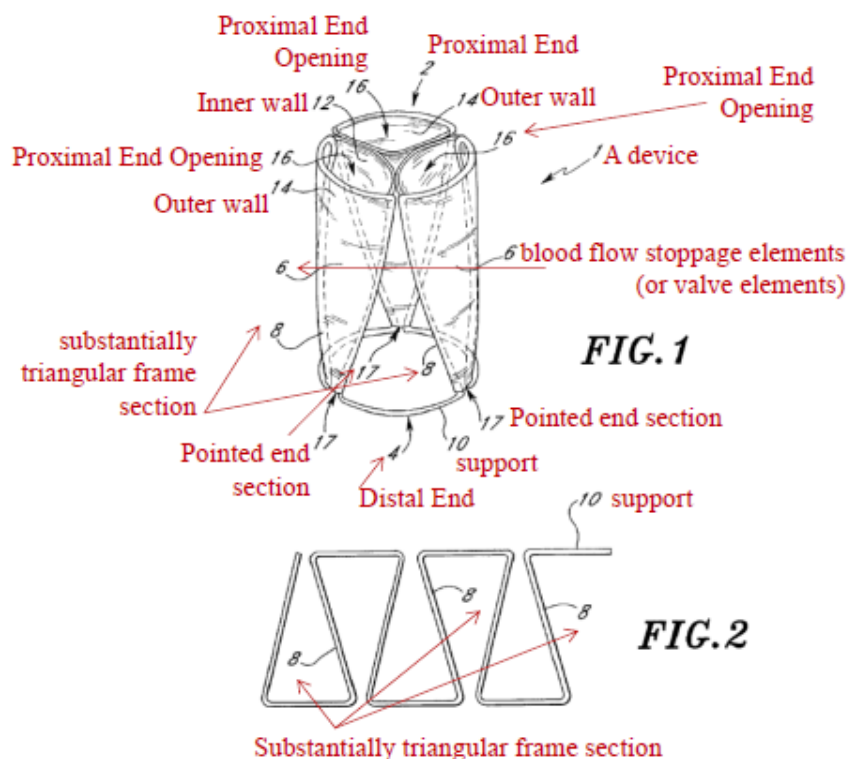
EX1006, Figs. 3, 27, 28, ¶[0010] (“pericardium material ... folded over on itself into a two-layer configuration”). In the Figures 27-28 embodiment pictured above, a “dual-layered sheet of material 250 with layers that are attached to each other [is

provided] to form a polygonal pattern for leaflets. ... The triangular areas created by these angled components can eliminate or minimize possible areas of stasis and can also provide a non-abrasive surface over which the corresponding leaflet can hinge.” *Id.*, ¶[0061]; EX1026, ¶¶45-47.

2. Prior Art Not Disclosed During Prosecution of the ’400 Patent

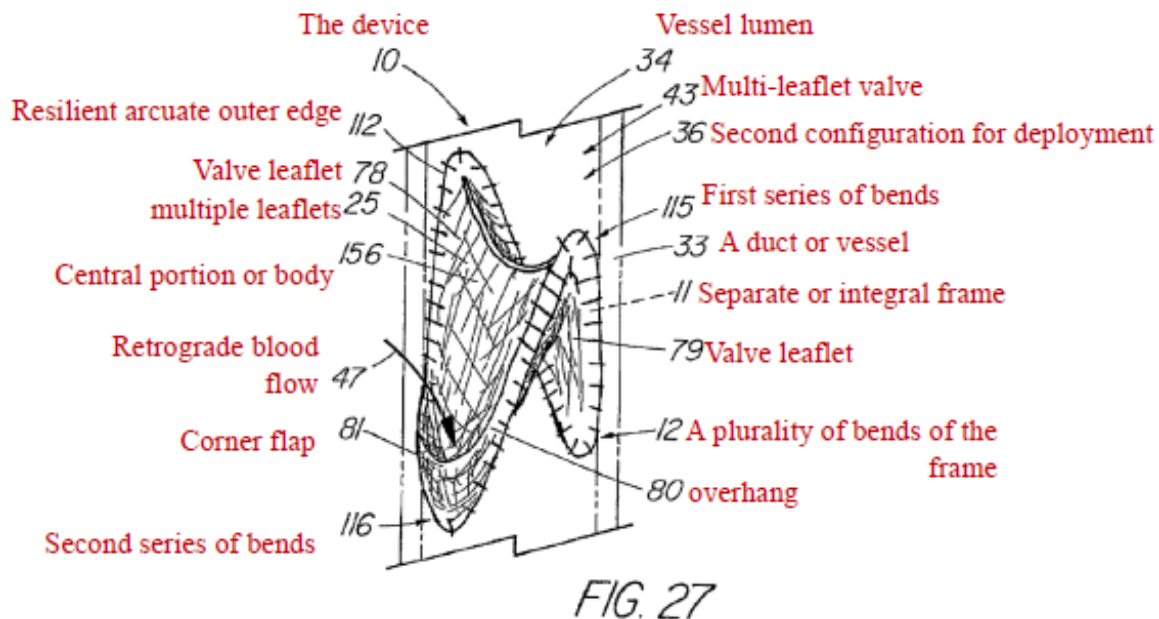
Several transcatheter valve designs with features claimed by the ’400 Patent that were not disclosed during prosecution of the ’400 Patent are also relevant to the instant Petition. These include U.S. Patent No. 6,287,334 (“Moll”, EX1005) and U.S. Patent Application Publication No. 2004/0186558 (“Pavcnik,” EX1008).

First, Moll discloses a transcatheter valve with a folded valve structure (“blood flow stoppage elements 6 having the form of flexible hollow cones”) supported by a frame:



EX1005, 3:18-20, Figs. 1-2. The blood stoppage elements have “a flareable proximal end, flareable between a flared, flow stoppage configuration and a substantially flattened, flow permitting configuration.” *Id.*, 1:40-46; EX1026, ¶34.

Second, Pavcnik disclosed a transcatheter valve with a frame and folded valve structure. EX1008, ¶[0006]. A preferred embodiment is annotated below:



Id., ¶[0098], Fig. 27. The “corner flaps” detailed in Fig. 27 are formed by folding the valve tissue radially outward and attaching it to the outside of the frame and “serve to catch retrograde blood flow 47 to provide a better seal between the [prosthetic valve] device 10 and the vessel wall 70 as well as providing an improved substrate for ingrowth of native intimal tissue from the vessel 33” *Id.*; EX1026, ¶¶40-41.

Like Andersen, Pavcnik appreciated that transcatheter valve technology had applications elsewhere in a patient’s vasculature, and disclosed that the prosthesis could be deployed in the heart or in a blood vessel. EX1008, ¶[0006]. Indeed, Pavcnik prototyped this device, and reported on successful in vitro and in vivo studies in the aortic and venous positions, *see* EX1009, 3-5, and on successful

implants in patients in the venous position, EX1029, 5; EX1026, ¶41.

D. The Inventors' Own Work a Decade Prior to the '400 Patent's Priority Date

The inventors of the '400 Patent themselves filed patent applications nearly 10 years prior to the filing of the '400 Patent that acknowledged a number of common features in transcatheter valve designs, including features claimed by the '400 Patent. *See, e.g.*, EX1007 (U.S. Patent App. Pub. No. 2005/0113910 (“Paniagua”)); EX1026, ¶¶42-43. For example, in Paniagua the inventors recognized, like the work of others that preceded it, that the frame and valve portions of a transcatheter valve could be made with a broad range of materials and designs. EX1007, ¶¶[0041]-[0042], [0046]. This earlier work by the inventors also identified purported benefits of using a folded valve structure: “[t]he folded design provides a number of advantages over prior designs, including improved resistance to tearing at suture lines. ... The method of the present invention also greatly reduces the risk of tearing of the cusps or leaflets, since they are formed by folding a single uncut portion of material forming the valve rather than being attached by suturing.” *Id.*, ¶¶[0024], [0026].

III. '400 PATENT

A. Overview

The '400 Patent issued from Application No. 13/326,196 (the “'196 Application”). The '400 Patent names R. David Fish, David Paniagua, and Eduardo

[sic] Induni as inventors, who are three of the five inventors listed on the prior art Paniagua reference discussed above.

The '400 Patent primarily relates to transcatheter heart valves, but recognizes like, *e.g.*, Andersen and Pavcnik did in the prior art, that the device can alternatively be “configured for implantation in a vascular system of a patient,” which would include use as a venous valve. EX1001, 1:15-17, 6:13-38; EX1026, ¶¶58-59. The '400 Patent acknowledges various features of transcatheter valves known as of December 2010. EX1026, ¶¶60, 64, 194. It recognizes that stent-mounted transcatheter valves typically include valve membrane leaflets mounted within a collapsible frame. EX1001, 1:54-58. It recognizes that the valve membrane leaflets can be formed with biocompatible pericardium tissue or synthetic material, and that the frame can be formed from a metal alloy. *Id.*, 11:41-49, 12:32-36. The '400 Patent further acknowledges that “a cylindrical cuff layer, interior or exterior to the frame, is usually employed that acts as a seal and provides some latitude in the positioning and alignment of the PHV along the axis of flow” *Id.*, 1:65-2:3. Finally, echoing the design goals of the transcatheter valve art that preceded it, the '400 Patent identifies “[t]wo goals of at least some embodiments of the inventions,” which are (1) to use a valve geometry that “mimics the natural form of inflow into the valve” to “maximize effective orifice area and minimize opening pressure gradients” and (2) to use a valve geometry that

“mimics the natural effect of the sinuses of Valsalva” “to minimize the inward tension on the leaflet commissures in the close[d] position.” *Compare id.*, 2:29-40 *with* EX1011, 25:39-65 (“One of the main goals in valve design, in general, is to distribute the stresses in a homogeneous way in the pericardium material and the attachment areas.”); EX1026, ¶61.

The '400 Patent purports to meet its design goals through the use of valve “cusps [that] include a flat sheet of processed mammalian tissue membrane ... folded into a substantially conical shape according to a flat folding pattern” EX1001, 3:26-57; EX1026, ¶¶62-65. There are seven “integrated cusp and leaflet structure” folding patterns disclosed, each having polygonal-shaped “mobile leaflets” and “diagonal folds separating a mobile leaflet layer from a cusp wall layer of the integrated cusp and leaflet folded structure.” *See, e.g.*, EX1001, Figs. 1A-G, 2, 3, 4, 5A-F, 6, 7A-K. By way of example, “Folded Valve Pattern Variation No. 7” is annotated below:

Figure 7B

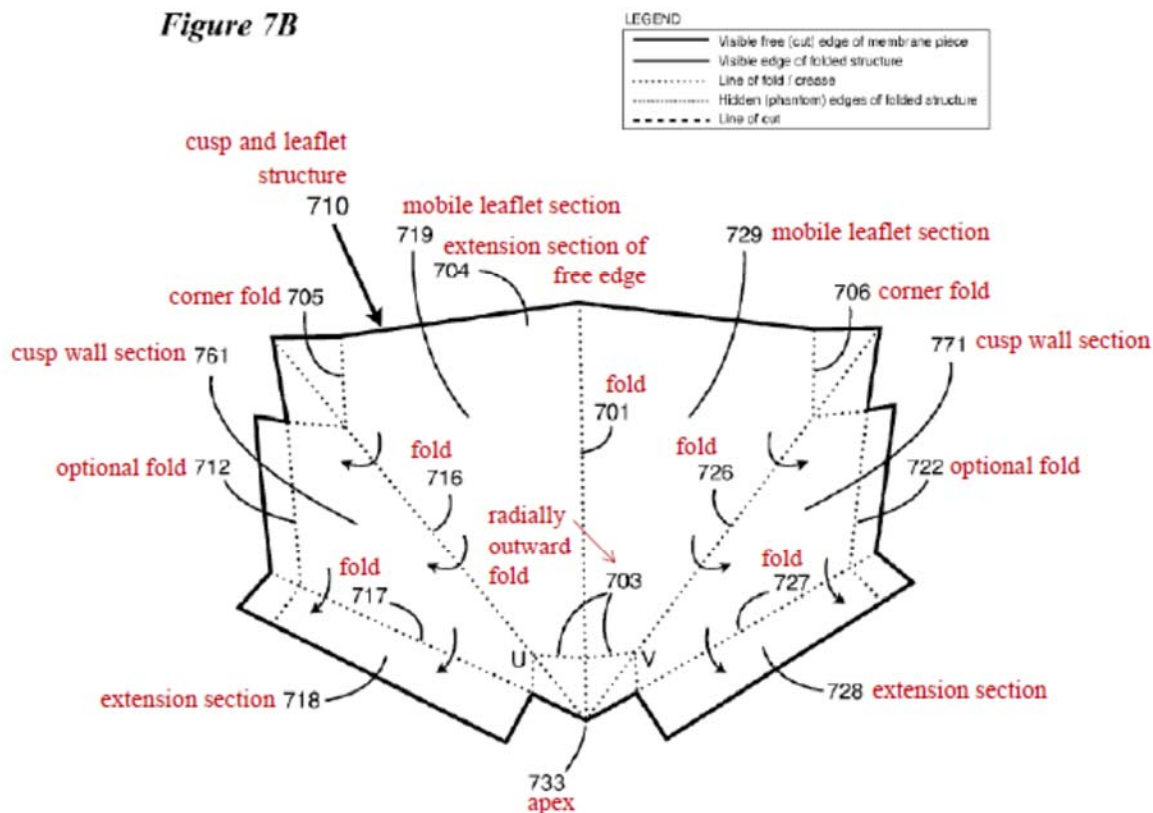


Figure 7I

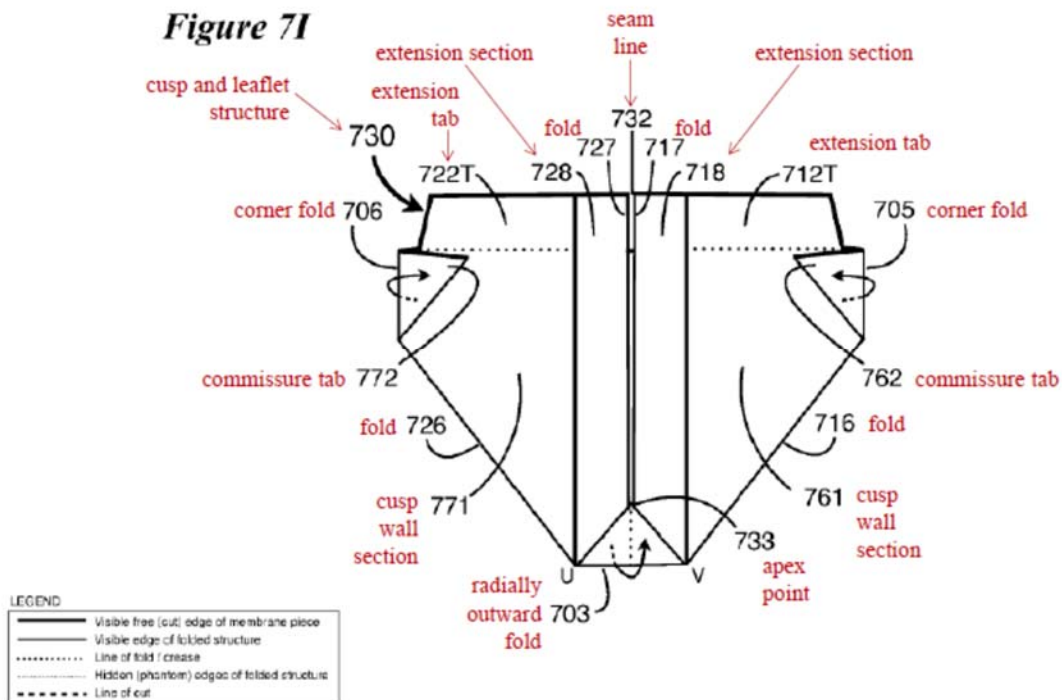
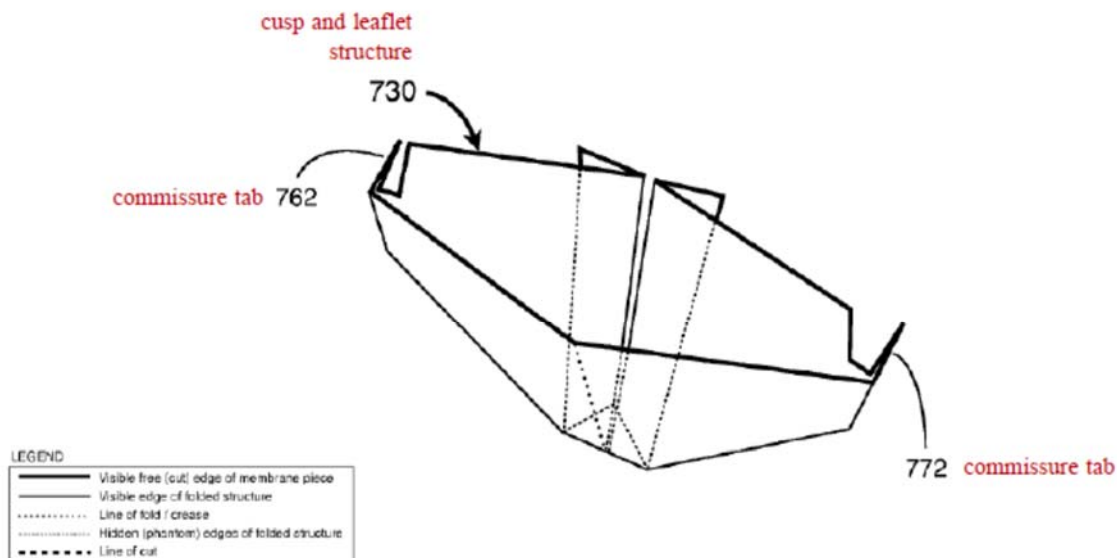
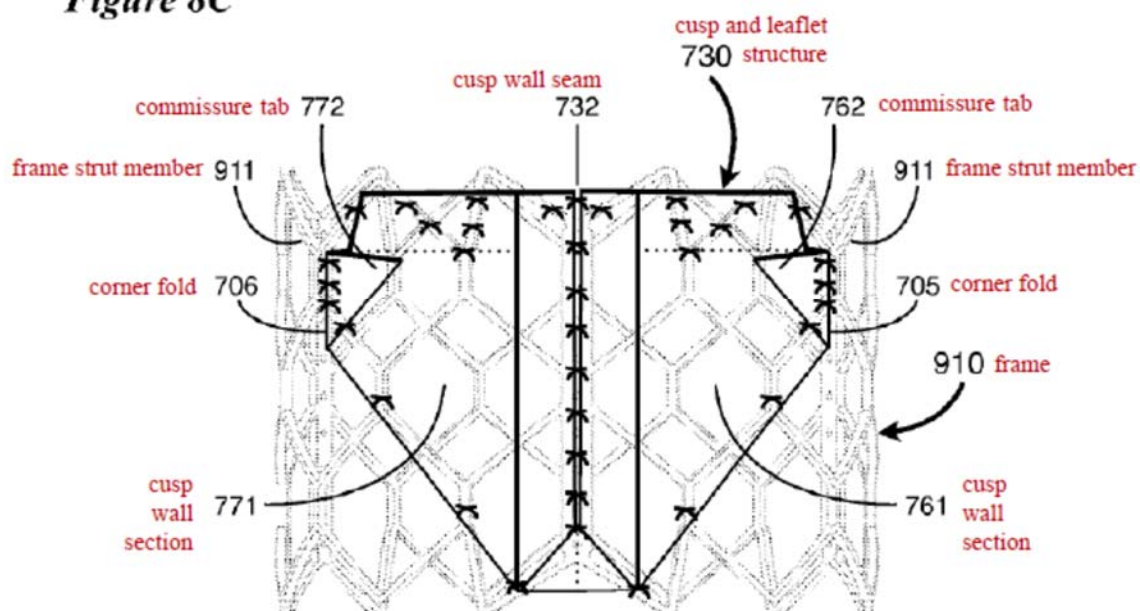


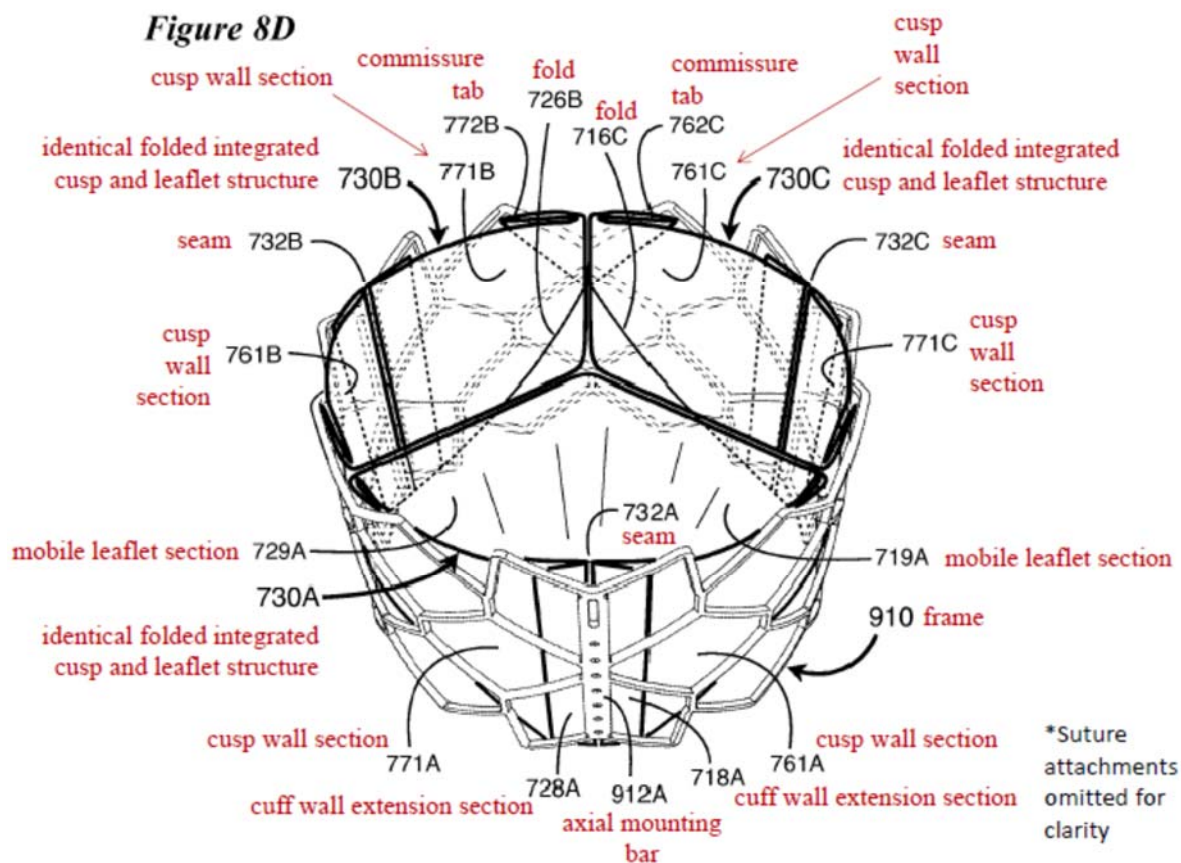
Figure 7J



Id., Figs. 7B, I, J. Figure 8 of the '400 Patent details this folded structure assembled and attached to a lattice frame:

Figure 8C





Id., 24:43-46, 25:7-12, Figs. 8C-D.

The '400 Patent highlights that in embodiments such as Figure 7 where “the membrane valve leaflet is attached at a non-commissural seam or edge, effecting a coaxial (to the flow axis) line of attachment at an area of the structure that advantageously bears load, ... the leaflet commissure attachments, thus located at points where the leaflet membrane is continuous and uncut, advantageously need only bear the centripetal loads associated with the radially inward movement and operation of the free edges of the leaflets.” *Id.*, 3:26-57; EX1026, ¶¶66-67. This, however, is not a structural limitation in any of the Challenged Claims, which do

not provide any limitations directed to the commissure attachment or the attachment of each valve leaflet.

B. Prosecution Overview

As initially filed, the '196 Application contained thirty-four claims. EX1002, 90-97. All originally filed claims were narrowly tailored as each was directed to a prosthetic heart valve having, in part, an “integrated cusp and leaflet folded structure,” a feature explicitly defined by the specification to be limited to “a membrane folded in accordance with one of the [seven] patterns described herein.” *See id.*; *see also* EX1001, 13:14-16; EX1026, ¶¶68, 82. Applicant subsequently added sixty-one new claims, including broad independent claims 65, 70, and 77. New claims 65, 70, and 77 were directed to a “vascular system implant,” and thus not limited to heart valves, and did not require an “integrated cusp and leaflet folded structure.” EX1002, 2140-55; EX1026, ¶¶69-70. These three claims ultimately issued as Claims 55, 60, and 67, which are the three independent claims challenged in this Petition. EX1002, 3905; EX1026, ¶¶71-77.

During prosecution, Applicant listed in its Information Disclosure Statements several search reports from the World Intellectual Property Organization (“WIPO”), IP Australia (“IPAU”), State Intellectual Property Office of China (“SIPO”) and Japan Patent Office (“JPO”), concerning related foreign applications, each of which claimed priority to the '196 Application and included

claims limited to prosthetic heart valves having an “integrated cusp and leaflet folded structure.” Even with respect to these more narrowly tailored claims, three of the four foreign authorities—IPAU, SIPO, and JPO—issued preliminary opinions finding the as-filed claims invalid in view of certain prior art. EX1002, 2113-21 (PCT Search Report, cited by IDS at 2094-98); 3267-69 (IPAU Report No. 1, cited by IDS at 2165-74); 3303-12 (IPAU Report No. 2, cited by IDS at 3303-12); 3512-26 (SIPO Report, cited by IDS at 3387-90); 3614-22 (JPO Report, cited in IDS at 3569-72)). Among the prior art identified and relied upon by these foreign authorities were Melsheimer, Braidó, and Eberhardt. Despite the identification and reliance on these prior art references by multiple foreign authorities, none of these references were relied upon by the Examiner during prosecution of the ’196 Application. EX1026, ¶78.

The initial review of the ’196 Application was driven by a series of three restriction requirements. EX1002, 2133-38, 3276-80, 3528-32. In response to the second restriction requirement, Applicant amended the claims such that each independent claim required “non-transverse folds” that are “diagonally oriented relative to an axial flow direction.” *Id.*, 3315-34. And, in response to the third restriction requirement, Applicant elected to prosecute species of the claimed invention “with an exposed apex” as illustrated in Figure 7A of the ’196 Application. *Id.*, 3533-53. No claims were further amended prior to issuance.

Following Applicant's final election and amendments, the Examiner issued only two substantive Office Actions, both of which repeated nearly identical seven-sentence long rejections of all 85 pending claims based on the combination of a stentless valve with a stent. *See* EX1002, 3626-29, 3827-30 (first Office Action relying on U.S. Patent Application Publication No. 2002/0052651 (EX1014, "Myers") in view of U.S. Patent No. 6,287,335 (EX1015, "Drasler"); second Office Action relying on U.S. Patent Application Publication No. 2006/0229716 (EX1016, "Mitrev") in view of U.S. Patent Application Publication No. 2002/0198594 (EX1019, "Schreck")). Notwithstanding the merits of the Examiner's rejection, the Office Actions overlooked a series of required claim elements, including the "substantially conical shaped cusps" requirement in pending claim 65 and the "non-rectangular polygonal mobile leaflet" requirement in pending claims 70 and 77. EX1026, ¶¶72-76. Indeed, in Applicant's Responses to each Office Action, it argued that the Office Actions failed to establish a *prima facie* case of obviousness, as to each independent claim, "by not even discussing [certain claimed] limitations at all[.]" *See* EX1002, 3791-92, 3870-71 (emphasis in original).

Applicant conducted an interview with the Examiner on February 13, 2017. *Id.*, 3848. The Examiner's summary simply stated that Applicant's "arguments were persuasive, and no amendments to the claims will be required." *Id.* The

Examiner subsequently issued a Notice of Allowance on April 24, 2017. EX1002, 3889-95.

IV. GROUNDS (§§42.22 and 42.104(b))

Edwards requests IPR and cancellation of Claims 55-72, 78-80, and 83-85 of the '400 Patent as set forth below in Section V, Grounds 1-8.

V. DETAILED REASONS FOR RELIEF

A. Claim Construction

Under *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (*en banc*), claim terms are presumed to have their ordinary and customary meaning in light of the patent's specification as understood by a POSITA at the time of the invention, unless (1) the patentee acts as its own lexicographer by setting out a definition in the specification, or (2) the patentee disavows the full scope of a claim term in either the specification or during the prosecution of the patent.

The '400 Patent is somewhat unique given the sheer number of terms the Applicant defined in the specification and thus acted as its own lexicographer. EX1026, ¶81. Of those terms explicitly defined by the specification of the '400 Patent, the following pertain to claim terms in the Challenged Claims:

	<u>Term</u>	<u>Definition</u>	<u>Citation</u>
1	"cusp"	"[T]hat structural portion of a valve related to a single leaflet that encompasses a space closed	12:4-11

	<u>Term</u>	<u>Definition</u>	<u>Citation</u>
		toward the lower (proximal) direction and open to the upper (distal) direction, formed by the joined and/or continuous structures of the mobile leaflet portion on the radially inner side and the cusp wall portion on the radially outer side. The ‘cusp’ in the present invention is that structure described as having a substantially conical shape.”	
2	“cuff wall layer” ⁷	“[A] portion of the folded membrane structure that resides radially outward of both the cusp wall layer and the mobile leaflet layer, and where present, is radially closest to the frame of the three layers comprising the mobile leaflet layer, the cusp wall layer, and the cuff wall layer.”	12:25-31

⁷ Although the Challenged Claims recite only “cuff wall” (*e.g.*, Claim 62), there is no apparent distinction between this term and “cuff wall layer” as defined by the specification. EX1026, ¶81 n.6.

	<u>Term</u>	<u>Definition</u>	<u>Citation</u>
3	“cusp wall layer” ⁸	“[A] portion of the cusp that resides radially outward of the mobile leaflet layer.”	12:19-21
4	“frame”	“[A] substantially tubular member that holds a plurality of cusps and/or leaflets.”	12:32-33
5	“mobile leaflet layer” or “leaflet”	“[T]hat radially inward portion of the cusp that moves during operation of the valve”	12:12-14
6	“proximal”	“[S]ituated near or closer to the upstream or flow inlet end of the valve.”	11:59-60
7	“substantially conical”	“[R]esembling a cone or a portion thereof at some point in the practical use of the structure with the specific property that the transverse (that is, on a plane of section generally perpendicular to the axis of flow of the valve) cross-sectional perimeter or area of said structure in the operationally closed position	12:47-54

⁸ Although the Challenged Claims recite only “cusp wall” (*e.g.*, Claim 61), there is no apparent distinction between this term and “cusp wall layer” as defined by the specification. EX1026, ¶81 n.6.

	<u>Term</u>	<u>Definition</u>	<u>Citation</u>
		decreases monotonically moving from the level of the leaflet apposition to the proximal end of the valve.”	
8	[non-] “transverse”	“transverse” is defined by the specification as “on a plane of section generally perpendicular to the axis of flow of the valve”; “non-transverse” thus means “not on a plane of section generally perpendicular to the axis of flow of the valve.”	12:49-51
9	“two or more leaflets,” “two or more valve leaflets,” “a plurality of leaflets,” “or a similar term”	“[T]wo, three, four, or more valve leaflets.”	12:55-57

A claim term that is not explicitly defined by the specification but requires construction is “folds.” The specification does define the verb “folding” in the context of folding dry tissue as “the partition of a flat sheet section of material

along a sharp line of folding or crease into subsections each lying on separate planes, but without interruption of material continuity.” EX1001, 12:61-64. But dry tissue is not a requirement in any of the Challenged Claims. When referring to the resulting “folds” of the valve (as opposed to the “folding” of the valve), the inventors recognize that the folds are naturally relaxed when hydrated. “[W]hen applied to a dry sheet membrane, the folding initially results in a cusp shape of an inverted pyramid with a rhomboid base. On relaxation of the folds as occurs naturally with a flexible and pliable membrane, especially when the membrane is hydrated, the cusp shape becomes substantially conical in shape and will be described as such in the ensuing descriptions as it more closely represents the embodiment of the cusp in operation of the valve.” *Id.*, 10:6-19. Accordingly, “folds” as claimed are lines that partition a flat-sheet section of material into subsections each lying on separate planes, but without interruption of material continuity. EX1026, ¶83. If the material is dry, the “fold” forms a sharp line or crease; if the material is hydrated, the “fold” will be relaxed. *Id.*

Finally, the ’400 Patent does not explicitly define a biocompatible membrane that “does not comprise a treated tissue” as required by Challenged Claims 58, 65, and 71. The specification provides no additional disclosure concerning the meaning of this term, but read in context, a POSITA would understand a biocompatible membrane that “does not comprise a treated tissue” at

least includes a biocompatible membrane made with a synthetic material. EX1026, ¶84. Read literally, this limitation would also include a biocompatible membrane made with untreated biological tissue, but a POSITA would recognize that as an impractical option due to biocompatibility risks. *Id.* at ¶84 n.9.

B. Level of Ordinary Skill

As proposed by Jonathan Rourke and adopted herein by Edwards, a POSITA as of the priority date of the '400 Patent would have been a mechanical engineer, medical device engineer, or an interventional cardiologist with a working knowledge of stent-based prostheses for use in a patient's heart or vasculature to replace and/or repair a diseased valve, intravascular delivery systems for the delivery of such prostheses, and methods associated with the delivery and implantation of such prostheses in a patient. EX1026, ¶27.

C. Anticipation

1. Ground 1: Claims 55-56, 58-59, 60-61, 63, and 65-66 are anticipated by Melsheimer (EX1003)

a) Element 55[p]

Melsheimer discloses a vascular system implant. EX1026, ¶87. “The present invention relates to medical devices, and in particular to prosthetic valves having at least one leaflet and a receptacle connected thereto for implantation in a body site for regulation of fluid flow through the body site.” EX1003, ¶[0036]. Melsheimer discloses that the valves are suitable for use as valves in the heart,

veins, and other passageways in the body. *Id.*

b) Element 55[a]

Melsheimer discloses a lattice frame, which it refers to as a “support frame that provides a stenting function.” *Id.*, ¶[0050]-[0051]; EX1026, ¶¶88-89. One embodiment of Melsheimer’s support frame is shown in Figure 6, element 150:

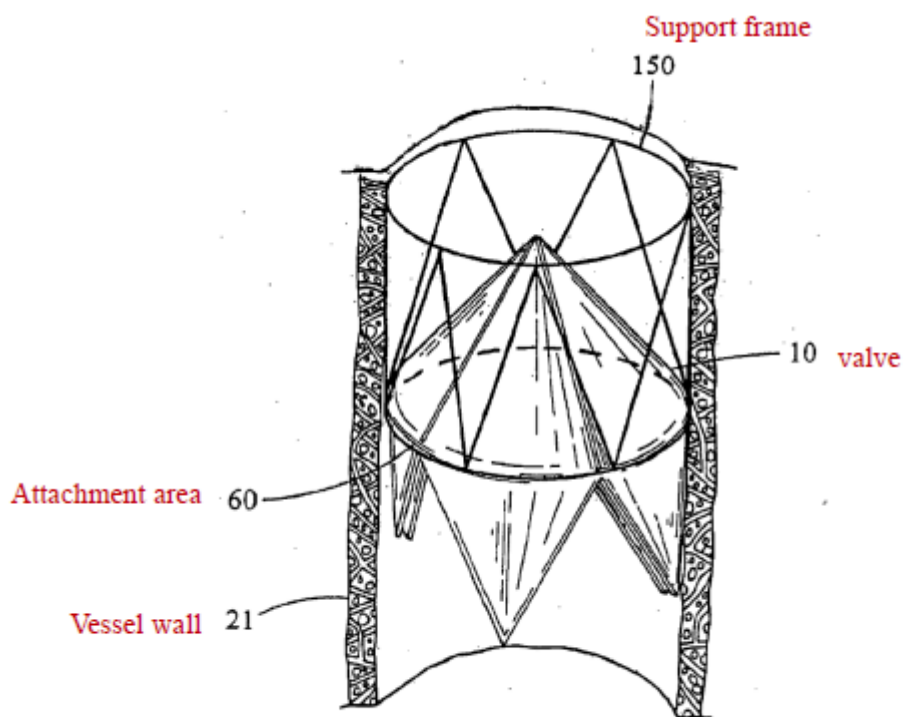
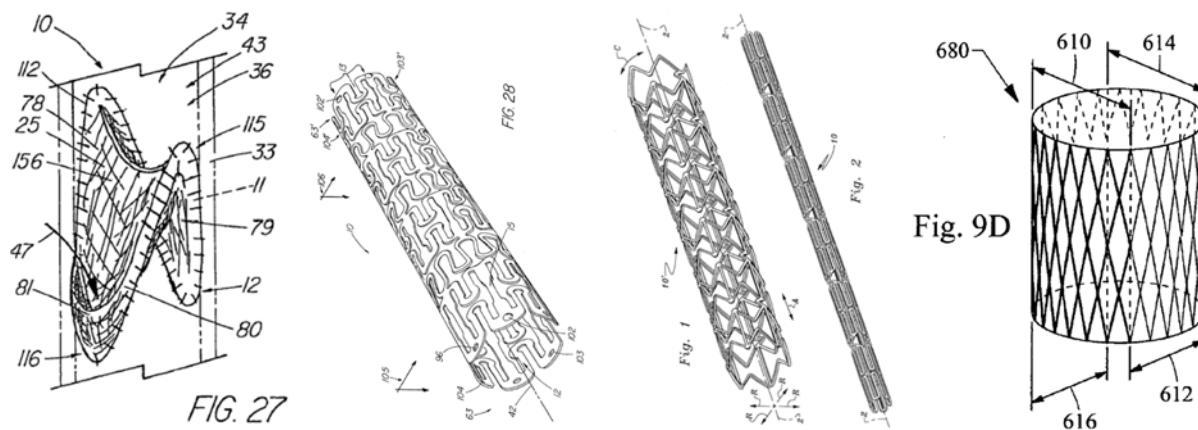


Fig. 6

EX1003, Fig. 6.

Melsheimer also incorporates by reference multiple prior art lattice frames as alternatives to the frame in Figure 6. “Examples of suitable frames 150 for use in the valve of the present invention include those described in U.S. Pat. Nos.

6,508,833; 6,464,720; 6,231,598; 6,299,635; 4,580,568; and U.S. Patent Application Publication Nos. 2004/018658 A1 [sic⁹] and 2005/0228472 A1, all of which are hereby incorporated by reference in their entirety.” EX1003, ¶[0053]; EX1008, EX1020-1025. Several of these alternative frame structures are depicted below:



EX1008, Fig. 16; EX1021, Fig. 28; EX1023, Figs. 1-2; EX1025, Fig. 9D.

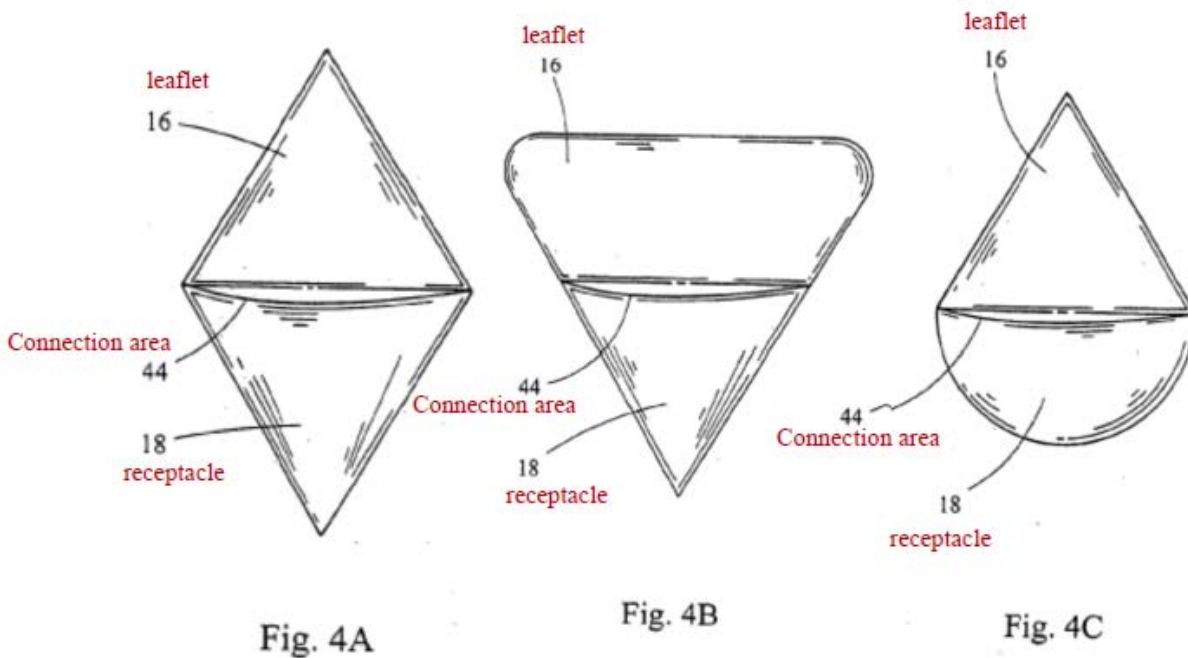
c) Element 55[b]

Melsheimer discloses a plurality of substantially conical shaped cusps preferably formed from a folded sheet of material, each having a “receptacle” and a

⁹ Melsheimer appears to have intended to incorporate Pavcnik’s U.S. Patent Application Publication No. 2004/0186558 (Ex. 1008), which shares a common assignee with Melsheimer, not “2004/018658,” which is an application unrelated to heart valve prostheses. *See* Ex. 1030 (IDS filed during prosecution of Melsheimer, which lists “2004/0186558,” not “2004/018658.”); EX1026, ¶89 n.10.

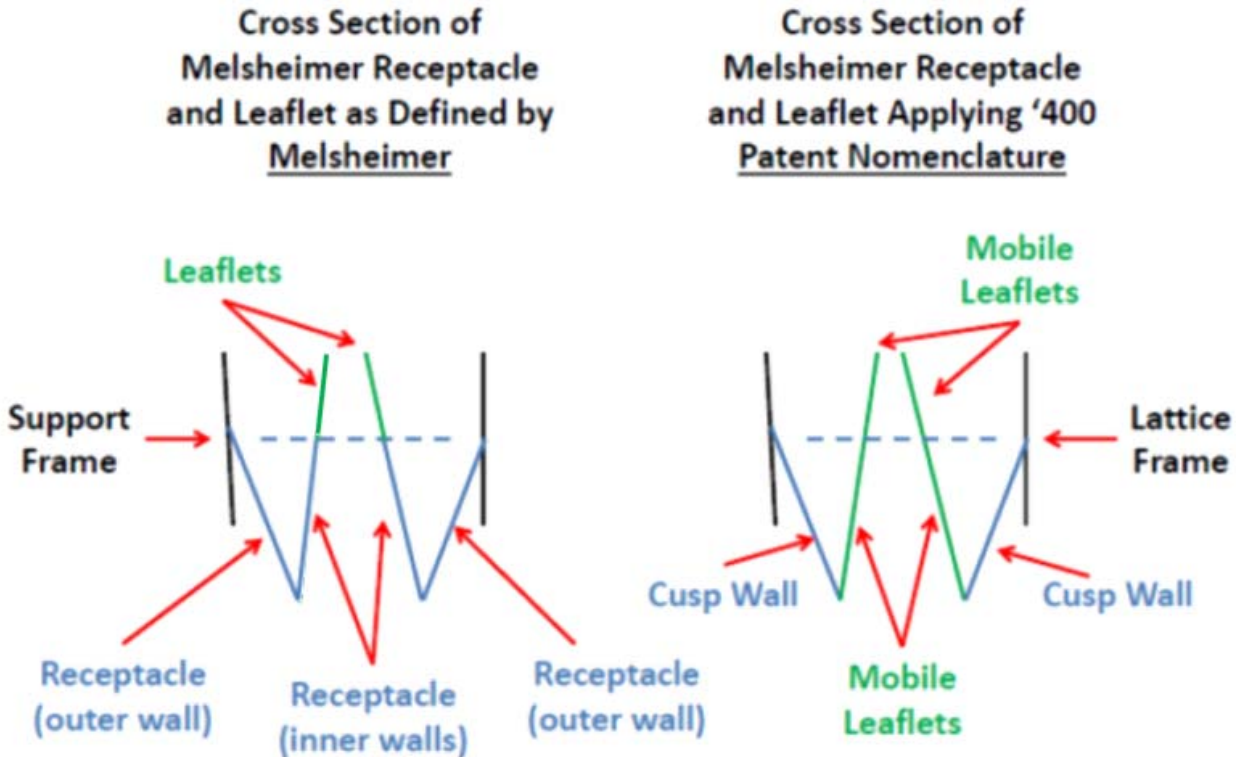
“leaflet”, wherein the cusps are attached to the surrounding lattice frame. EX1003, ¶¶[0038], [0048]-[0053], Fig. 6 (valve (10) and attachment area (60); EX1026, ¶¶90-94. “Each receptacle 18 is operatively connected to each leaflet 16 and moves in response to fluid flow in the first direction 20 and the second direction 22. As shown in FIG. 1A, the receptacles 18 extend proximally from the leaflets 16 and expand to form a conically shaped pocket for receiving fluid when the flow is in the second direction 22. Each receptacle 18 includes an inner wall 40 generally toward the center of the vessel 21 and outer wall 42 generally toward the wall of the vessel 21. The inner wall 40 and the outer wall 42 are joined together at a perimeter 46 to form the receptacle 18 for receiving fluid in the second direction 22.” EX1003, ¶[0040] (emphasis added).

“As shown in FIGS. 4A-C, the shape of the leaflets 16 and chambers 18 may be triangular, curvilinear, or any shape that will allow the leaflets 16 to form a contact region and the receptacle 18 to form a pocket for receiving fluid in the second direction 22. The shape of the leaflet 16 may be the same as the shape of the receptacle 18 or different.” *Id.*, ¶[0041].



Id., Figs. 4A-4C.

As supported by Jonathan Rourke, the entire structure shown in, *e.g.*, Figures 4A-4C of Melsheimer makes up a single “cusp” as claimed by the ’400 Patent, which, in turn, comprises “cusp wall” and “mobile leaflet” portions as claimed by the ’400 Patent. EX1026, ¶93. Viewing Melsheimer in the context of the ’400 Patent, the combination of Melsheimer’s “inner wall” of the “receptacle” and the “leaflet” portion make up the “mobile leaflet” detailed by the ’400 Patent, and the “outer wall” of Melsheimer makes up the “cusp wall” detailed by the ’400 Patent. That is, there is no structural difference between the ’400 Patent’s “leaflet” and Melsheimer’s “inner wall”/“leaflet” combination. *Id.* It is a difference only in nomenclature, which is highlighted in the below schematic:



Id.

d) Element 55[c]

The substantially conical shaped cusps of Melsheimer include a biocompatible membrane, which can be formed from a host of biological materials, including pericardium. EX1003, ¶¶[0058] (“The material or materials need only be biocompatible or able to be rendered biocompatible.”), [0063] (listing “pericardium” among other “bioremodelable materials”); EX1026, ¶¶95-96.

e) Element 55[d]

Melsheimer discloses that “the valve device 10 may preferably be formed by folding a sheet 200 of material to form the leaflets 16 and the receptacles 18 and the opening 26 therethrough.” EX1003, ¶[0106]. As visually represented in

Figures 8A-8H (and described at Paragraph [0108]), Melsheimer provides a series of instructions detailing how to form an exemplary folded valve structure:

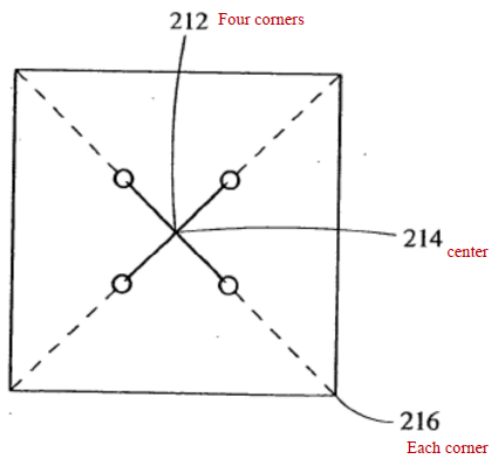


Fig. 8B

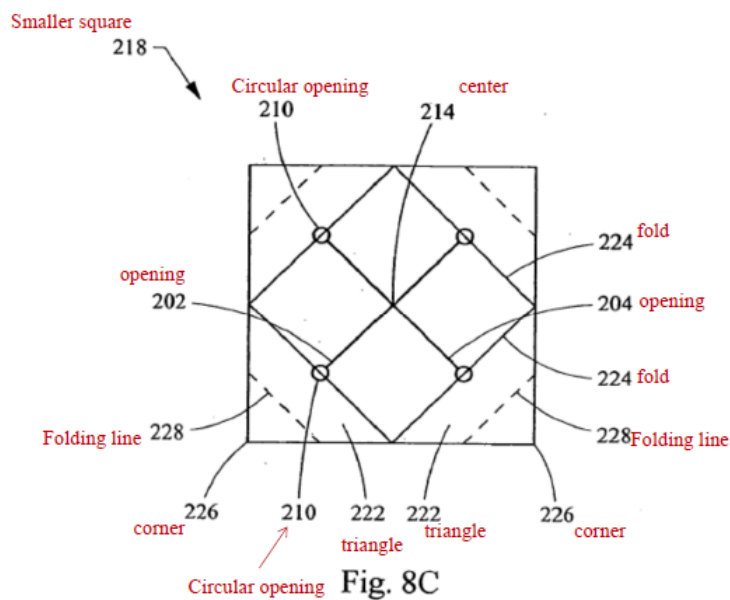


Fig. 8C

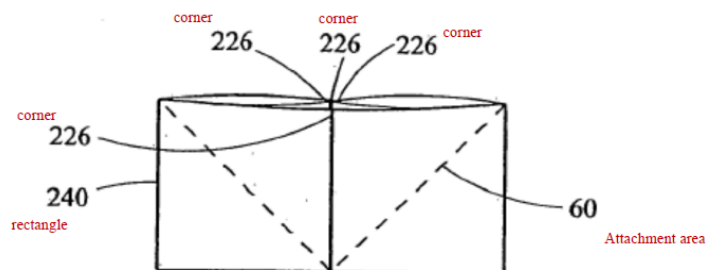
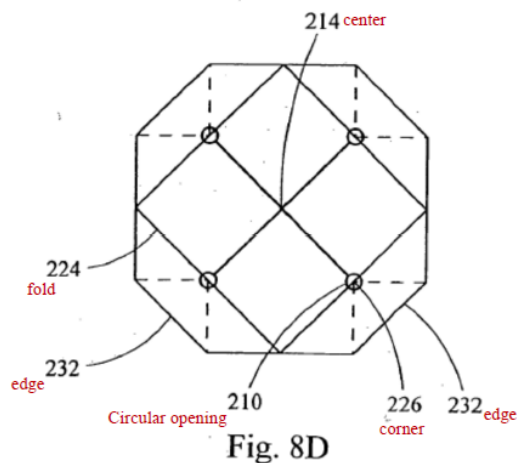


Fig. 8G

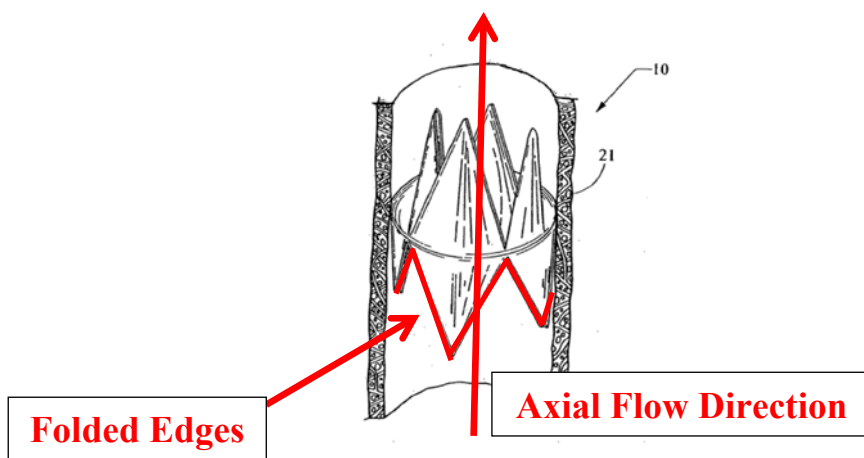
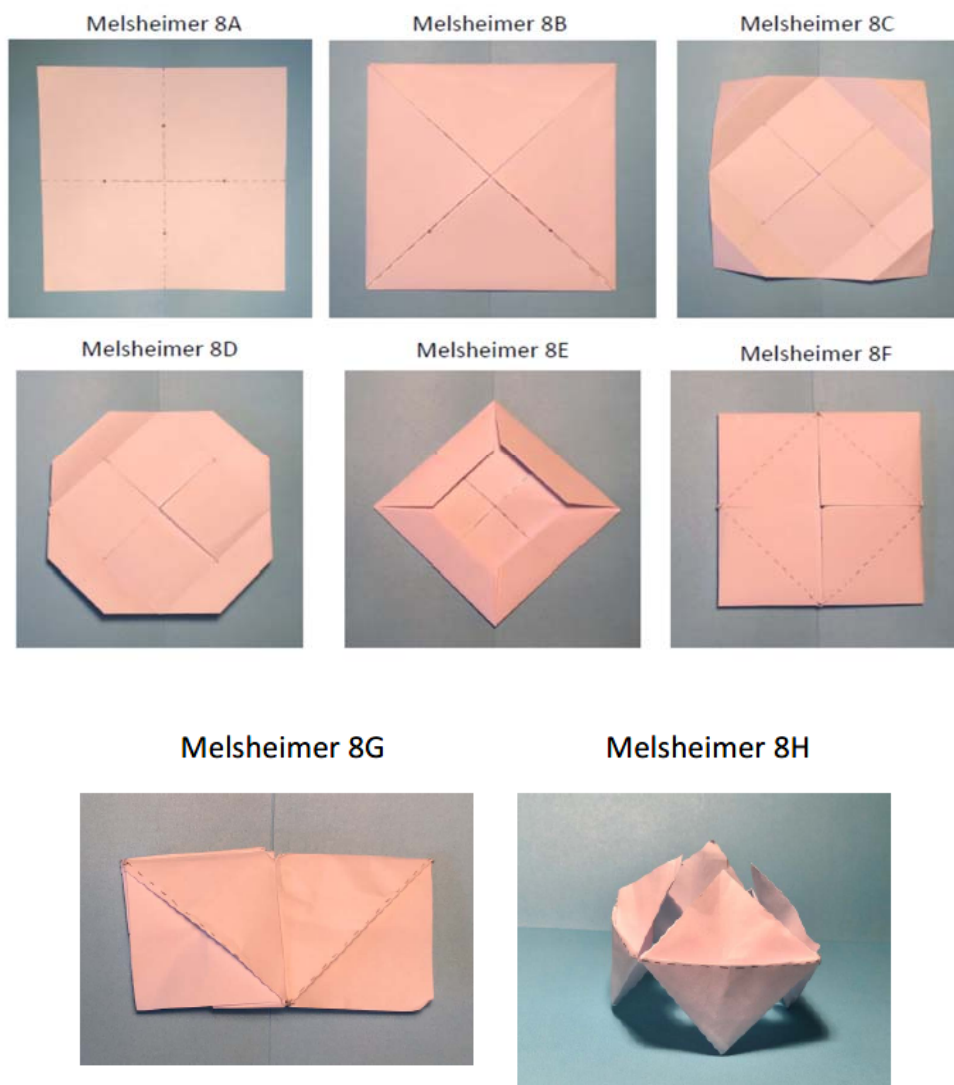


Fig. 8H

Id., Figs. 8B-D, G, H. As shown in annotated Fig. 8H above, the plurality of substantially conical cusps of Melsheimer comprise non-transverse diagonally

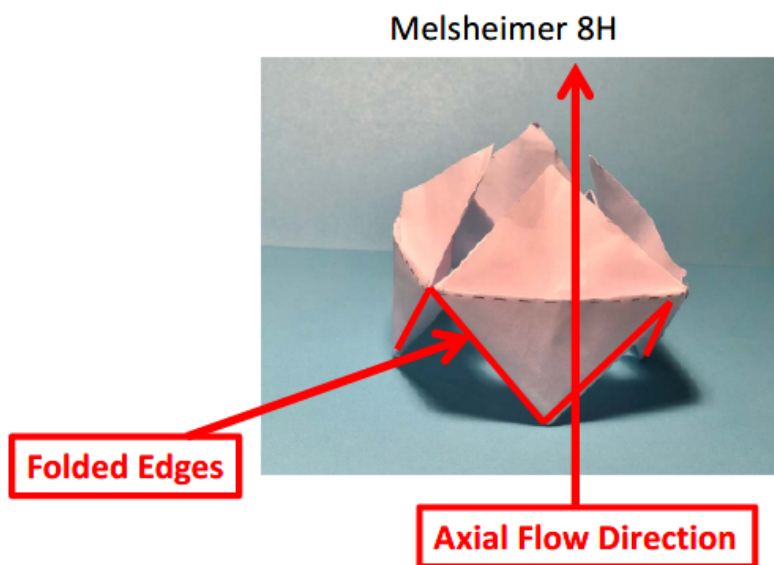
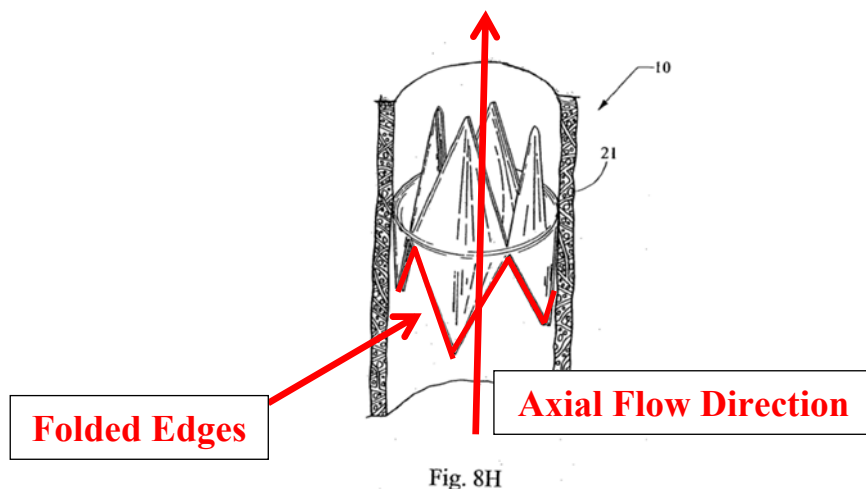
oriented folds angled relative to an axial flow direction. EX1026, ¶¶97-99.

To further illustrate Melsheimer's disclosure, a paper sample was made of Melsheimer's folded valve structure depicted in Figures 8A-H by following the folding instructions of Melsheimer. EX1026, ¶¶100-101. Below are pictures at various stages of the folding sequence:



EX1028. As expected, the paper model includes folded edges that would be

angled relative to an axial flow direction, and which correspond to annotated Figure 8H of Melsheimer above:



See EX1028; EX1026, ¶101.

f) Claim 56

Melsheimer discloses the vascular system implant of Claim 55 as detailed above.

The lattice frames disclosed by Melsheimer are tubular stent members, *see*

supra Section V.C.1.(b), which are collapsible and expandable. EX1003, ¶¶[0050-0051] (“support frame 150 can be compressed ... and allowed to subsequently expand to another configuration.”); EX1026, ¶¶103-104. The frame may be formed with a number of materials, including metal alloy. EX1003, ¶[0070] (listing, *e.g.*, stainless steel, nickel titanium (*i.e.*, Nitinol), MP35N, cobalt chromium, and “other biocompatible metals and/or alloys”).

g) Claim 58

Melsheimer discloses the vascular system implant of Claim 55 as detailed above.

Melsheimer further discloses that its biocompatible membrane can be formed from biological and synthetic materials. EX1003, ¶[0058]. When using a synthetic material such as polyurethane, *see id.*, ¶[0072], the biocompatible membrane “does not comprise a treated tissue” as claimed. EX1026, ¶¶105-106.

h) Claim 59

Melsheimer discloses the vascular system implant of Claim 55 as detailed above.

As noted above, the biocompatible membrane of Melsheimer can be formed with biological or synthetic materials. *Supra* Section V.C.1.(g) (citing, *e.g.*, EX1003, ¶[0072] (“The valves ... may be formed with ... biocompatible polyurethanes.”)); EX1026, ¶¶107-108.

i) Element 60[p]

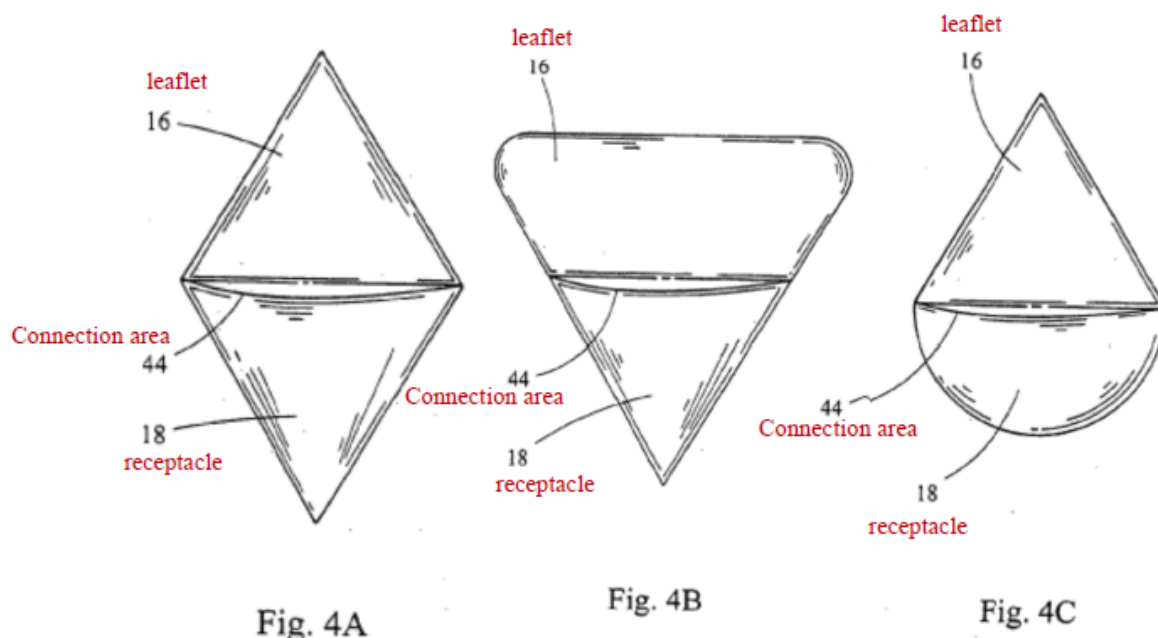
Melsheimer discloses a vascular system implant as detailed above. *Supra* Section V.C.1.(a).

j) Element 60[a]

Melsheimer discloses a lattice frame as detailed above. *Supra* Section V.C.1.(b).

k) Element 60[b]

As detailed above, *supra* Section V.C.1.(c), Melsheimer discloses a plurality of leaflets attached to the lattice frame. These leaflets can be non-rectangular polygonal in shape. EX1003, ¶[0041] (“the shape of the leaflets 16 and chambers 18 may be triangular, curvilinear, or any shape that will allow the leaflets 16 to form a contact region and the receptacle 18 to form a pocket for receiving fluid in the second direction 22.”); EX1026, ¶¶111-115. Non-limiting examples of leaflet shapes are shown in Figures 4A-4C:



EX1003, Figs. 4A-4C.

Again, as supported by Jonathan Rourke, the entire structure shown in, *e.g.*, Figures 4A-4C of Melsheimer makes up a single “cusp” as claimed by the ’400 Patent, which comprises a “mobile leaflet” portion. EX1026, ¶113. The combination of Melsheimer’s “inner wall” of the “receptacle” and the “leaflet” portion make up the “mobile leaflet” described by the ’400 Patent. As shown in Fig. 4A above and in Fig. 8G below, this “mobile leaflet” structure can take the form of a diamond/rhombus-shaped non-rectangular polygon:

Fig. 8G

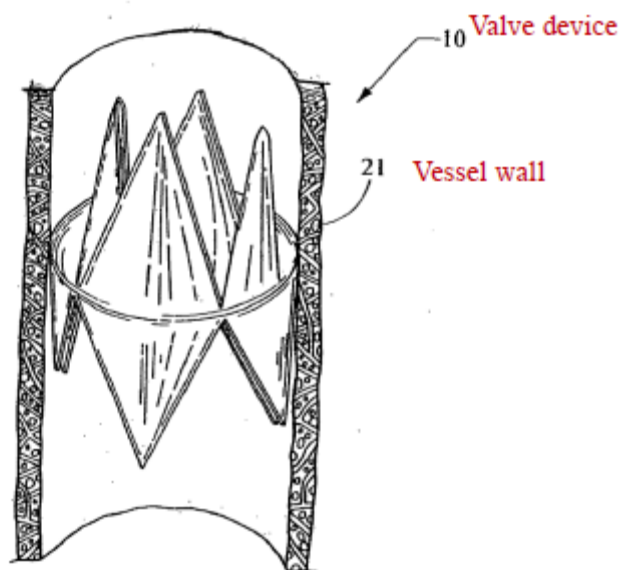
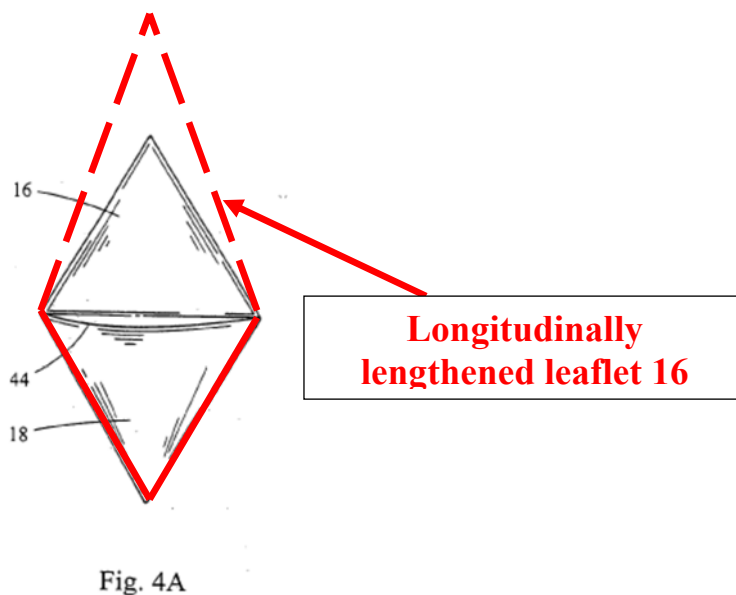


Fig. 8H

EX1003, Fig. 8H.

In addition, “[o]ne of skill in the art will understand how to maximize the leaflet contact region 28, for example, by lengthening the leaflets 16 longitudinally along the longitudinal axis of the vessel 21 with respect to the diameter of the vessel 21 into which the valve device 10 is implanted. Preferably, by lengthening the leaflet contact region 28, the valve device 10 will substantially seal during retrograde flow in the direction 22 so that undesired retrograde flow through the opening 26 may be minimized.” *Id.*, ¶[0043]. If the leaflet portions in, *e.g.*, Melsheimer’s Figure 4A embodiment are lengthened longitudinally, a non-rectangular polygonal leaflet would still be present, but the polygonal shape would

no longer be a rhombus, and instead would be akin to the polygonal shape highlighted in red below:



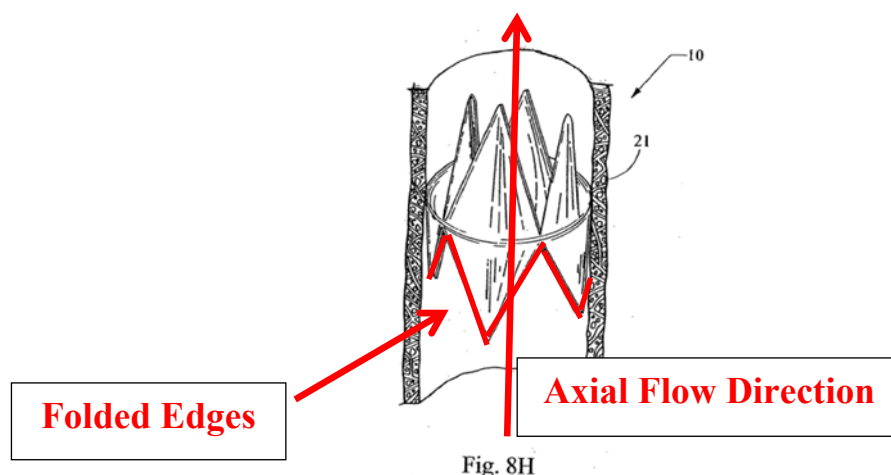
Id., Fig. 4A; EX1026, ¶¶114-115.

l) Element 60[c]

Melsheimer discloses that its mobile leaflets are formed with a biocompatible membrane as noted above. *Supra* Section V.C.1.(d).

m) Element 60[d]

Melsheimer discloses non-transverse diagonally oriented folds that are angled relative to an axial flow direction as detailed above. *Supra* Section V.C.1.(e). The folds border the plurality of non-rectangular polygonal mobile leaflets:



EX1003, Fig. 8H; EX1026, ¶117.

n) Claim 61

Melsheimer discloses the vascular system implant of Claim 60 as detailed above.

Melsheimer further discloses that each of the plurality of non-rectangular polygonal mobile leaflets is attached in a continuous manner to a corresponding cusp wall located radially exterior to each of the plurality of non-rectangular polygonal mobile leaflets. EX1026, ¶¶118-119. Again, it is Melsheimer's "leaflet 16" combined with the "inner wall 40" of "receptacle 18" that forms the "mobile leaflet" as claimed by the '400 Patent. *Supra* Section V.C.1.(c). "The leaflet 16 and the receptacle 18 may be integrally connected, formed by unitary construction from the same material" EX1003, ¶[0042]. The outer wall of the receptacle forms the "cusp wall" as claimed, which is located radially exterior to each of the plurality of non-rectangular polygonal mobile leaflets. "The inner wall 40 and the

outer wall 42 are joined together at a perimeter 46 to form the receptacle 18 for receiving fluid in the second direction 22.” *Id.*, ¶[0040].

o) Claim 63

Melsheimer discloses the vascular system implant of Claim 60 as detailed above.

Melsheimer further discloses a lattice frame that is collapsible and expandable and comprises a metal alloy substantially configured as a tubular stent member as detailed above. *Supra* Section V.C.1.(f).

p) Claim 65

Melsheimer discloses the vascular system implant of Claim 60 as detailed above.

Melsheimer further discloses a biocompatible membrane that does not comprise a treated tissue as detailed above. *Supra* Section V.C.1.(g).

q) Claim 66

Melsheimer discloses the vascular system implant of Claim 60 as detailed above.

Melsheimer further discloses a biocompatible membrane that comprises a synthetic material as detailed above. *Supra* Section V.C.1.(h).

D. Obviousness

1. Ground 2: Claims 57, 64, 78, and 79 are obvious over Melsheimer (EX1003) alone or in combination with Eberhardt (EX1006)

a) Claim 57

Melsheimer discloses the vascular system implant of Claim 55 as detailed above.

As noted, pericardium is among the biological materials disclosed by Melsheimer as suitable for use with the device. EX1003, ¶¶[0058], [0063]. The pericardium can be crosslinked with glutaraldehyde for “increased resistance to biodegradation and reduced antigenicity.” *Id.*, ¶[0103]. As supported by Jonathan Rourke and texts published contemporaneously with the ’400 Patent’s priority date, a POSITA would understand that Melsheimer’s broad disclosure of pericardium includes processed mammalian pericardium given that mammalian pericardium was the only type of pericardium used in prosthetic heart valves as of the priority date of the ’400 Patent. EX1026, ¶¶123-126; EX1027, 230, 233; EX1032, 1-2 (noting that “[p]ericardial valves are fabricated from sheets of bovine pericardium mounted inside or outside a supporting stent” and also detailing the CoreValve device, which is made with porcine pericardium).

Nevertheless, to avoid any doubt, it separately would have been obvious to a POSITA to select mammalian pericardium for use in Melsheimer. EX1026,

¶¶127-128. By way of example, Eberhardt, like Melsheimer, discloses a transcatheter valve that can be formed with a biocompatible membrane made with pericardial tissue or synthetic material, and further discloses that the pericardial tissue is processed mammalian pericardial tissue. “In accordance with the invention, a relatively flat sheet of pericardium material 10 is provided, which may be obtained, for example, from a porcine heart. It is understood that other donor species may alternatively be used, or that the material used is not a pericardium material but instead is a different type of tissue or material, such as a polymer or bio-engineered film. The pericardium material 10 may be at least partially fixed or cross-linked with a buffered gluteraldehyde solution or other solution at some point during the assembly process, in order to make the material easier for an operator to handle and manipulate.” EX1006, ¶[0038]; *see also id.*, ¶[0040] (“The pericardium material 10 is folded on itself at fold line 16 to effectively double the thickness of at least a portion of the material 10.”).

As supported by Jonathan Rourke, a POSITA would have been motivated to select processed mammalian pericardium, and would have had a reasonable expectation of success in doing so, given that processed mammalian pericardium was regularly used with prosthetic valves as of the '400 Patent's priority date, and, in particular, the two commercially approved transcatheter aortic heart valves known as of the priority date used processed mammalian (*i.e.*, bovine and porcine)

pericardium. EX1026, ¶128; EX1027, 230, 233; EX1032, 1-2. Ultimately, all the claimed elements of Claim 57 were known in the prior art as evidenced by the teachings of Melsheimer and Eberhardt and a POSITA could have combined the teachings of these elements as claimed by known methods with no change in their respective functions, and the combination would have yielded nothing more than predictable results to a POSITA. EX1026, ¶128.

b) Claim 64

Melsheimer discloses the vascular system implant of Claim 55 as detailed above.

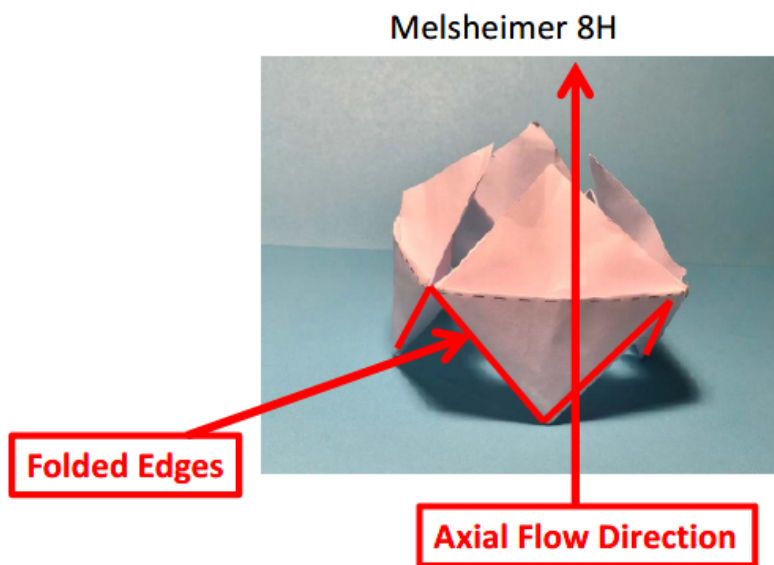
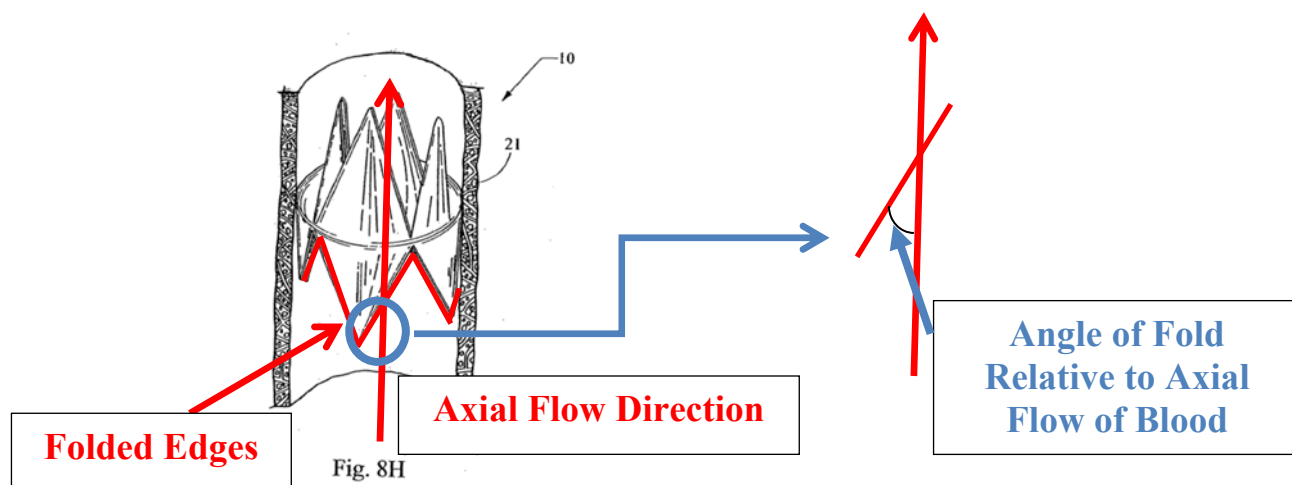
Moreover, Melsheimer discloses, or, alternatively, it would have been obvious to modify Melsheimer in view of Eberhardt to use, processed mammalian pericardium tissue as explained above. *Supra* Section V.D.1.(a).

c) Claim 78

Melsheimer discloses the vascular system implant of Claim 55 as detailed above.

Melsheimer does not explicitly disclose the angle of its non-transverse diagonally oriented folds relative to the axial flow direction, but it would have been apparent to a POSITA from the folding instructions provided for the exemplary Figure 8 embodiment, EX1003, ¶¶[0106]-[0109], that the angle of the folds relative to the axial flow direction fall approximately in the middle of the

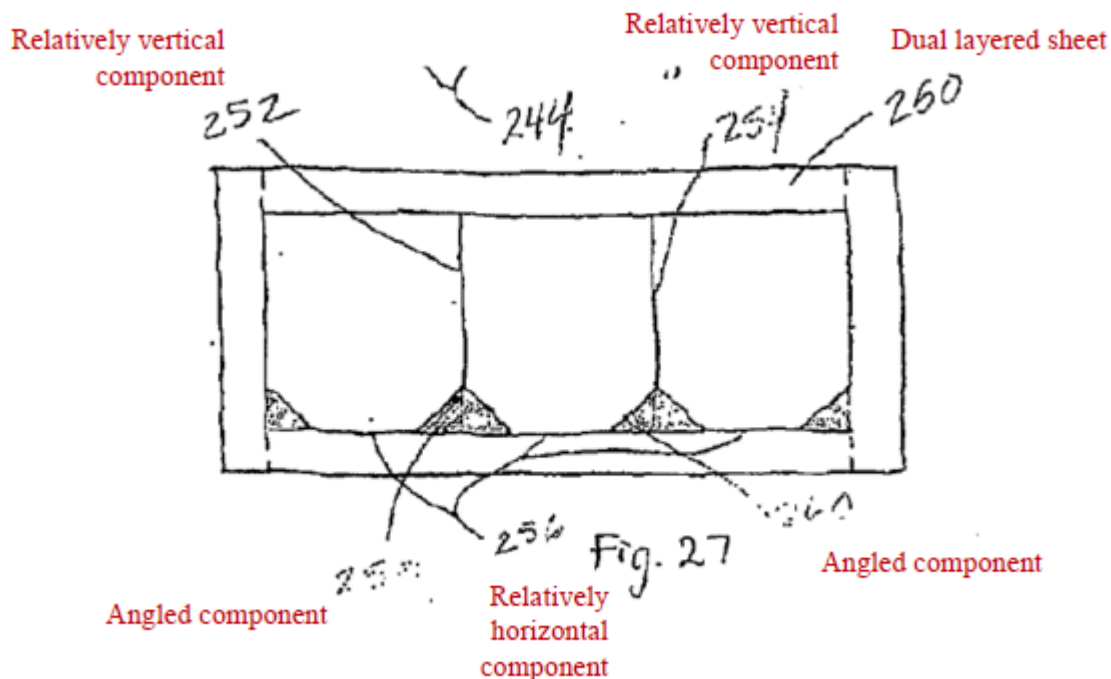
claimed range of 10-80 degrees:



Id., Fig. 8H; EX1028; EX1026, ¶¶130-131.

Moreover, to avoid any doubt, it separately would have been obvious to a POSITA to select an angle for the non-transverse diagonally oriented folds between about 10 to 80 degrees from the axial flow direction in view of the teachings of Eberhardt. EX1026, ¶¶132-135. Eberhardt teaches a prosthetic transcatheter valve having non-rectangular polygonal leaflet structures with angled

walls at their proximal end:



EX1006, Fig. 27. The angled walls are angled “slightly greater than approximately 0 degrees and at least slightly smaller than approximately 90 degrees” to “eliminate or minimize possible areas of stasis” and to “provide a non-abrasive surface over which the corresponding leaflet can hinge.” *Id.*, ¶[0061].

As supported by Jonathan Rourke, it would have been obvious to a POSITA to modify the angle of the of the non-transverse diagonally oriented folds of Melsheimer to fall within the range of slightly greater than approximately 0 degrees and at least slightly smaller than approximately 90 degrees, which encompasses the '400 Patent's claimed range of about 10 to 80 degrees from the

axial flow direction, to best minimize or eliminate possible areas of stasis and to provide a hinge point for adjacent leaflets. EX1026, ¶133. Further motivation is found in the teachings of Spenser, which recognized nearly a decade before the priority date of the '400 Patent that a “main goal[] in valve design ... is to distribute the stresses in a homogeneous way in the pericardium material and the attachment areas” and “[t]he shape of the leaflets in the valve assembly is determined by the boundary conditions,” which “can be designed to have an optimal shape regarding the stress distribution in accordance with geometrical restrictions.” EX1011, 25:39-65; EX1026, ¶134.

Moreover, all the claimed elements of Claim 78 were known in the prior art as evidenced by Melsheimer and Eberhardt, and a POSITA could have combined the teachings of these elements as claimed by known methods with no change in their respective functions, and the combination would have yielded nothing more than predictable results to a POSITA. EX1026, ¶135. Given that both Melsheimer and Eberhardt are directed to transcatheter valves having folded leaflets with angled side walls and the only feature of Claim 78 missing an express disclosure in Melsheimer is the angle of its folded edges, which is addressed by Eberhardt, a POSITA in the art would have had a reasonable expectation of success in combining these teachings. *Id.*

d) Claim 79

Melsheimer discloses the vascular system implant of Claim 60 as detailed above.

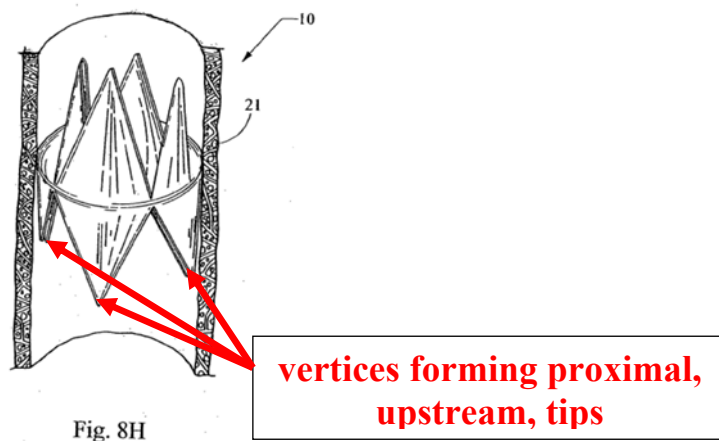
Moreover, Melsheimer inherently discloses, or, alternatively, it would have been obvious to modify Melsheimer in view of Eberhardt to use, non-transverse diagonally oriented folds that are angled between about 10 to 80 degrees from the axial flow direction as explained above. *Supra* Section V.D.1.(c).

2. Ground 3: Claims 62, 83, and 84 are obvious over Melsheimer (EX1003) in view of Pavcnik (EX1008)

a) Claim 62

Melsheimer discloses the vascular system implant of Claim 61 as detailed above.

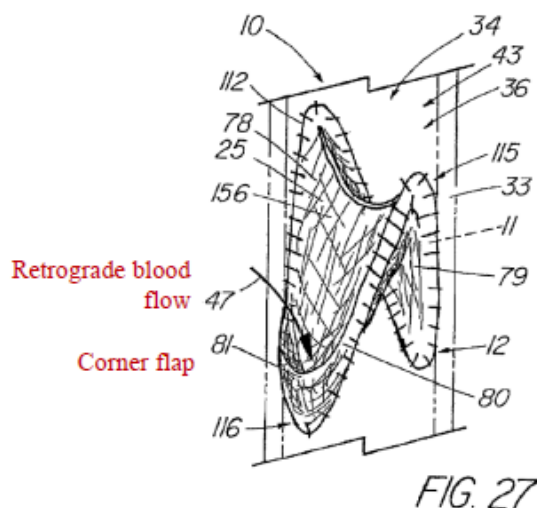
Moreover, the plurality of conical shaped cusps disclosed by Melsheimer each include a vertex forming a proximal, upstream tip, as highlighted below:



EX1003, Fig. 8H. Melsheimer does not explicitly disclose whether these tips can

be folded over in a radially outward direction and attached to the lattice frame as claimed by the '400 Patent (in, *e.g.*, Claim 83), such that a cuff wall located radially exterior to each of the non-rectangular polygonal mobile leaflets and cusp walls is formed and attached to the lattice frame as claimed in Claim 62.

Pavcnik discloses valve cusps that include a vertex forming a proximal, upstream tip that can be folded over in a radially outward direction and attached to the lattice frame to form a “corner flap.” EX1008, ¶[0104]. “This corner flap 81 can serve to catch retrograde blood flow 47 to provide a better seal between the device 10 and the vessel wall 70 as well as providing an improved substrate for ingrowth of native intimal tissue from the vessel 33, if made of SIS or another material with remodeling properties.” *Id.*



Id., Fig. 27.

It would have been obvious to a POSITA to combine the teachings of

Melsheimer and Pavcnik such that the plurality of conical shaped cusps of Melsheimer that form a proximal, upstream tip are provided with sufficient tissue to form an overhang, which can be folded over in a radially outward direction and attached to the lattice frame radially exterior to the mobile leaflets and cusp walls to form a cuff wall (i.e., “corner flap”) as taught by Pavcnik. EX1026, ¶¶137-141. A POSITA would have been motivated to do so to provide a sealing structure that catches retrograde blood flow between the device and the vessel wall (*i.e.*, perivalvular leak). *Id.* Further motivation is found in the teachings of the Textbook of Interventional Cardiology, which recognized at the outset of transcatheter valve development that valve designs should aim to minimize perivalvular leak. EX1013, 7; EX1026, ¶140.

Moreover, all of the claimed elements of Claim 62 were known in the prior art as evidenced by the teachings of Melsheimer and Pavcnik, and a POSITA could have combined the teachings of these elements as claimed by known methods with no change in their respective functions, and the combination would have yielded nothing more than predictable results to a POSITA. EX1026, ¶141. Indeed, there would have been a reasonable expectation of success in combining the teachings of Melsheimer and Pavcnik given that the prosthetic valve structure taught by Pavcnik is incorporated by reference by Melsheimer. *Id.*; EX1003, ¶[0053]; EX1020, Fig. 16.

b) Claim 83

Melsheimer discloses the vascular system implant of Claim 55 as detailed above.

Moreover, as detailed above, it would have been obvious to modify Melsheimer in view of Pavcnik by taking the vertex forming a proximal, upstream tip of Melsheimer and folding it over in a radially outward direction and attaching it to the lattice frame. *Supra* Section V.D.2.(a).

c) Claim 84

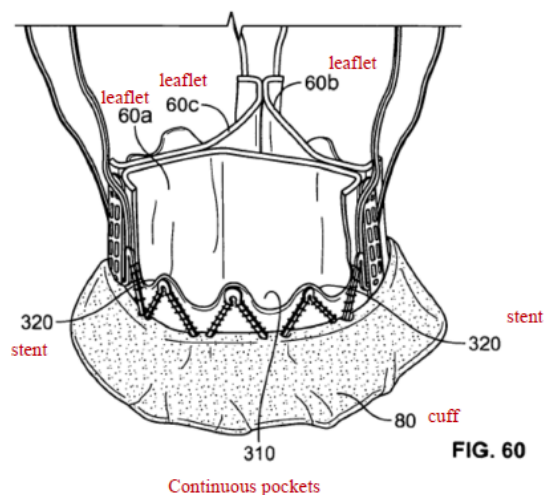
Melsheimer discloses the vascular system implant of Claim 62 as detailed above.

Moreover, as detailed above, it would have been obvious to modify Melsheimer in view of Pavcnik by taking the vertex forming a proximal, upstream tip of Melsheimer and folding it over in a radially outward direction and attaching it to the lattice frame. *Supra* Section V.D.2.(a).

3. Ground 4: Claims 60-72 and 79-80 are obvious over Braido (EX1004) in view of Eberhardt (EX1006)

a) Element 60[p]

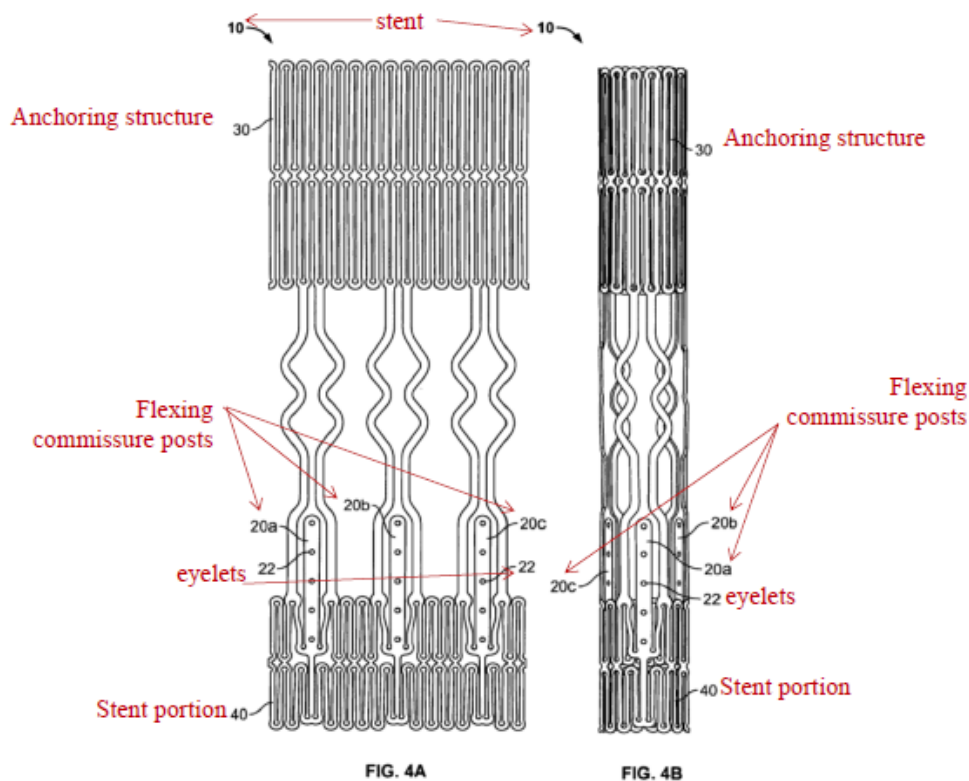
Braido discloses a vascular system implant. EX1026, ¶144. “The prosthetic heart valves disclosed herein incorporate a collapsible valve ... and unique ways in which to assemble the leaflets and ancillary components.” EX1004, ¶[0003].



Id., Fig. 60.

b) Element 60[a]

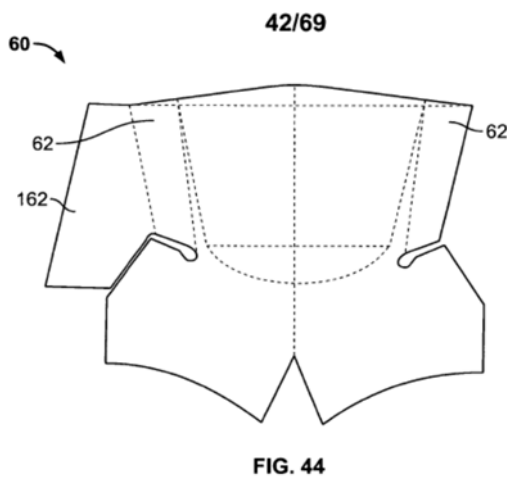
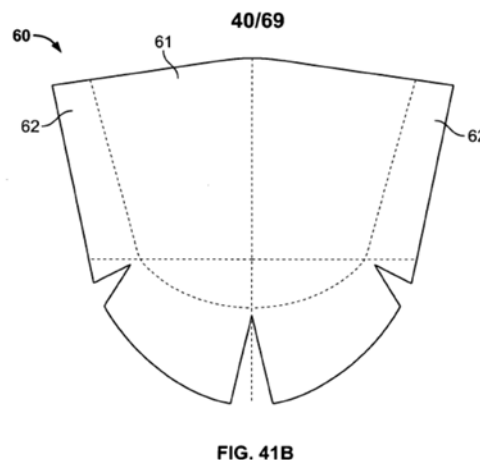
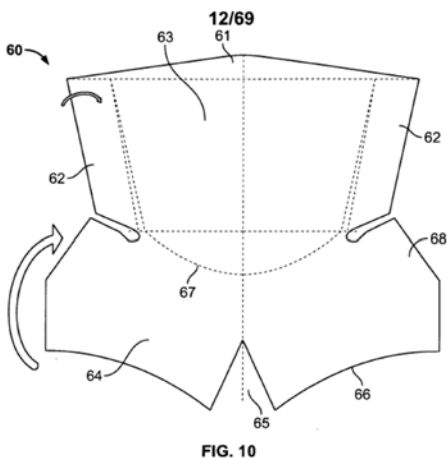
Braido discloses a lattice frame, which is detailed in, *e.g.*, Figures 4A-B:



EX1004, Figs. 4A, 4B; *see also id.*, ¶[0114]; EX1026, ¶145.

c) Element 60[b]

Braido discloses multiple integrated cusp structures:



See, e.g., EX1004, Figs. 10, 41B, 44. These structures include a mobile leaflet portion (*e.g.*, Fig. 10 element 61/63) and cusp wall portions (*e.g.*, Fig. 10 elements 62, 64, 66). EX1026, ¶¶146-149. Braido's cusp wall portions can be folded radially outward and act as a buffer layer between the leaflets and the frame, or

they can wrap around the outside of the frame. *See, e.g.*, EX1004, ¶¶[0120] (outside of frame), [0129] (buffer layer inside frame).

In a number of Braido's embodiments, dotted lines outline the artificial divide that forms the mobile leaflet portion of the integrated cusp. *Id.*, ¶[0120]. The mobile leaflets in the above-pictured embodiments are substantially polygonal, but include a curved lower edge, as outlined in red below:

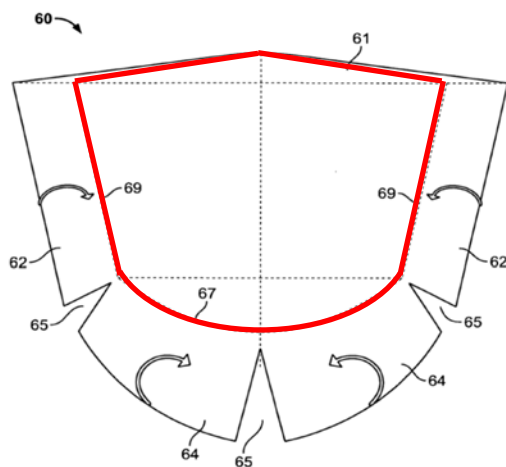
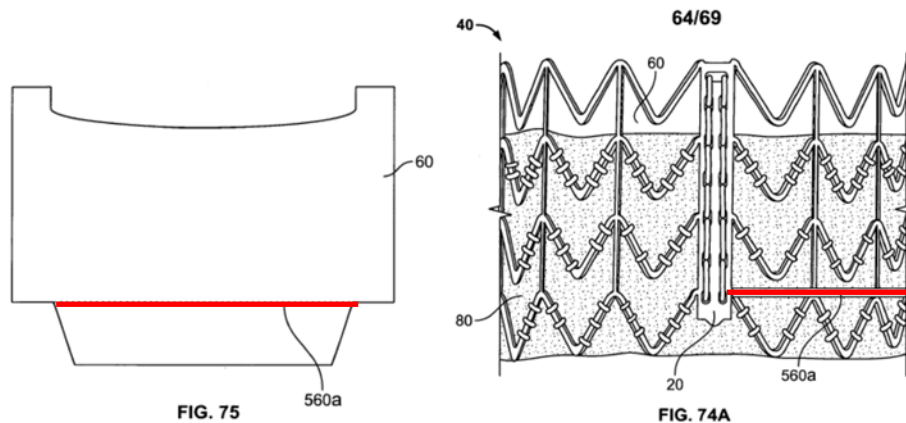


FIG. 19

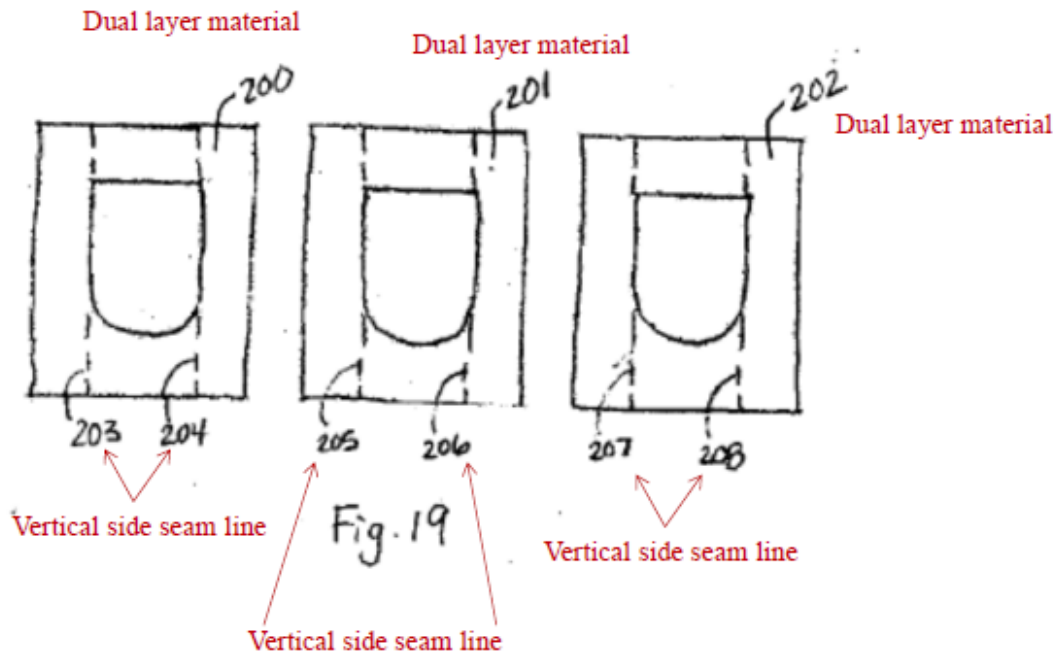
Id., Fig. 19 (annotated mobile leaflet). In further embodiments, Braido also discloses that this curved lower edge can instead be a horizontal straight edge depending on how the integrated cusp is attached to the lattice frame:



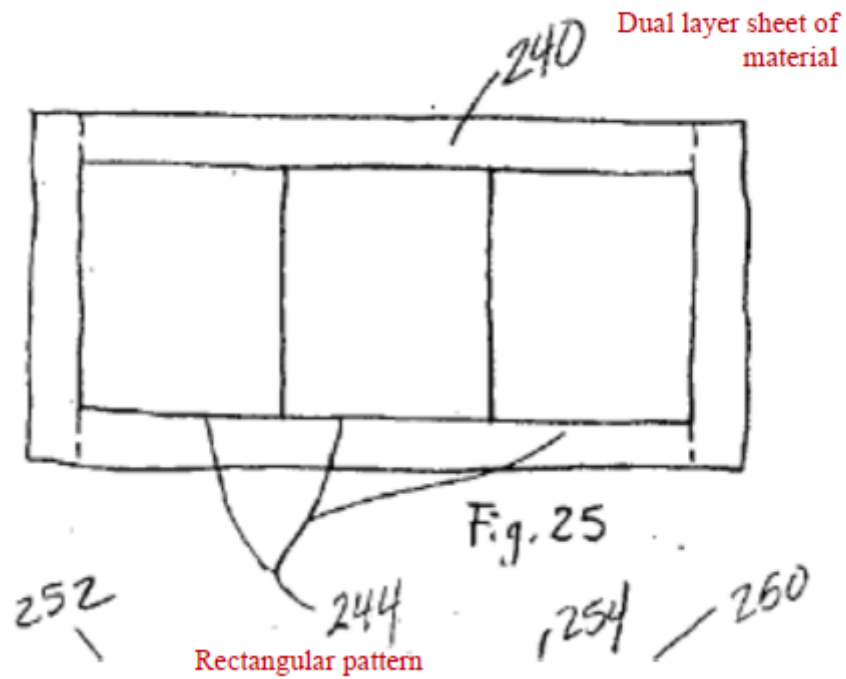
Id., Figs. 74A, 75 (annotated base of mobile leaflet), ¶[0182] (“Reference line 560a in FIG. 74a shows the lower portion of the leaflet attached straight across from the bottom eyelet 22 of one commissure post 20 to the next commissure post 20.”). Thus, it would have been obvious to a POSITA to modify those mobile leaflet structures in Braido with curved bottom edges to have straight bottom edges depending on the desired attachment of the integrated cusp to the lattice frame. EX1026, ¶149. This would result in a mobile leaflet in the shape of a non-rectangular polygon as claimed. *Id.*

Separate from Braido’s own teachings, it also would have been obvious to modify those mobile leaflets of Braido that have curved bottom edges with straight edges as taught by Eberhardt. EX1026, ¶¶150-153. Eberhardt teaches various transcatheter valve leaflet structures, including leaflets having a curved bottom edge, a straight bottom edge, or a polygonal leaflet having a bottom edge formed with two angled sides connected by a horizontal side:

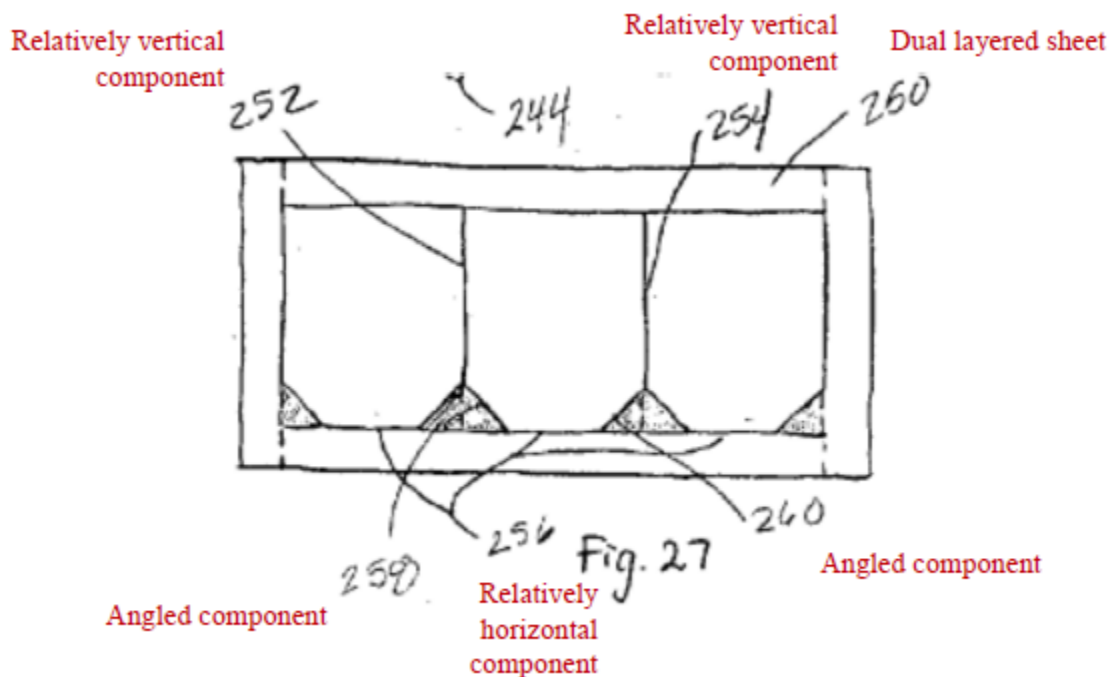
Curved Bottom Edge



Straight Bottom Edge



Polygonal Leaflet with Angled Sides



EX1006, Figs. 19, 25, 27; *see also id.*, ¶¶[0056], [0060], [0061]. Eberhardt’s polygonal leaflet embodiment is taught as an “alternative embodiment” that includes “a dual-layered sheet of material” with angled sidewalls greater than 0 but less than 90 degrees to “eliminate or minimize possible areas of stasis and ... [to] provide a non-abrasive surface over which the corresponding leaflet can hinge.” *Id.*, ¶[0061].

It would have been obvious to modify the bottom edges of Braido’s mobile leaflets with Eberhardt’s alternative polygonal structure to form a non-rectangular, polygonal mobile leaflet that eliminates or minimizes possible areas of stasis and provides a non-abrasive surface over which corresponding leaflets can hinge.

EX1026, ¶152. This modification is further supported by Braido’s teachings that a technician can start with a “simplified version [of the integrated cusp structure that] allows the technician to assemble and trim the valve as needed, since there can be variability in how the tissue behaves”, EX1004, ¶[0163]:

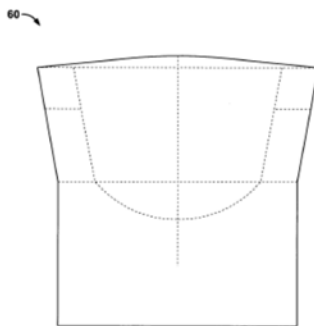


FIG. 52

Id., Fig. 52; EX1026, ¶156. The teachings of Spenser provide further motivation to combine, which recognized that it would have been obvious to modify boundary conditions of the valve leaflets to optimize stress distribution. EX1011, 25:39-65; EX1026, ¶152.

Moreover, all of the claimed elements of Claim 60 were known in the prior art as evidenced by, *e.g.*, Braido and Eberhardt, and a POSITA could have combined the teachings of these elements as claimed by known methods with no change in their respective functions, and the combination would have yielded nothing more than predictable results to a POSITA. EX1026, ¶153. Given that both Braido and Eberhardt are directed to transcatheter valves with multi-layered valve components and Eberhardt explicitly teaches a polygonal leaflet structure as

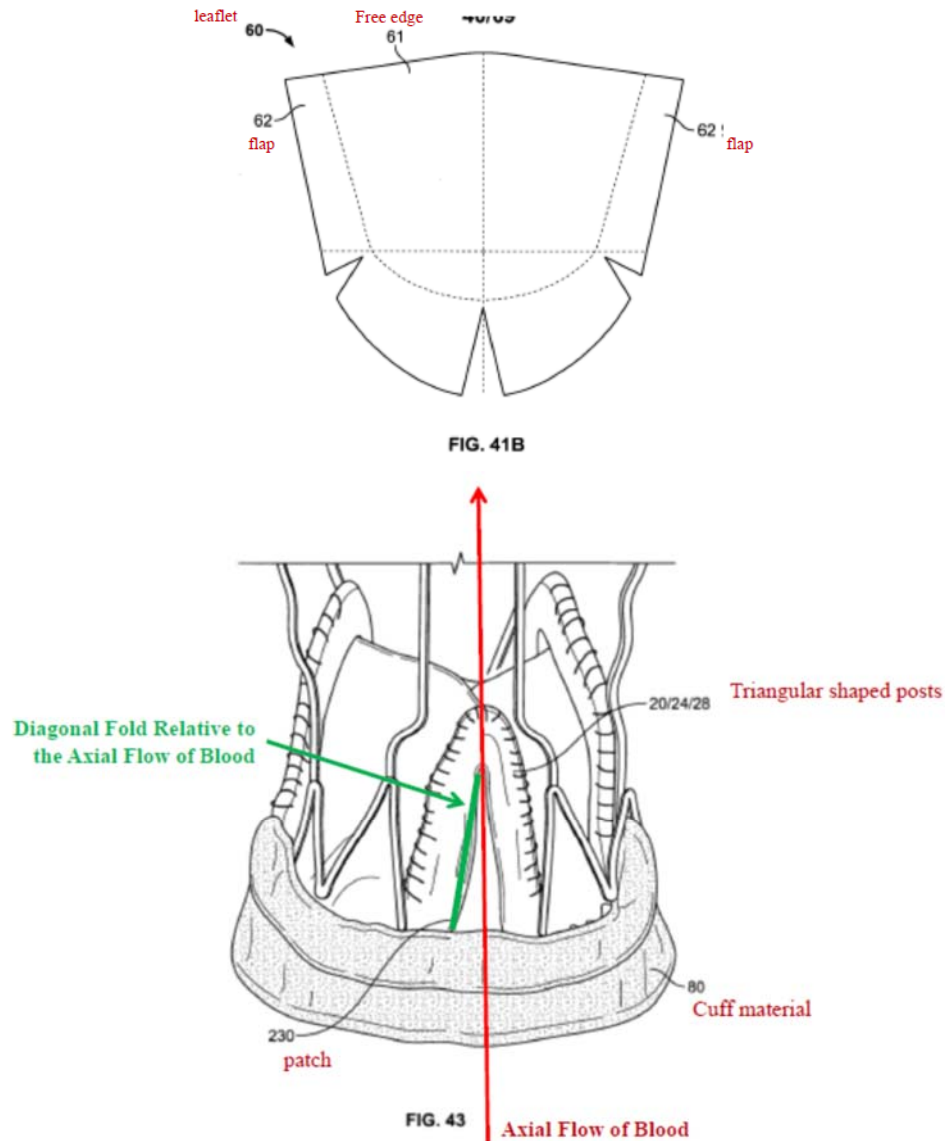
an alternative to leaflet designs with curved or straight bottom edges like those taught by Braido, a POSITA would have had a reasonable expectation of success in combining these teachings. *Id.*

d) Element 60[c]

Braido discloses that each of the plurality of mobile leaflets includes a biocompatible membrane. The membrane can be formed with, *e.g.*, a pericardial tissue sheet that is fixed for biocompatibility with glutaraldehyde and treated with an anti-calcification agent. EX1004, ¶[0112]; EX1026, ¶154.

e) Element 60[d]

Braido discloses embodiments wherein each mobile leaflet is bordered by non-transverse diagonally oriented folds that are angled relative to an axial flow direction. EX1026, ¶¶155-156. For example, Figure 41B depicts angled dotted lines representing where folds are formed to partition the mobile leaflet from cusp wall portions (i.e., “side flaps”). EX1004, ¶¶[0152], [0155]. As shown in Figure 43, these folds can be formed along commissure supports of the lattice frame that are triangular in shape, which results in angled folds that are angled relative to the axial flow of blood:



Id., Figs. 41B, 43; EX1026, ¶155.

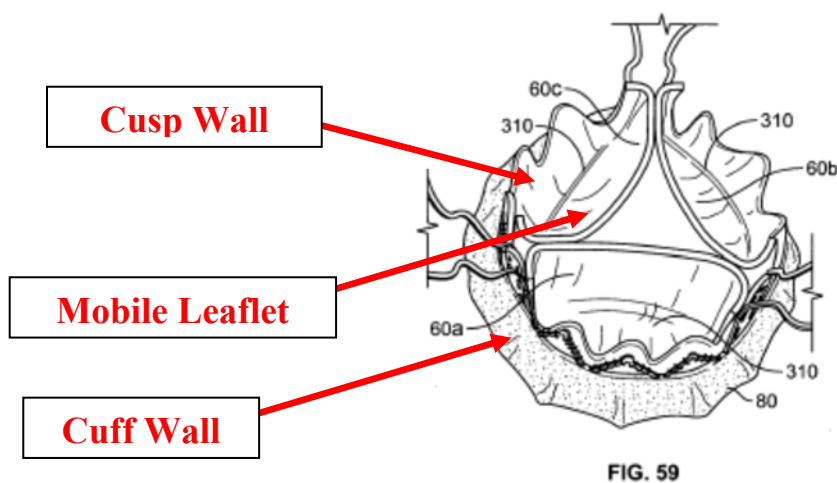
Moreover, as detailed above, it would have been obvious to a POSITA to modify the curved or straight lower edge of the leaflets disclosed by Braido by forming angled and horizontal edges in this region as taught by Eberhardt. *Supra* Section V.D.3.(c). This would result in the formation of additional non-transverse diagonally oriented folds bordering the mobile leaflet, including folds bordering

the “angled components” along the bottom of the polygonal valve structure that can be angled between 0 and 90 degrees as taught by Eberhardt and are thus angled relative to an axial flow direction. EX1026, ¶156.

f) Claim 61

Braido, in combination with Eberhardt, teaches the vascular system implant of Claim 60 as detailed above.

As described above, the cusp wall portions of the integrated cusp structures taught by Braido can act as a buffer layer between the leaflets and the frame. *See supra* Section V.D.3.(c) (citing EX1004, ¶¶[0120], [0129])). The cusp wall and mobile leaflet are attached in a continuous manner such that the cusp wall is radially exterior to the mobile leaflet. EX1026, ¶¶157-158. Figure 59 “is a top view showing continuous pockets 310” formed by mobile leaflets 60a-c, cusp walls (not numbered), and a cuff wall 80:



Id., Fig. 59.

g) Claim 62

Braido, in combination with Eberhardt, teaches the vascular system implant of Claim 61 as detailed above.

As pictured, *supra* Section V.D.3.(f), Braido further discloses the use of a cuff wall (“cuff 80”). EX1004, ¶[0112]. The cuff wall can “aid in better sealing and tissue in-growth when pushed against native aortic root tissue,” *id.*, ¶[0154], and can also aid in attachment of the leaflets and cusp walls, *id.*, ¶¶[0139], [0168]. EX1026, ¶¶159-160.

h) Claim 63

Braido, in combination with Eberhardt, teaches the vascular system implant of Claim 60 as detailed above.

The lattice frame of Braido is collapsible and expandable and comprises a metal alloy (*e.g.*, Nitinol or cobalt chromium) substantially configured as a tubular stent member. EX1004, ¶[0114]; EX1026, ¶¶161-162.

i) Claim 64

Braido, in combination with Eberhardt, teaches the vascular system implant of Claim 60 as detailed above.

Braido further discloses that the biocompatible membrane may be made with “pericardial tissue”, EX1004, ¶[0112], and more generally references porcine and bovine tissue (*i.e.*, mammalian), *id.*, ¶[0181]. As supported by Jonathan Rourke

and texts published contemporaneously with the priority date of the '400 Patent, a POSITA would appreciate that Braido's disclosure of "pericardial tissue" includes mammalian pericardium (*e.g.*, bovine and porcine pericardium). EX1026, ¶¶163-164; EX1027, 230, 233; EX1032, 1-2.

Nonetheless, to avoid any doubt as to the scope of Braido's disclosure, it separately would have been obvious to a POSITA to select mammalian pericardium for use in Braido in view of Eberhardt. EX1026, ¶¶165-166. Eberhardt discloses the use of a transcatheter valve with processed mammalian pericardial tissue. Ex. 1006, ¶[0038] (disclosing, *e.g.*, porcine pericardium); *see also id.*, ¶[0040] ("The pericardium material 10 is folded on itself at fold line 16 to effectively double the thickness of at least a portion of the material 10.")).

For the same reasons discussed above, *supra* Section V.D.1.(a), a POSITA would have been motivated to select processed mammalian pericardium, and would have had a reasonable expectation of success in doing so.

j) Claim 65

Braido, in combination with Eberhardt, teaches the vascular system implant of Claim 60 as detailed above.

Braido teaches that the biocompatible membrane can be made with a polymer sheet, and thus discloses an embodiment of a biocompatible membrane that does not comprise a treated tissue. EX1004, ¶[0112]; EX1026, ¶¶167-168.

k) Claim 66

Braido, in combination with Eberhardt, teaches the vascular system implant of Claim 60 as detailed above.

As noted above, Braido teaches that the biocompatible membrane can be made with a polymer sheet, and thus discloses an embodiment of a biocompatible membrane comprising a synthetic material. EX1004, ¶[0112]; EX1026, ¶¶169-170.

l) Element 67[p]

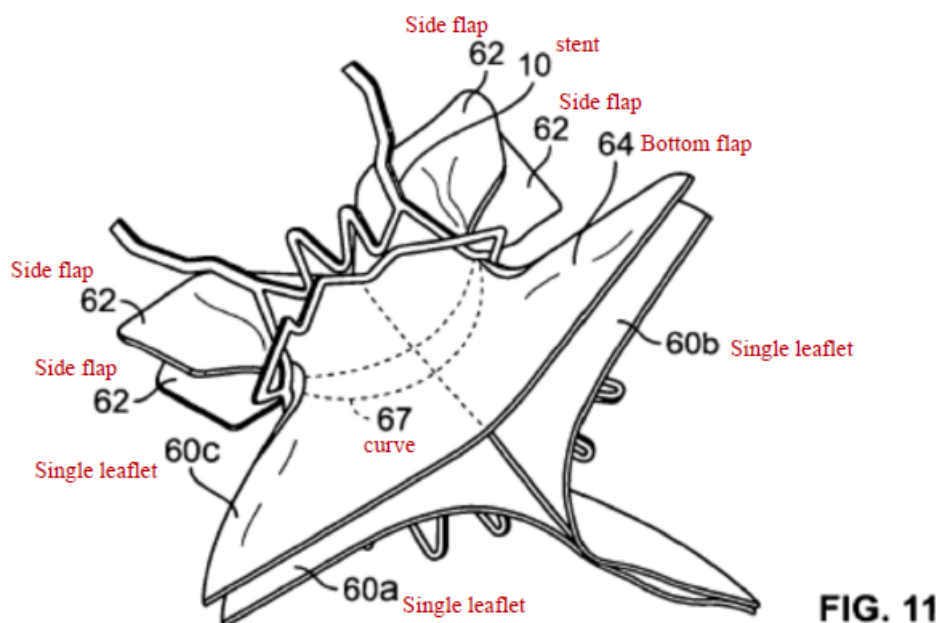
Braido discloses a vascular system implant as detailed above. *Supra* Section V.D.3.(a).

m) Element 67[a]

Braido discloses a lattice frame as detailed above. *Supra* Section V.D.3.(b).

n) Element 67[b]

Braido discloses mobile leaflets formed with biocompatible membrane sheets attached to the lattice frame as detailed above. *Supra* Section V.D.3.(c)-(d). Braido's preferred embodiment is a trileaflet valve structure with each leaflet formed with a folded biocompatible membrane. EX1004, ¶¶[0120], [0121].



Id., Fig. 11; EX1026, ¶¶173-174.

o) Element 67[c]

Braido alone or in combination with Eberhardt renders obvious a plurality of non-rectangular polygonal mobile leaflets attached to the lattice frame as detailed above, *supra* Section V.D.3.(c), such that each of the folded membrane sheets includes a non-rectangular polygonal mobile leaflet. EX1026, ¶175.

p) Element 67[d]

Braido alone or in combination with Eberhardt renders obvious that each of the plurality of non-rectangular polygonal mobile leaflets are bordered by non-transverse diagonally oriented folds that are angled relative to an axial flow direction as detailed above, *supra* Section V.D.3.(c), and thus discloses that each of the non-rectangular polygonal mobile leaflets include non-transverse diagonally

oriented folds that are angled relative to an axial flow direction. EX1026, ¶176.

q) Claim 68

Braido, in combination with Eberhardt, teaches the vascular system implant of Claim 67 as detailed above.

Both Braido and Eberhardt further disclose that each of the at least two folded biocompatible membrane sheets comprises two or more pieces of biocompatible membrane material. EX1026, ¶¶177-179. Braido, for example, teaches that “[i]ntermediate materials of one or more layers (sheets) between stent 10 and leaflet material 60 may be applied for attachment, friction buffering, and tissue in-growth purposes.” EX1004, ¶[0112]. Eberhardt likewise teaches the use of two or more pieces of biocompatible membrane material to form each biocompatible membrane. Figure 19, for example, “includes first, second, and third pieces of dual-layer material ... each of which may be a dual-layer piece of pericardium material or other material, which may be provided with two separate material pieces or by folding a piece of material along a fold line to create two material layers.” Ex. 1006, ¶[0056].

r) Claim 69

Braido, in combination with Eberhardt, teaches the vascular system implant of Claim 67 as detailed above.

Braido discloses that the lattice frame is collapsible and expandable and

comprises a metal alloy substantially configured as a tubular stent member as detailed above. *Supra* V.D.3.(h); EX1026, ¶¶180-181.

s) Claims 70-72

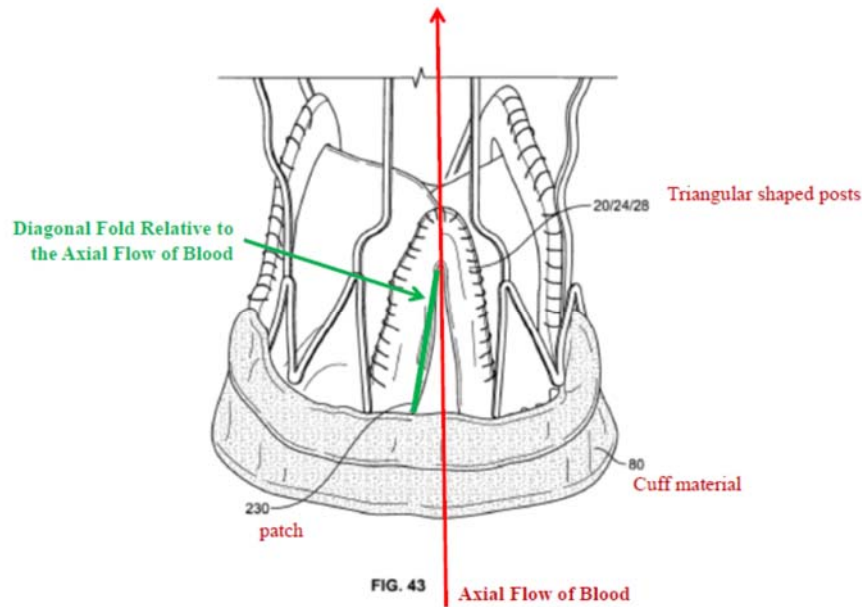
Braido, in combination with Eberhardt, teaches the vascular system implant of Claim 67 as detailed above.

Braido, alone or in combination with Eberhardt, also discloses that the folded biocompatible membrane sheets comprise processed mammalian pericardium tissue (Claim 70) as detailed above, *supra* Section V.D.3.(i); EX1026, ¶¶182-183. Braido further discloses that the folded biocompatible membrane sheets may not comprise a treated tissue (Claim 71), *supra* Section V.D.3.(j), and that the folded biocompatible membrane sheets may also comprise a synthetic material (Claim 72), *supra* Section V.D.3.(k). EX1026, ¶¶184-187.

t) Claim 79

Braido, in combination with Eberhardt, teaches the vascular system implant of Claim 60 as detailed above.

In those embodiments of Braido having triangular commissure supports, the cusp wall portions wrapped around the angled posts of the triangular commissure supports form folds that are angled relative to an axial flow direction:



See EX1026, ¶¶188-189. It would have been obvious to a POSITA that these angles would have been formed between 10 and 80 degrees from the axial flow direction, or otherwise could have been formed in this range depending on the desired boundary conditions. *Id.*

Separately, as noted, it would have been obvious to a POSITA to modify the curved or straight lower edge along the mobile leaflet of Braido with the angled and horizontal edges along the bottom of Eberhardt's polygonal leaflet embodiment, and there would have been a reasonable expectation of success in doing so. See *supra* Section V.D.3.(c). The angled edges of Eberhardt are taught as being greater than 0 degrees and less than 90 degrees, which encompasses the '400 Patent's claimed range of about 10 to 80 degrees from the axial flow direction. EX1006, ¶[0061]; EX1026, ¶190.

u) Claim 80

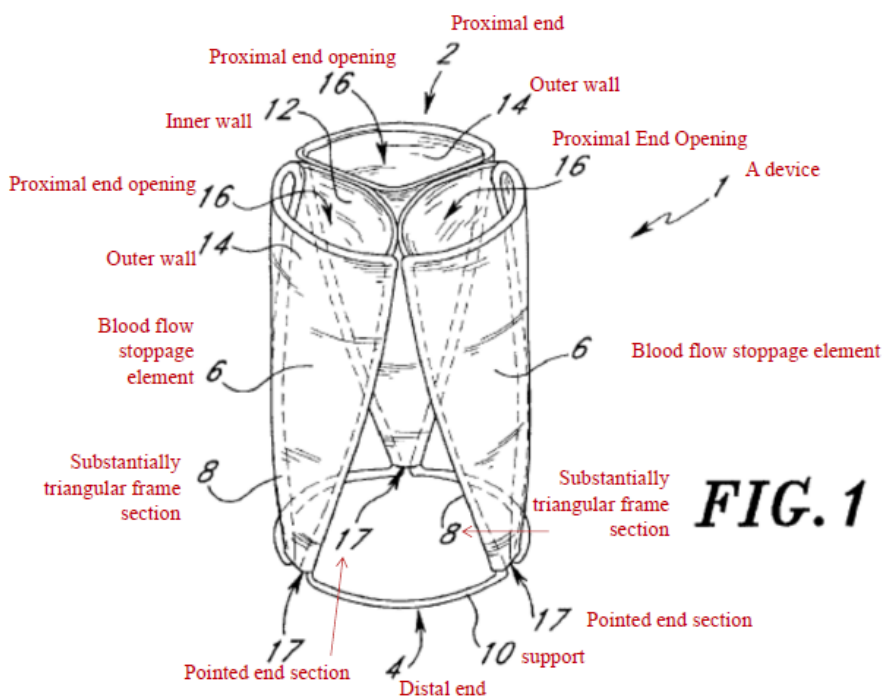
Braido, in combination with Eberhardt, teaches the vascular system implant of Claim 67 as detailed above.

Braido, in combination with Eberhardt, further teaches that the non-transverse diagonally oriented folds are angled at between about 10 to 80 degrees from the axial flow direction as detailed above. *Supra* Section V.D.3.(t); EX1026, ¶¶191-192.

4. Ground 5: Claims 55-61 and 63-67 and 69-72 are obvious over Moll (EX1005) in combination with Paniagua (EX1007)

a) Element 55[p]

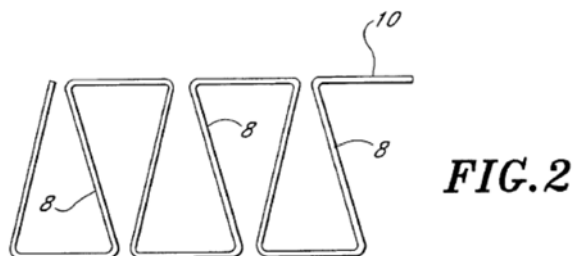
Moll discloses a vascular system implant, which is preferably used as a venous valve:



EX1005, Fig. 1, 1:40-43; EX1026, ¶193.

b) Element 55[a]

The '400 Patent broadly defines “frame” as “a substantially tubular member that holds a plurality of cusps and/or leaflets,” and states that the “frame may be a wire lattice or a lattice cut from a single tubular piece of metal alloy, that is both collapsible and expandable.” EX1001, 12:32-36; EX1026, ¶194. Moll discloses a wire lattice, which is “preferably made of a continuous length of memory metal, having, as shown in FIG. ... 2, three substantially separate frame sections 8 for supporting each valve element 6”:

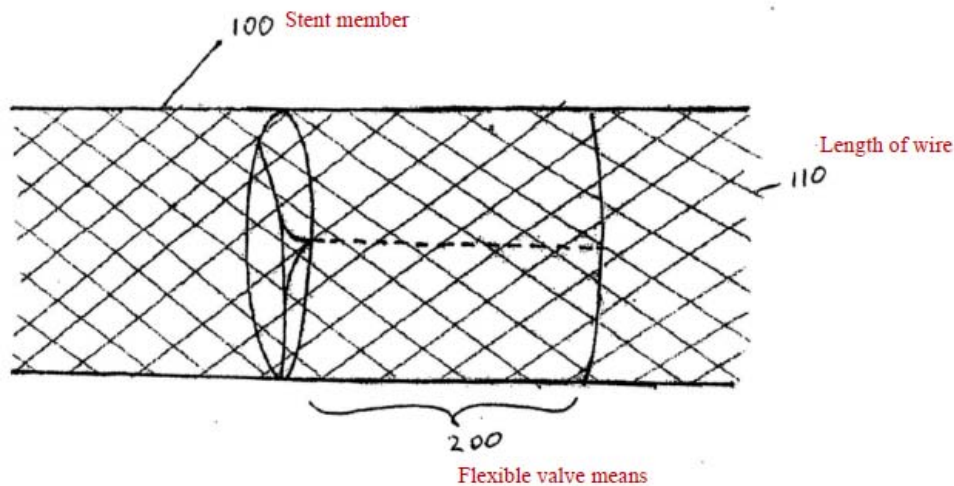


EX1005, 3:25-28, Fig. 2. This undulating structure is akin to the lattice frame (“attachment means”) taught by Drasler (EX1015), which is a stent graft structure with a lattice frame that the Examiner relied upon during prosecution and the Patent Owner did not challenge. EX1026, ¶¶194-195.

To the extent it is argued that the stent structure in Figure 2 of Moll is not a “lattice frame” as claimed, it would have been obvious to a POSITA to modify the stent structure of Moll accordingly. EX1026, ¶¶196-199.

For example, Paniagua discloses a transcatheter valve that includes a folded

valve and lattice frame. “The configuration [of the lattice frame] may be the zigzag configuration shown or a sine wave configuration, mesh configuration or similar configuration which will allow the stent to be readily collapsible and self-expandable. ... The purpose of the stent is to maintain a semi-rigid patent channel through the diseased cardiac valve following its implantation.” EX1007, ¶¶[0041]-[0042].



Id., Fig. 5.

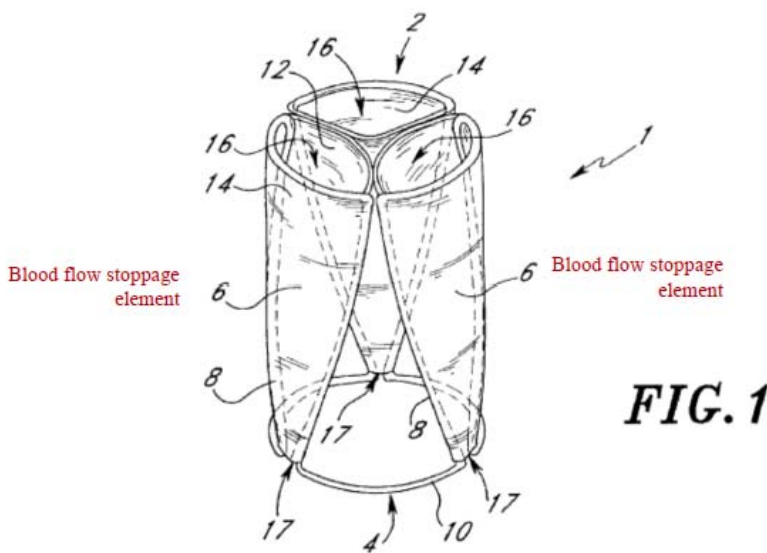
It would have been obvious to modify Moll in view of the lattice frame structures taught by Paniagua in order to provide a number of alternative frame structures that can be readily collapsible and expandable and sufficiently strong to maintain a semi-rigid patent channel in the vascular system. EX1026, ¶198.

Moreover, all of the claimed elements of Claim 55 were known in the prior art as evidenced by, *e.g.*, Moll and Paniagua, and a POSITA could have combined

the teachings of these elements as claimed by known methods with no change in their respective functions, and the combination would have yielded nothing more than predictable results to a POSITA. *Id.* at ¶199. Given that both Moll and Paniagua are directed to transcatheter valves, a POSITA would have had a reasonable expectation of success in combining these teachings, particularly given that the lattice frame structures of Paniagua are more akin to the commercially approved transcatheter valves that were known as of the relevant priority date (i.e., the SAPIEN and CoreValve devices). *Id.*; EX1027, 230, 233.

c) Element 55[b]

Moll discloses a plurality of substantially conical shaped cusps. EX1005, 3:18-20 (“blood flow stoppage element 6, having the form of flexible hollow cones”); EX1026, ¶200.



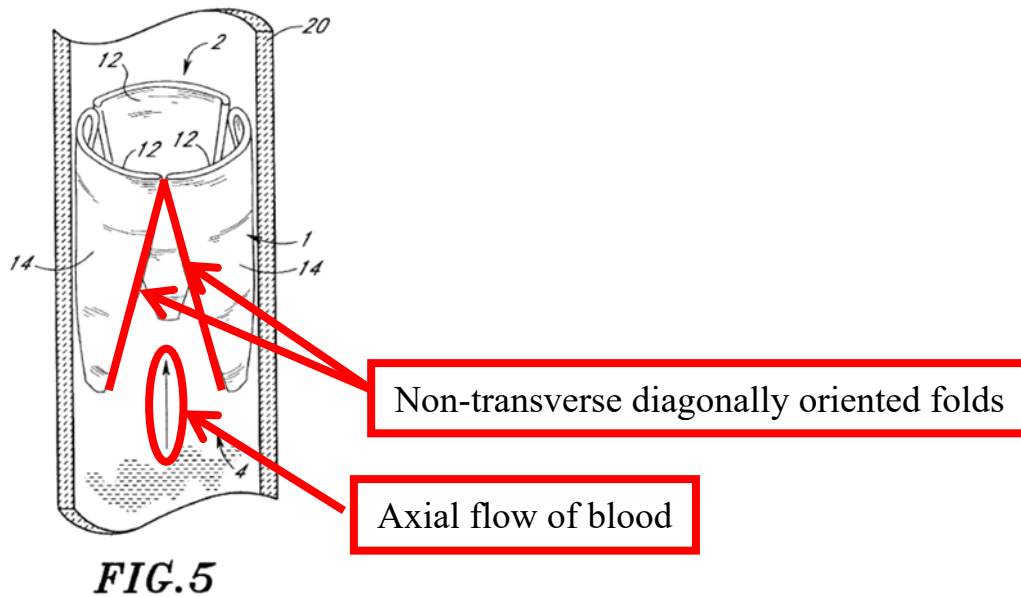
EX1005, Fig. 1.

d) Element 55[c]

Moll discloses that each of the plurality of substantially conical shaped cusps includes a biocompatible membrane. EX1005, 3:41-44 (“biocompatible material” most preferably PTFE); EX1026, ¶201.

e) Element 55[d]

Although Moll does not explicitly state that the sidewalls of the conical shaped flow stoppage elements have folds, it is inherent in Moll’s teachings that the flow stoppage elements have folds as claimed by the ’400 Patent. That is, a POSITA would recognize that a “substantially flattened” configuration wherein “one or more sidewalls lie substantially flat adjacent to each other”, EX1005, 1:40-46, 58-61, would form “non-transverse diagonally oriented folds that are angled relative to an axial flow direction” as claimed. Figure 5, for example, depicts how the flow of blood “forces the inner walls 12 of the stoppage elements 6 against the outer walls 14”:



Id., 3:62-65, Fig. 5; EX1026, ¶¶202-203. These teachings are consistent with those of the '400 Patent, which highlights that “the cusp shape becomes substantially conical in shape” and the folds are relaxed when the membrane is hydrated. EX1001, 10:6-19; EX1026, ¶203.

Moreover, even if not inherent in Moll, it would have been obvious to a POSITA to form non-transverse diagonally oriented folds along the flow stoppage elements of Moll in view of the teachings of Paniagua. EX1026, ¶204. Paniagua teaches the use of folds in a valve structure for “improved resistance to tearing at suture lines,” and to aid in the patterned movement of the valve. EX1007, ¶[0024]. Both of these benefits of a folded valve structure would have motivated a POSITA to modify Moll to include folds along the conical flow stoppage elements. EX1026, ¶204.

All of the claimed elements of Claim 55 were known in the prior art as evidenced herein by, *e.g.*, Moll and Paniagua, and a POSITA could have combined the teachings of these elements as claimed by known methods with no change in their respective functions, and the combination would have yielded nothing more than predictable results to a POSITA. *Id.* at ¶205. Given that both Moll and Paniagua are directed to transcatheter valves, a POSITA would have had a reasonable expectation of success in combining these teachings as folding two layers of valve material that lie substantially flat adjacent to one another would yield predictable results. *Id.*

f) Claim 56

Moll in combination with Paniagua teaches the vascular system implant of Claim 55 as detailed above.

As noted, Moll alone or in combination with Paniagua teaches a lattice frame.

The lattice frame of Moll is collapsible and expandable and comprises a memory metal substantially configured as a tubular stent member. EX1005, 3:25-28 (“continuous length of memory metal”), Claim 5 (“tubular configuration ... adapted to be compressed ... [and] automatically expands”); EX1026, ¶¶206-208. A POSITA would appreciate that “memory metal” is a metal alloy, and thus Moll’s disclosure of “memory metal” is a disclosure of metal alloy. EX1026, ¶208;

EX1031, 45, 48 (“A memory metal is an alloy that ‘remembers’ its original shape.”).

Moreover, Paniagua discloses that “[t]he stent member 100 preferably comprises a self-expanding nickel-titanium alloy stent, also called ‘nitinol,’ in a sine wave-like configuration as shown in FIG. 5.” EX1007, ¶¶ [0040], [0041]. Thus, to the extent Moll is modified in view of the teachings of Paniagua, the lattice frame of Paniagua preferably includes a memory metal alloy construction (*i.e.*, Nitinol). EX1026, ¶209. For the same reasons set forth above, *supra* Section V.D.4.(b), it would have been obvious to modify the frame of Moll in view of Paniagua’s disclosure of memory metal alloy lattice frames, and there would have been a reasonable expectation of success in doing so.

g) Claim 57

Moll in combination with Paniagua teaches the vascular system implant of Claim 55 as detailed above.

Moll discloses that each of the plurality of substantially conical shaped cusps includes a biocompatible membrane such as PTFE as detailed above, but does not explicitly disclose whether processed mammalian pericardium tissue can be used to form the blood stoppage elements.

Paniagua discloses PTFE as a potential biocompatible membrane material, and also notes that “[t]he preferred material for the valve means 200 is mammal

pericardium tissue, particularly juvenile-age animal pericardium tissue.” EX1007, ¶[0046].

It would have been obvious to a POSITA to modify the blood stoppage elements of Moll to include processed mammalian pericardium tissue as an alternative to PTFE in view of the teachings of Paniagua. EX1026, ¶¶210-214.

Moreover, all of the claimed elements of Claim 57 were known in the prior art as evidenced by, *e.g.*, Moll and Paniagua, and a POSITA could have combined the teachings of these elements as claimed by known methods with no change in their respective functions, and the combination would have yielded nothing more than predictable results to a POSITA. *Id.* at ¶214. Indeed, given that both Moll and Paniagua are directed to transcatheter valves comprising biocompatible membranes, a POSITA would have had a reasonable expectation of success in combining these teachings, particularly given that processed mammalian pericardium was successfully used in prosthetic valves for decades prior to the ’400 Patent’s priority date, and the two commercially approved transcatheter aortic valves as of the ’400 Patent’s priority date used processed mammalian pericardium tissue (bovine pericardium (SAPIEN) and porcine pericardium (CoreValve)). *Id.*; EX1027, 230, 233.

h) Claim 58

Moll in combination with Paniagua teaches the vascular system implant of

Claim 55 as detailed above.

As noted above, Moll discloses that “the blood stoppage elements are most preferably made of polytetrafluoroethylene (PTFE),” EX1005, 3:41-44, which is a synthetic material and thus “does not comprise a treated tissue” as claimed. EX1026, ¶215.

i) Claim 59

Moll in combination with Paniagua teaches the vascular system implant of Claim 55 as detailed above.

Moll further discloses that the biocompatible membrane may comprise a synthetic material. *Supra* Section V.D.4.(h); EX1026, ¶216.

j) Element 60[p]

Moll discloses a vascular system implant as detailed above. *Supra* Section V.D.4.(a); EX1026, ¶217.

k) Element 60[a]

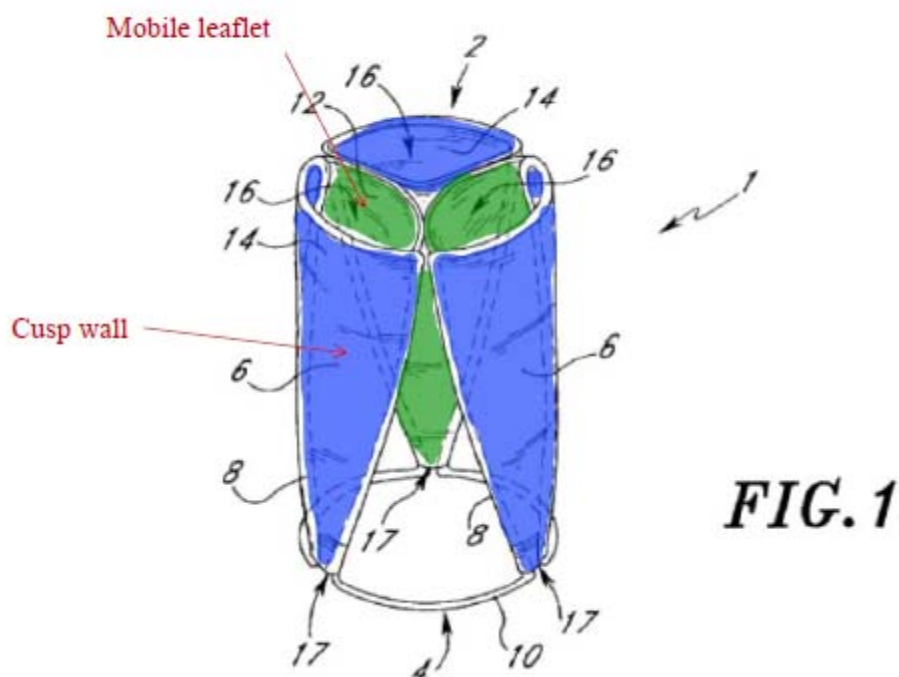
Moll alone or in combination with Paniagua teaches a lattice frame as detailed above. *Supra* Section V.D.4.(b); EX1026, ¶218.

l) Element 60[b]

Moll discloses a plurality of non-rectangular polygonal mobile leaflets attached to the lattice frame. EX1026, ¶¶219-220.

Moll’s “flow stoppage elements” are integrated structures each comprising a

non-rectangular polygonal mobile leaflet portion (*i.e.*, triangular inner-wall portions highlighted in green below) and a cusp wall (triangular outer-wall portions highlighted in blue below) attached to the lattice frame:



EX1005, Fig. 1, 3:18-20.

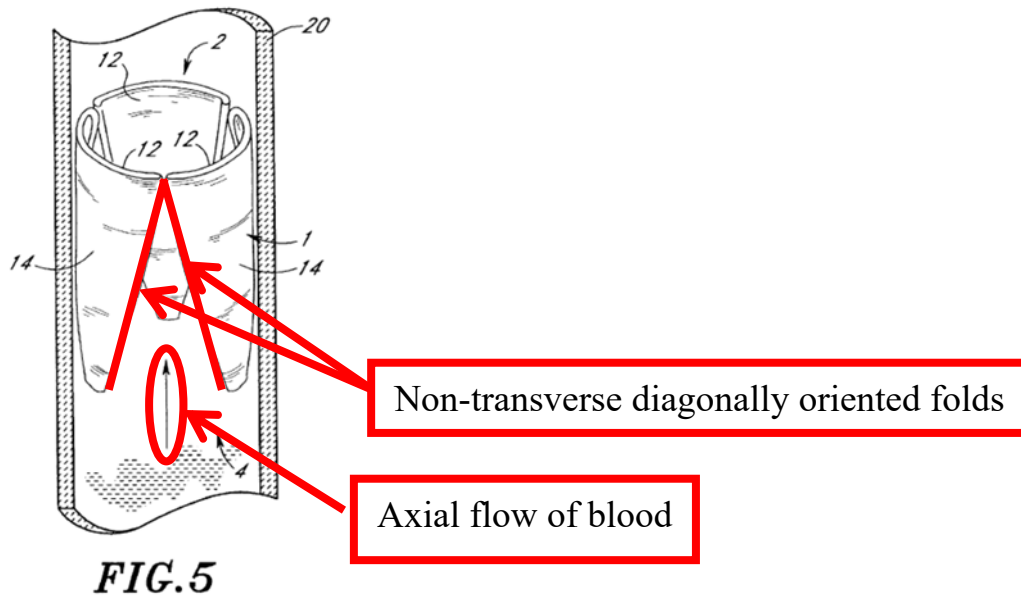
m) Element 60[c]

Moll discloses that each of the plurality of non-rectangular polygonal mobile leaflets includes a biocompatible membrane as detailed above. *Supra* Section V.D.4.(d); EX1026, ¶221.

n) Element 60[d]

Moll discloses non-transverse diagonally oriented folds that are angled relative to an axial flow direction as detailed above. *Supra* Section V.D.4.(e). For

the same reasons, Moll discloses non-rectangular polygonal mobile leaflets that are bordered by non-transverse diagonally oriented folds that are angled relative to an axial flow direction.

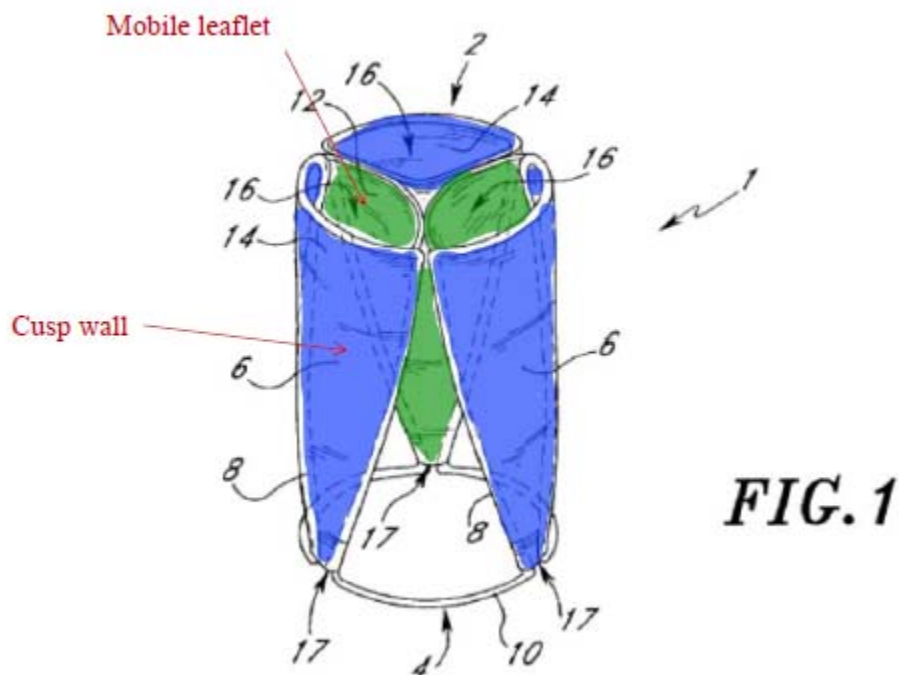


Id., Fig. 5; EX1026, ¶222.

o) Claim 61

Moll in combination with Paniagua teaches the vascular system implant of Claim 60 as detailed above.

Moll further discloses that each of the plurality of non-rectangular polygonal mobile leaflets is attached in a continuous manner to a corresponding cusp wall. EX1026, ¶¶223-224. The “flow stoppage element 6” of Moll is an integrated structure comprising a triangular mobile leaflet portion and a triangular cusp wall portion. *Supra* Section V.D.4.(1). The cusp wall is located radially exterior to each of the plurality of non-rectangular polygonal mobile leaflets:



EX1005, Fig. 1.

p) Claim 63

Moll in combination with Paniagua teaches the vascular system implant of Claim 60 as detailed above.

Moll alone, or in combination with Paniagua, further teaches that the lattice frame is collapsible and expandable and comprises a metal alloy substantially configured as a tubular stent member as detailed above. *Supra* Section V.D.4.(f); EX1026, ¶¶225-226.

q) Claim 64

Moll in combination with Paniagua teaches the vascular system implant of Claim 60 as detailed above.

Moll in combination with Paniagua teaches that the biocompatible membrane comprises processed mammalian pericardium tissue as explained above. *Supra* Section V.D.4.(g); EX1026, ¶¶227-228.

r) Claim 65

Moll in combination with Paniagua teaches the vascular system implant of Claim 60 as detailed above.

Moll further discloses that the biocompatible membrane does not comprise a treated tissue as explained above. *Supra* Section V.D.4.(h); EX1026, ¶¶229-230.

s) Claim 66

Moll in combination with Paniagua teaches the vascular system implant of Claim 60 as detailed above.

Moll further discloses that the biocompatible membrane comprises a synthetic material as explained above. *Supra* Section V.D.4.(i); EX1026, ¶¶231-232.

t) Element 67[p]

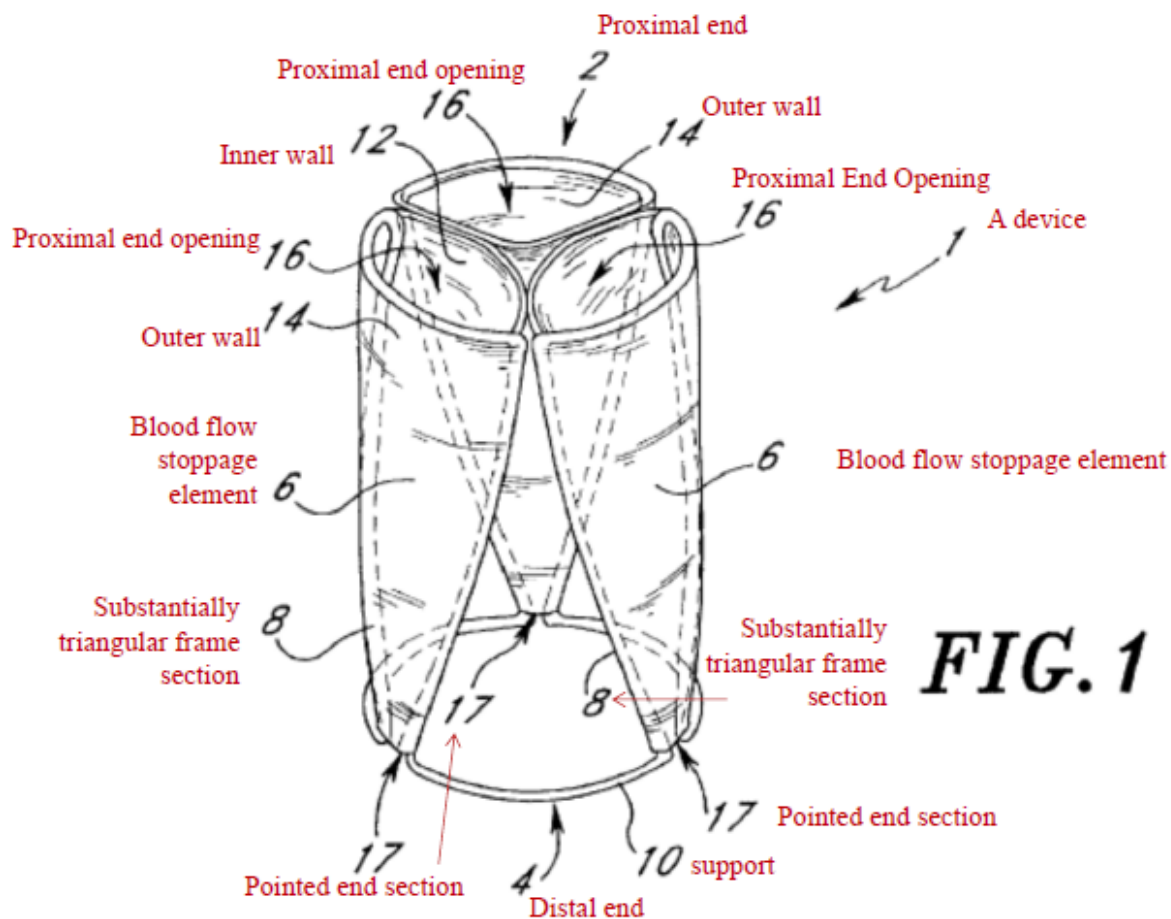
Moll discloses a vascular system implant as detailed above. *Supra* Section V.D.4.(a); EX1026, ¶233.

u) Element 67[a]

Moll alone or in combination with Paniagua teaches a lattice frame as explained above. *Supra* Section V.D.4.(b); EX1026, ¶234.

v) Element 67[b]

Moll discloses the use of at least two folded biocompatible membrane sheets (“blood flow stoppage elements”) attached to the lattice frame. EX1005, 3:18-20, 1:40-46 (“one or more flow stoppage elements”); EX1026, ¶235.



EX1005, Fig. 1.

w) Element 67[c]

Moll discloses a plurality of non-rectangular polygonal mobile leaflets attached to the lattice frame as detailed above, *supra* Section V.D.4.(1), such that each of the folded membrane sheets includes a non-rectangular polygonal mobile

leaflet. EX1026, ¶236.

x) Element 67[d]

Moll discloses that each of the plurality of non-rectangular polygonal mobile leaflets are bordered by non-transverse diagonally oriented folds that are angled relative to an axial flow direction as detailed above, *supra* Section V.D.4.(e), (n), and thus discloses that each of the non-rectangular polygonal mobile leaflets include non-transverse diagonally oriented folds that are angled relative to an axial flow direction. EX1026, ¶237.

y) Claim 69

Moll in combination with Paniagua teaches the vascular system implant of Claim 67 as detailed above.

Moll alone, or in combination with Paniagua, further teaches that the lattice frame is collapsible and expandable and comprises a metal alloy substantially configured as a tubular stent member as detailed above. *Supra* Section V.D.4.(f); EX1026, ¶¶238-239.

z) Claim 70

Moll in combination with Paniagua teaches the vascular system implant of Claim 67 as detailed above.

Moll in combination with Paniagua teaches that the folded biocompatible membrane sheets comprise processed mammalian pericardium tissue as detailed

above. *Supra* Section V.D.4.(g); EX1026, ¶¶240-241.

aa) Claim 71

Moll in combination with Paniagua teaches the vascular system implant of Claim 67 as detailed above.

Moll further discloses that the folded biocompatible membrane sheets do not comprise a treated tissue as detailed above. *Supra* Section V.D.4.(h); EX1026, ¶¶242-243.

bb) Claim 72

Moll in combination with Paniagua teaches the vascular system implant of Claim 67 as detailed above.

Moll further discloses that the folded biocompatible membrane sheets comprise a synthetic material as detailed above. *Supra* Section V.D.4.(i); EX1026, ¶¶244-245.

5. Ground 6: Claims 62 and 83-85 are obvious over Moll (EX1005) in view of Paniagua (EX1007) and Pavcnik (EX1008)

a) Claim 62

Moll in combination with Paniagua teaches the vascular system implant of Claim 61 as detailed above.

Moll does not explicitly disclose the use of a cuff wall attached to the lattice frame as claimed by the '400 Patent.

As detailed above, *supra* Section V.D.2.(a), Pavcnik discloses valve cusps

that include a vertex forming a proximal, upstream tip akin to the proximal end of the “flow stoppage elements” of Moll that can be folded over in a radially outward direction and attached to the lattice frame to form a “corner flap.” *See* EX1008, ¶¶0104]; EX1026, ¶¶246-248.

It would have been obvious to a POSITA to combine the teachings of Moll, Paniagua, and Pavcnik such that the proximal ends of Moll’s blood flow stoppage elements can be folded over in a radially outward direction and attached to the lattice frame to form corner flaps as taught by Pavcnik. EX1026, ¶249. These corner flaps form “cuff walls” as claimed by the ’400 Patent, which would be located radially exterior to each of the plurality of non-rectangular polygonal mobile leaflets and to the corresponding cusp wall. *Id.* A POSITA would have been motivated to modify the conical cusps of Moll in view of the teachings of Pavcnik at least to provide a sealing structure that catches retrograde blood flow between the device and the vessel wall. *Id.* Further motivation is found in the teachings of the Textbook of Interventional Cardiology, which recognized at the outset of transcatheter valve development that valve designs should aim to minimize perivalvular leak. *Id.*; EX1013, 7.

Moreover, all of the claimed elements of Claim 62 were known in the prior art as evidenced by the teachings of, *e.g.*, Moll, Paniagua, and Pavcnik, and a POSITA could have combined the teachings of these elements as claimed by

known methods with no change in their respective functions, and the combination would have yielded nothing more than predictable results to a POSITA. EX1026, ¶250. Indeed, there would have been a reasonable expectation of success in combining the teachings of Moll, Paniagua, and Pavcnik given that each are directed to transcatheter valve structures and the structures disclosed by Pavcnik were shown to have been successfully implanted in animals (in both veins and in the aortic valve position) and in patients' veins. *Id.*; EX1009, 5 (“The square stent is a new device with the potential to improve minimally-invasive treatment as a venous and aortic valve.”); EX1029, 5.

b) Claims 83-85

Moll in combination with Paniagua teaches the vascular system implant of claims 55, 62, and 67 as detailed above.

For the same reasons that Moll in combination with Paniagua and Pavcnik teaches a cuff wall attached to the lattice frame, *supra* Section V.D.5.(a), Moll in combination with Paniagua and Pavcnik teaches that each of the plurality of conical shaped cusps includes a vertex forming a proximal, upstream tip that has been folded over in a radially outward direction and attached to the lattice frame. EX1026, ¶¶251-256.

6. Ground 7: Claim 68 is obvious over Moll (EX1005) in view of Paniagua (EX1007) and Melsheimer (EX1003)

a) Claim 68

Moll in combination with Paniagua teaches the vascular system implant of Claim 67 as detailed above.

Moll does not explicitly disclose whether each of the at least two folded biocompatible membrane sheets comprises two or more pieces of biocompatible membrane material.

Melsheimer (EX1003), however, teaches that two or more pieces of biocompatible membrane material in a valve cusp construction can be used where different properties are sought from each piece of material. EX1003, ¶[0042] (detailing that the “leaflet” and “receptacle” (which make up the “mobile leaflet” and “cusp wall” as claimed by the ’400 Patent) may be formed with a unitary construction from the same material or, alternatively, the leaflet and receptacle can be made with different materials with differing properties).

It would have been obvious to a POSITA to modify the teachings of Moll such that the flow stoppage elements are formed with two or more pieces of biocompatible membrane material as taught by Melsheimer in order to form a structure with varying properties such as flexibility. EX1026, ¶¶257-260.

Moreover, all of the claimed elements of Claim 68 were known in the prior art as evidenced by the teachings of, *e.g.*, Moll, Paniagua, and Melsheimer, and a

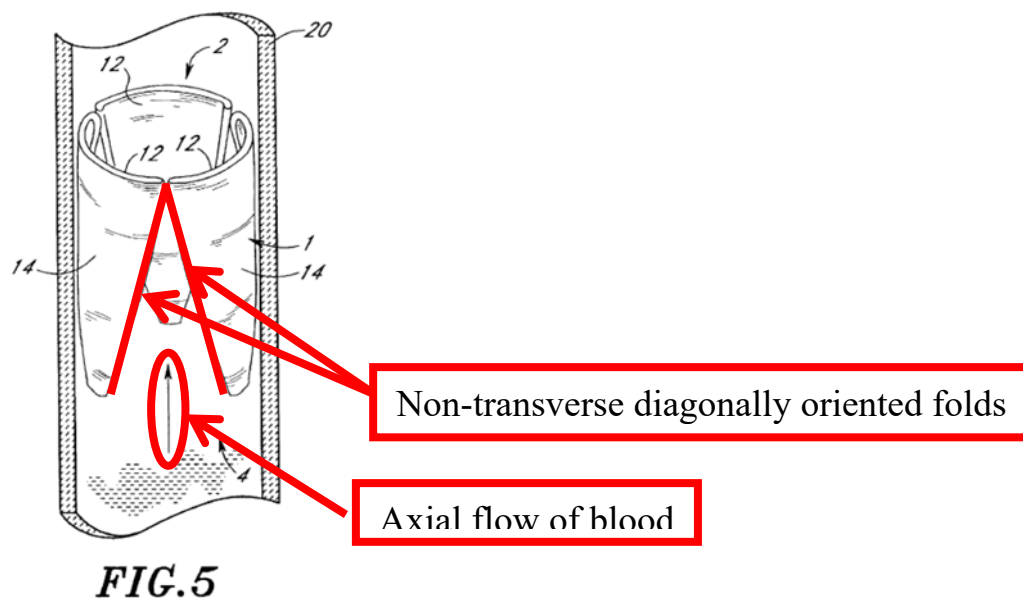
POSITA could have combined the teachings of these elements as claimed by known methods with no change in their respective functions, and the combination would have yielded nothing more than predictable results to a POSITA. *Id.* at ¶261. Indeed, there would have been a reasonable expectation of success in combining the teachings of Moll, Paniagua, and Melsheimer given that each are directed to transcatheter valve structures and Melsheimer teaches a multi-piece construction of a valve cusp as an available alternative to a uniform construction depending on the desired properties of the mobile leaflet and cusp wall. *Id.*

7. Ground 8: Claims 78-80 are Obvious over Moll (EX1005) in view of Paniagua (EX1007) and Eberhardt (EX1006)

a) Claim 78

Moll in combination with Paniagua teaches the vascular system implant of Claim 55 as detailed above.

Although Moll does not explicitly disclose the angle of the non-transverse diagonally oriented folds, it would have been obvious to a POSITA that use of, e.g., the stent structure depicted in Figure 2 of Moll would form sidewalls with angles between 10 and 80 degrees, which is supported by visual inspection of the folds in Figure 5:



EX1005, Fig. 5; EX1026, ¶¶262-263.

Even if not rendered obvious by Moll alone, it also would have been obvious to modify Moll to form angled folds along the valve leaflet with angles in the range of greater than 0 degrees and less than 90 degrees in view of the teachings of Eberhardt. EX1026, ¶264. Eberhardt teaches a prosthetic valve having polygonal leaflet structures with angled walls at their proximal end that fall within the claimed range as detailed above. *See supra* Section V.D.1.(c). It would have been obvious to a POSITA to modify the angles of Moll's non-transverse diagonally oriented folds to fall within the range of greater than 0 degrees and less than 90 degrees, which encompasses the '400 Patent's claimed range of about 10 to 80 degrees from the axial flow direction, to minimize or eliminate possible areas of stasis and to provide a hinge point for the adjacent leaflet. EX1026, ¶264. The

teachings of Spenser provide further motivation to combine, which recognized that it would have been obvious to modify boundary conditions of the valve leaflets to optimize stress distribution. *Id.*; EX1011, 25:39-65.

Moreover, all the claimed elements of Claim 78 were known in the prior art as evidenced by, *e.g.*, Moll, Paniagua, and Eberhardt, and a POSITA could have combined the teachings of these elements as claimed by known methods with no change in their respective functions, and the combination would have yielded nothing more than predictable results to a POSITA. EX1026, ¶265. Indeed, given that each of Moll, Paniagua, and Eberhardt are directed to transcatheter valves and the only feature of Claim 78 missing an explicit disclosure in Moll is recitation of the angle of its folded edges, which is explicitly addressed by Eberhardt, a POSITA would have had a reasonable expectation of success in combining these teachings. *Id.*

b) Claims 79-80

Moll in combination with Paniagua teaches the vascular system implant of Claims 60 and 67 as detailed above.

Moll in combination with Paniagua and Eberhardt teaches that the non-transverse diagonally oriented folds are angled at between about 10 to 80 degrees from the axial flow direction as explained above. *Supra* Section V.D.7.(a); EX1026, ¶¶266-269.

VI. OBJECTIVE INDICIA OF NON-OBVIOUSNESS

Petitioners are not aware of any evidence that supports any objective indicia of non-obviousness, but reserve the right to respond to any such purported evidence by Patent Owner. EX1026, ¶270.

VII. §314(a) AND §325(d) DO NOT SUPPORT DENIAL

A. §314(a)

This is the first Petition challenging any claims of the '400 Patent. Given the merits of this Petition, along with the fact that Petitioners are not parties to any co-pending district court litigation involving the '400 Patent, neither the *General Plastic* factors nor the *Fintiv* factors favor discretionary denial of this Petition. *See General Plastic Industrial Co., Ltd. v. Canon Kabushiki Kaisha*, IPR2016-1357, Paper 19 (P.T.A.B. Sept. 6, 2017); *Apple, Inc. v. Fintiv, Inc.*, IPR2020-0019, Paper 11 (P.T.A.B. Mar. 20, 2020).

B. §325(d)

The Board should also decline to deny this Petition under 325(d) because the art and arguments in this Petition were not substantively considered during prosecution. *Supra* Section II.C.1. Two references, Moll (EX1005) and Pavcnik (EX1008), were not even cited. *Supra* Section III.C.2. Thus, under step 1 of *Advanced Bionics, LLC v. MED-EL Elektromedizinische Geräte GmbH*, IPR2019-1469, Paper 6 (P.T.A.B. Feb. 13, 2020), factors (a), (b), and (d) demonstrate that the art relied on in this Petition, as well as the prior art combinations, are not the

same or substantially the same as what was considered by the Examiner—*i.e.* art raised here was never substantively considered and is uniquely situated over other prior art references relied upon during prosecution. Even if step 1 is met, the USPTO materially erred by “overlooking specific teachings of the relevant prior art.” *Id.* at 8 n.9 (“An example of a material error may include misapprehending or overlooking specific teachings of the relevant prior art where those teachings impact patentability of the challenged claims.”); *Supra* Section II.C.2.

VIII. MANDATORY NOTICES

A. Petitioner and Real Parties in Interest Under §42.8(b)(1):

Edwards Lifesciences Corporation and Edwards Lifesciences LLC are the real parties-in-interest.

B. Related Matters Under §42.8(b)(2):

Edwards is not aware of any other judicial or administrative matter involving the '400 Patent that would affect, or be affected by, a decision in this proceeding.

C. Lead and Back-Up Counsel and Service Information Under §§42.8(b)(3)-(4):

Edwards designates the following:

Lead Counsel	Back-Up Counsel
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D. Service Information Under §42.8(b)(4):

Counsel's service information is provided above. Edwards consents to electronic service by email to began@morrisnichols.com, gcordrey@jmbm.com, and mmiddleton@morrisnichols.com.

E. Payment of Fees

The undersigned authorizes the Office to charge the fee required by §42.15(a) and any additional fees that might be due to Deposit Account No. 603910.

IX. STANDING (§42.104(A))

Edwards certifies that the '400 Patent is available for *inter partes* review and

that Edwards is not barred or estopped from requesting *inter partes* review challenging Claims 55-72, 78-80, and 83-85 of the '400 Patent on the grounds identified herein.

X. CONCLUSION

Petitioners submit that the substantial evidence presented in this Petition demonstrates that there is a reasonable likelihood that Claims 55-72, 78-80, and 83-85 of the '400 Patent are invalid in view of the prior art described herein.

Dated: April 15, 2022

Respectfully Submitted,

/s/ Brian P. Egan

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APPENDIX

U.S. Patent No. 9,737,400
Claims 55-72, 78-80, and 83-85

Element-by-Element Breakdown

Claim No.	Claim Element
55[p].	A vascular system implant, comprising:
55[a].	a lattice frame; and
55[b].	a plurality of substantially conical shaped cusps attached to the lattice frame,
55[c].	wherein each of the plurality of substantially conical shaped cusps includes a biocompatible membrane,
55[d].	and wherein each of the plurality of substantially conical shaped cusps include non-transverse diagonally oriented folds that are angled relative to an axial flow direction.
56.	The vascular system implant of claim 55, wherein the lattice frame is collapsible and expandable and comprises a metal alloy substantially configured as a tubular stent member.
57.	The vascular system implant of claim 55, wherein the biocompatible membrane comprises processed mammalian pericardium tissue.
58.	The vascular system implant of claim 55, wherein the biocompatible membrane does not comprise a treated tissue.
59.	The vascular system implant of claim 55, wherein the biocompatible membrane comprises a synthetic material.

Claim No.	Claim Element
60[p].	A vascular system implant, comprising:
60[a].	a lattice frame; and
60[b].	a plurality of non-rectangular polygonal mobile leaflets attached to the lattice frame,
60[c].	wherein each of the plurality of non-rectangular polygonal mobile leaflets includes a biocompatible membrane,
60[d].	and wherein each of the plurality of non-rectangular polygonal mobile leaflets are bordered by non-transverse diagonally oriented folds that are angled relative to an axial flow direction.
61.	The vascular system implant of claim 60, wherein each of the plurality of non-rectangular polygonal mobile leaflets is attached in a continuous manner to a corresponding cusp wall located radially exterior to each of the plurality of non-rectangular polygonal mobile leaflets.
62.	The vascular system implant of claim 61, further comprising a cuff wall attached to the lattice frame, wherein the cuff wall is located radially exterior to each of the plurality of non-rectangular polygonal mobile leaflets and to the corresponding cusp wall.

Claim No.	Claim Element
63.	The vascular system implant of claim 60, wherein the lattice frame is collapsible and expandable and comprises a metal alloy substantially configured as a tubular stent member.
64.	The vascular system implant of claim 60, wherein the biocompatible membrane comprises processed mammalian pericardium tissue.
65.	The vascular system implant of claim 60, wherein the biocompatible membrane does not comprise a treated tissue.
66.	The vascular system implant of claim 60, wherein the biocompatible membrane comprises a synthetic material.
67[p].	A vascular system implant, comprising:
67[a].	a lattice frame; and
67[b].	at least two folded biocompatible membrane sheets attached to the lattice frame,
67[c].	wherein each of the at least two folded biocompatible membrane sheets has been formed to include a non-rectangular polygonal mobile leaflet,
67[d].	wherein each of the non-rectangular polygonal mobile

Claim No.	Claim Element
	leaflets include non-transverse diagonally oriented folds that are angled relative to an axial flow direction.
68.	The vascular system implant of claim 67, wherein each of the at least two folded biocompatible membrane sheets comprises two or more pieces of biocompatible membrane material.
69.	The vascular system implant of claim 67, wherein the lattice frame is collapsible and expandable and comprises a metal alloy substantially configured as a tubular stent member.
70.	The vascular system implant of claim 67, wherein the at least two folded biocompatible membrane sheets comprise processed mammalian pericardium tissue.
71.	The vascular system implant of claim 67, wherein the at least two folded biocompatible membrane sheets do not comprise a treated tissue.
72.	The vascular system implant of claim 67, wherein the at least two folded biocompatible membrane sheets comprise a synthetic material.
78.	The vascular system implant of claim 55, wherein the

Claim No.	Claim Element
	non-transverse diagonally oriented folds are angled at between about 10 to 80 degrees from the axial flow direction.
79.	The vascular system implant of claim 60, wherein the non-transverse diagonally oriented folds are angled at between about 10 to 80 degrees from the axial flow direction.
80.	The vascular system implant of claim 67, wherein the non-transverse diagonally oriented folds are angled at between about 10 to 80 degrees from the axial flow direction.
83.	The vascular system implant of claim 55, wherein each of the plurality of conical shaped cusps includes a vertex forming a proximal, upstream, tip that has been folded over in a radially outward direction and attached to the lattice frame.
84.	The vascular system implant of claim 62, wherein each of the plurality of non-rectangular polygonal mobile leaflets includes a vertex forming a proximal, upstream, tip that has been folded over in a radially outward direction and

Claim No.	Claim Element
	attached to the lattice frame.
85.	The vascular system implant of claim 67, wherein each of the non-rectangular polygonal mobile leaflets includes a vertex forming a proximal, upstream, tip that has been folded over in a radially outward direction and attached to the lattice frame.

37 C.F.R. § 42.24(D) CERTIFICATION

The undersigned hereby certifies that this submission, excluding the table of contents, table of authorities, exhibit list, mandatory notices under §42.8, certificate of word count, certificate of service, and appendix of claim listing, contains 13,875 words, as determined using the standard word counting feature of the Microsoft Word program.

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CERTIFICATION OF SERVICE (37 C.F.R. §§ 42.6(E), 42.105(A))

I hereby certify that, on April 15, 2022, I caused a true and correct copy of the foregoing Petition for *inter partes* review of U.S. Patent No. 9,737,400 (“the ’400 Patent”) and all associated supporting materials to be served via Express Mail delivery at the correspondence address of record for the ’400 Patent:

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