

Filed: January 31, 2023

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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EDWARDS LIFESCIENCES CORPORATION AND  
EDWARDS LIFESCIENCES LLC,

PETITIONERS,

V.

COLIBRI HEART VALVE LLC,

PATENT OWNER.

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

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**PATENT OWNER'S RESPONSE  
UNDER 37 C.F.R. § 42.120**

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## **I. INTRODUCTION**

U.S. Patent No. 9,737,400 (“the ’400 patent”) was invented by Drs. Fish, Paniagua, and Induni, and is owned by Colibri Heart Valve LLC (“Colibri”). Colibri was co-founded by two of the patent’s three inventors—Drs. David Paniagua and R. David Fish—who are both leading cardiovascular surgeons and innovators in the field of cardiovascular intervention, and were responsible for one of the first percutaneous heart valve implants. Dr. Paniagua also performed the world’s first retrograde transcatheter aortic valve implantation procedure on a human in 2003. Their work has resulted in the discovery and development of artificial heart valves and treatment methodologies that could offer patients an opportunity to receive less invasive heart valve therapy, and became the basis for Colibri’s patented inventions.

One such patent—the ’400 patent at issue here—simultaneously achieves two goals that solve problems in the field of percutaneous stent-mounted heart valve (“PHV”) devices—it teaches a device that mimics the optimal natural form of inflow into the valve, while at the same time minimizing the stress on the leaflet commissures. In disclosing devices that achieve these goals, Colibri’s patent is directed to a vascular system implant, and generally includes:

- a lattice frame;
- two or more substantially conical shaped cusps that:

- include two or more non-rectangular polygonal mobile leaflets that:
  - are attached to the lattice frame;
  - are made from a biocompatible membrane; and
  - include non-transverse diagonally oriented folds that are angled relative to an axial flow direction.

In particular, Petitioners failed to demonstrate at least that the prior art anticipates or renders obvious every element of *any* of the '400 patent's Challenged Claims, including at least “substantially conical shaped cusps,” cusps/leaflets/folded membrane sheets that are “attached to the lattice frame,” and additionally for Grounds 5-8, a “lattice frame,” and that the leaflets and membrane sheets contain “folds.”

Accordingly, Colibri requests that the Board find Petitioners failed to demonstrate that the Challenged Claims are unpatentable.

## **II. LEVEL OF ORDINARY SKILL**

For purposes of this Response only, Colibri does not dispute Petitioners' definition of a person of ordinary skill in the art (“POSA”) that the Board adopted in its Institution Decision. (ID, 10.)



### III. OVERVIEW OF THE '400 INVENTION

Heart disease is the leading cause of death in the United States. In severe cases, the heart valve must be replaced with an artificial heart valve. Over 100,000 defective heart valves are replaced in the U.S. each year. The '400 patent is directed to one such valve— “[a] transcatheter, percutaneously implantable, prosthetic heart valve [“PHV”]...that comprises a lattice frame and two or more integrated cusp and leaflet folded structures attached to the lattice frame.” (EX1001, Abstract.)

As the '400 patent describes, Colibri’s inventors recognized certain challenges to the formation of a PHV, and their efforts to address these challenges resulted in the patent’s claimed inventions. Among these challenges were “how to confine operating leaflets within a partially sealed tubular structure while preserving ideal opening and closing valve behavior without the benefit of the natural mechanism of the sinuses of Valsalva in a single valve and leaflet geometry...” (*Id.*, 2:11-16.) Additional challenges include the fact that “[t]he spherical geometry of the native aortic valve leaflets is difficult to replicate in a transcatheter valve.” (*Id.*, 2:55-56.) This challenge stems from the fact that this shape “is not suited to efficient radial compression typically required for collapse into a small diameter delivery catheter used in transcatheter valve delivery systems,” as well as the fact that “tissue bioprosthetic valve leaflets...are typically

constructed of flat sheet tissue membrane from which rendering of cusps with leaflets of a spherical contour” would create a “threat to the material integrity of the thin tissue membrane.” (*Id.*, 2:55-3:5.)

In addressing these challenges, the '400 patent enumerates two goals: (1) to maximize effective orifice area and minimize opening pressure gradients through geometry that mimics the natural form of inflow into the valve—the tubular outflow tract of the heart pumping chamber; and (2) to minimize the inward tension on the leaflet commissures in the closed position through geometry that mimics the natural effect of the sinuses of Valsalva—an effect that prevents downward displacement of the leaflet free edges under closing pressure, thus distributing force along the lines of leaflet apposition rather than focusing it at the points of leaflet attachment to the frame. (*Id.*, 2:29-40.)

The '400 patent “answers these challenges by employing conical rather than spherical cusp geometry, thereby reproducing some benefits of the latter with near-elliptical leaflet cross-section that progressively decreases moving proximal to the plane of leaflet apposition while being readily conformed on outward radial compression in the valve opening phase into a substantially flat folded construct against the interior tubular walls of the containing frame.” (*Id.*, 3:6-14.) As the patent explains:

This favorable resolution of the conical geometry in opening phase expresses the opening efficiency of this valve design with a large

effective orifice area and low transvalvular energy losses. In the closed position, the free edges of the separate leaflets of the conical cusps meet in apposition, each cone acting as an independent valve; pressure load-bearing is enhanced by the material continuity of the cone structure with the inner apposing wall and outer wall of each cone being part of a single continuous membrane structure. Further, the conical cusps are particularly suited for compression and containment within a collapsible frame for transcatheter delivery.

(*Id.*, 3:14-25.)

The '400 patent's claims reciting the specific elements of these invention(s) at issue in this IPR are listed below.

#### **IV. CHALLENGED CLAIMS**

Petitioners challenge claims 55-72, 78-80, and 83-85 of the '400 patent, of which claims 55, 60, and 67 are independent. These Challenged Claims recite as follows:

Claim 55 recites:

A vascular system implant, comprising:

a lattice frame; and

a plurality of substantially conical shaped cusps attached to the lattice frame, wherein each of the plurality of substantially conical shaped cusps includes a biocompatible membrane, 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.

(*Id.*, 33:7-15.)

Claim 56 recites:

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.

(*Id.*, 33:16-19.)

Claim 57 recites:

The vascular system implant of claim 55, wherein the biocompatible membrane comprises processed mammalian pericardium tissue.

(*Id.*, 33:20-22.)

Claim 58 recites:

The vascular system implant of claim 55, wherein the biocompatible membrane does not comprise a treated tissue.

(*Id.*, 33:23-24.)

Claim 59 recites:

The vascular system implant of claim 55, wherein the biocompatible membrane comprises a synthetic material.

(*Id.*, 33:25-26.)

Claim 60 recites:

A vascular system implant, comprising:

a lattice frame; and

a plurality of non-rectangular polygonal mobile leaflets attached to the lattice frame, wherein each of the plurality of non-rectangular polygonal mobile leaflets includes a biocompatible membrane, 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.

(*Id.*, 33:27-36.)

Claim 61 recites:

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.

(*Id.*, 33:27-36.)

Claim 62 recites:

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.

(*Id.*, 33:27-36.)

Claim 63 recites:

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.

(*Id.*, 33:27-36.)

Claim 64 recites:

The vascular system implant of claim 60, wherein the biocompatible membrane comprises processed mammalian pericardium tissue.

(*Id.*, 33:27-36.)

Claim 65 recites:

The vascular system implant of claim 60, wherein the biocompatible membrane does not comprise a treated tissue.

(*Id.*, 33:27-36.)

Claim 66 recites:

The vascular system implant of claim 60, wherein the biocompatible membrane comprises a synthetic material.

(*Id.*, 33:27-36.)

Claim 67 recites:

A vascular system implant, comprising:

a lattice frame; and

at least two folded biocompatible membrane sheets attached to the lattice frame, wherein each of the at least two folded biocompatible membrane sheets has been formed to include a non-rectangular polygonal mobile leaflet, wherein each of the non-rectangular polygonal mobile leaflets include non-transverse diagonally oriented folds that are angled relative to an axial flow direction.

*(Id., 33:58-67.)*

Claim 68 recites:

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.

*(Id., 33:58-67.)*

Claim 69 recites:

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.

*(Id., 33:58-67.)*

Claim 70 recites:

The vascular system implant of claim 67, wherein the at least two folded biocompatible membrane sheets comprise processed mammalian pericardium tissue.

*(Id., 33:58-67.)*

Claim 71 recites:

The vascular system implant of claim 67, wherein the at least two folded biocompatible membrane sheets do not comprise a treated tissue.

*(Id., 33:58-67.)*

Claim 72 recites:

The vascular system implant of claim 67, wherein the at least two folded biocompatible membrane sheets comprise a synthetic material.

*(Id., 33:58-67.)*

Claim 78 recites:

The vascular system implant of claim 55, wherein the non-transverse diagonally oriented folds are angled at between about 10 to 80 degrees from the axial flow direction.

*(Id., 33:58-67.)*

Claim 79 recites:



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.

*(Id., 33:58-67.)*

Claim 80 recites:

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.

*(Id., 33:58-67.)*

Claim 83 recites:

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.

*(Id., 33:58-67.)*

Claim 84 recites:

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 attached to the lattice frame.

*(Id., 33:58-67.)*

Claim 85 recites:

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.

(*Id.*, 33:58-67.)

## **V. PROSECUTION HISTORY**

The '400 patent was filed on December 14, 2011, as Application No. 13/326,196, and claims priority to Provisional Application No. 61/423,051, filed on December 14, 2010. (*Id.*, Cover.)

Although Applicants amended their claims in response to a series of restriction/elections (EX1002, 2132-2157, 3275-3280, 3315-334, 3527-3553), Applicants did not amend their claims in response to any Office Action. (*See Id.*, 3625-3629, 3773-3790, 3794, 3828-3829, 3848, 3850-3869, 3873.)

On April 24, 2017, the Examiner issued a Notice of Allowance. (*Id.*, 3889.) Challenged Claims 55-72, 78-80, and 83-85 of the '400 patent issued on August 22, 2017. (*Id.*, 3920.)

## VI. CLAIM CONSTRUCTION

Colibri agrees with Petitioners that, for purposes of this Response, all terms of the '400 patent, other than as specified below, have their plain and ordinary meaning.

### A. “Attach”

In its Institution Decision, the Board found “the definition of the claim term ‘attached’ to be at issue in this proceeding,” and “invite[d] the parties to brief this issue in their respective responses...” (ID, 13.) A POSA reading the '400 patent would have understood that “attached,” as used in the '400 patent, means “to fasten or join two or more components at the same location.” (EX2001, ¶94.)

#### 1. **Construing “attach” as “to fasten or join two or more components at the same location” is consistent with the '400 patent’s specification.**

The claim construction “inquiry typically begins and ends with the intrinsic evidence. In fact, the specification is the single best guide to the meaning of the claim terms; it is usually dispositive.” *Ericsson, Inc. v. D-Link Sys., Inc.*, 773 F.3d 1201, 1218 (Fed. Cir. 2014). Thus, a POSA would first look to the '400 patent’s specification to determine the meaning of “attach” within the patent. Although the patent does not explicitly define “attach,” the patent uses the term with such frequency that a POSA can determine its meaning within the context of the patent. For example, the following is a passage from the specification describing Figure 9D, copied below, disclosing attaching integrated cusp and leaflet folded structures

to the frame and then attaching the commissure folds of the cusp/leaflet structures along their common length to both the frame and cusp wall:

**Figure 9D**

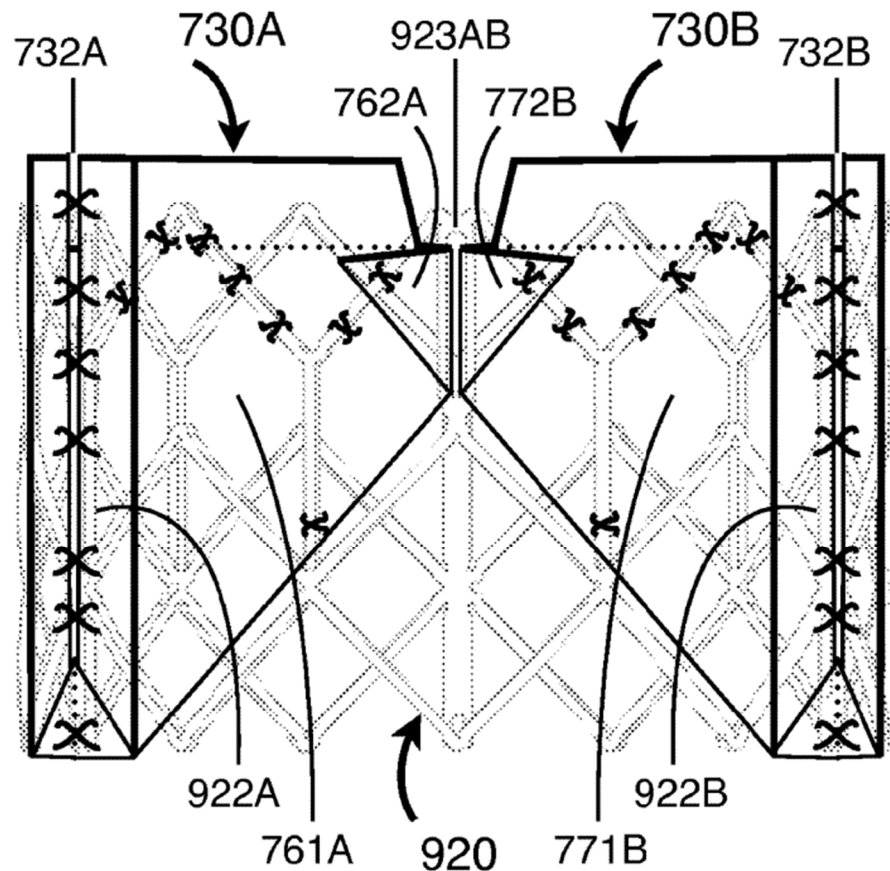


FIG. 9D shows a side perspective view of the frame 920 centered on the slotted frame member 923AB with a superimposed perspective view of the outer aspect of two circumferentially adjacent completely folded integrated cusp and leaflet structures 730A and 730B (of FIG. 7I) to demonstrate their relationships as mounted within the frame 920. An example suture pattern for attachment is shown. ***Suture attachment of the commissure folds 705 and 706 at the level of the***

*slot is notably absent. Rather, attachment of the bodies of the commissure tabs 762A and 772B to the outer aspect of the frame at points removed from the free edges and folds of the material* avoids suture penetration along the lines of traction in the slot and enhances the resistance of the structure to tearing at such suture attachments. The *cuspal wall seams 732A and 732B are aligned upon the inner surface* of the mounting bars 922A and 922B, respectively *of the frame 920 and attached by sutures* in this example. The *commissure tabs 762A and 772B are* to be understood as having been passed through the frame slot 924 from within the central space of the frame to the outer (abluminal) side and *folded along 705A and 706B*, respectively onto the outer surface of the cuspal and leaflet structure *where they are attached along their common length both to the frame member 923AB and*, through the interspaces of the frame 920, *to the radially underlying outer aspect of the cuspal wall sections 761A and 771B*, respectively.

(EX1001, 26:42-67<sup>1</sup>.)

A POSA reading the '400 patent would view the patent's definition of "attach" as consistent with the definitions found in dictionaries, such as "to fasten, secure, or join." (EX2001, ¶95-97.) However, a POSA would realize that the patent uses "attach" in more specific manner than as used in common parlance. Specifically, "a POSA reading this section would realize that the various components being described cannot be joined or attached in any manner. Rather,

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<sup>1</sup> All emphasis added unless otherwise indicated.

the attachment must fit within the context of the entire disclosure of the patent, which uses ‘attach’ to mean ‘to fasten or join two or more components at the same location.’” (EX2001, ¶98.)

That the ’400 patent’s use of “attach” is specific to fastening or joining two or more components at the *same location* is evident from the patent’s specification, including, for example, the patent’s discussion of Figure 9D, above. With respect to Figure 9D, the patent explains that the integrated cusp/leaflet structures are mounted within the frame such that: (1) the cusp wall seams are aligned on the inner surface of the frame’s mounting bars and attached by sutures (2) the commissure tabs—which are part of the cusp/leaflet structures already attached to the frame’s mounting bars—are attached to the frame along the common length of the commissure tabs, (3) the commissure tabs are *not* attached to the frame at points removed from the free edges and folds of the material or at the level of the slot, and (4) the commissure tabs are attached to the outer surface of the cusp wall through the interspaces of the frame. (EX2001, ¶99.)

Thus, the ’400 patent discloses structures being “mounted”—or joined—within the frame generally, but when disclosing the way these structures are “attached” within the frame, the patent provides specific locations at which two or more structures are attached to each other. In the context of Figure 9D, the structures that are attached *at the same location* are (1) the cusp wall seams and the

frame's mounting bars, (2) the commissure tabs and the frame along the common length of the commissure tabs, and (3) the commissure tabs and the outer surface of the cusp wall through the interspaces of the frame. (EX2001, ¶100.)

**2. The definition of “attach” applied by Petitioners’ expert is inconsistent with the ’400 patent’s specification.**

It is important to note that the ’400 patent’s use of “attach” conflicts with the use of the term by Petitioners’ expert in rendering his opinions in this IPR. At deposition, Petitioners’ expert defined “attach” as follows: “If I have two objects and they are attached, the attachment will generally result in, you know, a connection between those objects; such that our term of art on the engineering side is ‘load path,’ that a displacement or force or pressure will travel through the attachment from one material or object to another.” (Ex. 2002 at 36:13-37:5.) Petitioners’ expert later clarified that, applying his meaning of “attached” as “transmitting load in displacement” to an example, in his opinion, “if A is attached to B and B is attached to C, C is attached to A.” (Ex. 2002, 90:14-92:13.)

However, the ’400 patent’s use of “attached” in the context of Figure 9D, for example, makes clear that Petitioners’ expert’s definition is incorrect. Specifically, the patent’s description of Figure 9D states that the “completely folded integrated cusp and leaflet structures” are attached at the “cusp wall seams” on the “inner surface of the mounting bars...of the frame.” (EX1001, 26:45-58.) And the patent makes clear that commissure tabs 762A and 772B are part of these integrated cusp

and leaflet structures that are attached to the frame. (EX1001, 21:22-27, 23:30-32.)

Thus, under Petitioners' expert's definition of "attach," the commissure tabs are attached to the frame because they are attached to (and actually part of) the integrated cusp/leaflet structures that are attached to the frame. (EX2001, ¶¶101-102.)

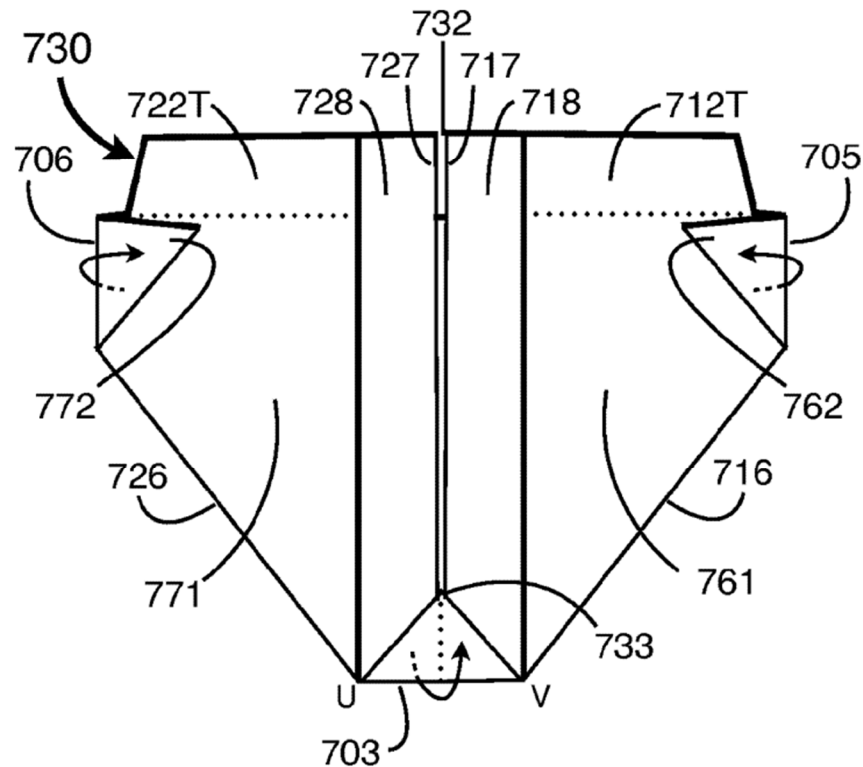
The '400 patent's description of Figure 9D goes on to state that commissure tabs 762A and 772B "***are attached along their common length both to the frame member 923AB and, through the interspaces of the frame 920, to the radially underlying outer aspect of the cusp wall sections 761A and 771B, respectively.***" (EX1001, 26:59-67.) But this disclosure is redundant under Petitioners' expert's definition of "attach," because under that definition, the commissure tabs are already attached to the frame by virtue of their attachment to the cusp/leaflet structures that are attached to the frame. (EX2001, ¶103.) Additionally, the patent's disclosure that the commissure tabs are attached to the "frame at points removed from the free edges and folds of the material" is impossible to achieve under the Petitioners' expert's definition of "attach," because according to that definition, ***all points*** of the commissure tabs would be attached to the frame since they are attached to the cusp/leaflet structures that are attached to the frame. (EX2001, ¶104.)



By contrast, the '400 patent's description of Figure 9D contains no redundancy when applying the patent's use of the term "attach"—two or more components fastened or joined *at the same location*. (EX2001, ¶105.) Under that definition, the commissure tabs are initially attached to the integrated cusp and leaflet structures at folds 705 and 706, as shown in Figure 7I (referenced by Figure 9D), below, but not to the frame. (EX2001, ¶105.) Then, only after the commissure tabs have "been passed through the frame slot 924 from within the central space of the frame to the outer (abluminal) side and folded...onto the outer surface of the cusp and leaflet structure," are the commissure tabs "attached along their common length both to the frame member [] and, through the interspaces of the frame [], to

the radially underlying outer aspect of the cusp wall...” (EX2001, ¶105.)

**Figure 7I**



Importantly, it is only by applying the '400 patent's location-specific definition of “attach” that a POSA can practice the patent's disclosures where, according to Figure 9D, (1) “attachment of the commissure folds [] at the level of the slot is notably absent,” and (2) “attachment of the bodies of the commissure tabs [] to the outer aspect of the frame at points removed from the free edges and folds of the material[, which] avoids suture penetration along the lines of traction in the slot and *enhances the resistance of the structure to tearing and such suture attachments.*” (EX2001, ¶106.) See *Littelfuse, Inc. v. Mersen USA EP Corp.*, 29

F.4th 1376, 1379, 1381 (Fed. Cir. 2022) (vacating claim construction as inconsistent “with the claims, specification, and prosecution history” because “[h]ow the term is used in the claims and the specification of the patent is strong evidence of how a [POSA] would understand the term.”).

**3. Construing “attach” as “to fasten or join two or more components at the same location” is consistent with the purpose of the invention disclosed in the ’400 patent’s specification.**

A POSA would have understood that key teachings of the ’400 patent include “various clever membrane folding methods and ways to attach them to a frame in a secure and atraumatic way while enhancing performance and durability.” (EX2001, ¶107.) An example of these clever folding and attachment methods is Figure 9D’s disclosure that (1) commissure tabs 762A and 772B ***“are attached along their common length both to the frame member 923AB and, through the interspaces of the frame 920, to the radially underlying outer aspect of the cusp wall sections 761A and 771B, respectively,”*** while (2) ***“attachment of the commissure folds [] at the level of the slot is notably absent,”*** and (2) ***“attachment of the bodies of the commissure tabs [] to the outer aspect of the frame at points removed from the free edges and folds of the material[, which] avoids suture penetration along the lines of traction in the slot and enhances the resistance of the structure to tearing and such suture attachments.”*** (EX2001, ¶107.)

But as this discussion of Figure 9D demonstrates, Petitioners’ broad definition of “attach” applies too generally to capture the specific types of attachments that are both “secure and atraumatic [] while also enhancing performance and durability” that are key features of the inventions disclosed and claimed in the ’400 patent. By contrast, Colibri’s expert’s location-specific definition of “attach” captures these key features of the ’400 patent’s inventions. (EX2001, ¶108.) This is because the location at which one component is joined with another is a key to achieving the purpose of certain of the ’400 patent’s inventions. (EX2001, ¶108.) *See Apple Computer, Inc. v. Articulate Sys., Inc.*, 234 F.3d 14, 25 (Fed. Cir. 2000) (Reversing claim construction as overbroad because claims “must be interpreted in light of the teachings of the written description and purpose of the invention described therein”).

**4. Petitioners’ expert’s definition of “attach” impermissibly renders claim terms meaningless.**

Moreover, applying Petitioners’ expert’s definition of “attach” impermissibly renders claim terms meaningless. *See Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc.*, 520 F.3d 1358, 1362 (Fed. Cir. 2008) (“[T]his court strives to reach a claim construction that does not render claim language in dependent claims meaningless.”). (EX2001, ¶109.) For example, claim 55 recites, in relevant part, “a plurality of substantially conical shaped *cusps attached to the lattice frame*.” And claim 83 recites: “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.*”

As with Figure 9D, according to Petitioners’ expert’s definition of “attach,” the “vertex forming a proximal, upstream, tip that has been folded over in a radially outward direction” would already be attached to the frame through its inclusion in the “substantially conical shaped cusps attached to the lattice frame” in claim 55. Thus, claim 83’s recitation of attaching this vertex “to the lattice frame” is rendered meaningless by Petitioners’ expert’s definition of “attach”—a result the Federal Circuit has repeatedly rejected. (EX2001, ¶¶110-111.) *See In re Power Integrations, Inc.*, 884 F.3d 1370, 1376 (Fed. Cir. 2018) (reversing “board’s claim construction [because] it renders claim language meaningless.”).

By contrast, Colibri’s expert’s definition of “attach”—“to fasten or join two or more components at the same location”—allows for “a plurality of substantially conical shaped cusps *attached to the lattice frame*” in claim 55, while still giving meaning to each “*cusp[] include[ing] a vertex* forming a proximal, upstream, tip that has been *folded over in a radially outward direction and attached to the lattice frame*” in dependent claim 83. (EX2001, ¶112.) Specifically, because claim 55 does not specify what portion(s) of the cusps are attached to the frame, Colibri’s expert’s location-specific definition of “attach” allows for the claim 55 attachment

at a location *other than* each cusps' vertex. (EX2001, ¶113.) In this way, each “vertex forming a proximal, upstream, tip that has been folded over in a radially outward direction” can be attached to the frame as in dependent claim 83, without having been attached to the frame previously through attachment of the cusps to the frame in independent claim 55. (EX2001, ¶113.)

**5. The definition of “attach” applied by Petitioners’ expert is impermissibly synonymous with a different term defined in the ’400 patent specification but not used in the claims.**

Finally, the definition of “attach” applied by Colibri’s expert matches a different term that the ’400 patent defines separately from—and more broadly than—its use of the term “attach.” Specifically, the ’400 patent states that, “[a]s used herein, ‘operably associated’ refers to components that are linked together in operable fashion, and encompasses embodiments in which components are linked directly, as well as embodiments in which additional components are placed between the two linked components.” (EX2001, ¶114.)

As Colibri’s expert explains, the patent’s definition of “operably associated” is broader than the patent’s use of the term “attach.” (EX2001, ¶115.) This is because “‘operably associated’ includes multiple components linked together directly in one location—as with components that are “attached” within the meaning of the ’400 patent—as well as one component linked to a second component that is separately linked to a third component. (EX2001, ¶115.) “For

example, as with ‘attach,’ ‘operably associated’ may describe three components, A, B, and C, with all three components joined at the same location.” (EX2001, ¶115.) However, ‘operably associated’—like the definition of “attach” applied by Petitioners’ expert—would also encompass three components, D, E, and F, with D joined to E at one location and E joined to F at a different location.” (EX2001, ¶115.)

Under the patent’s definitions according to Colibri’s expert, D would be “operably associated” with F but D would not be “attached” to F, because “attach” is a more narrowly defined joining method than “operably associated” within the context of the ’400 patent.” (EX2001, ¶116.) However, under the definition of “attach” applied by Petitioners’ expert, “attach” and “operably associated” are one and the same, despite the fact that the patentees defined “operably associated” in the patent and chose to use the term “attach” in the claims instead. This is a further indication that the definition of “attach” applied by Petitioners’ expert is incorrect. *See Horizon Pharma, Inc. v. Dr. Reddy’s Labs. Inc.*, 839 F. App’x 500, 504 (Fed. Cir. 2021) (“We agree with the district court that the use of both the terms ‘target’ and ‘produce’ at different points in the specification does not mean that these words have the same meaning. If anything, this ***suggests that the patent applicants were aware of their separate meanings and chose to use ‘target’ in the patent claims instead of ‘produce.’***”).

**B. “Substantially Conical”**

Colibri agrees with the Board’s Institution Decision, which states that the ’400 patent specification defines “substantially conical” as “resembling 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 decreases monotonically moving from the level of the leaflet apposition to the proximal end of the valve.” (ID, 12; EX1001, 12:47-54.)

**C. “Folds”**

Colibri agrees with the Board’s Institution Decision stating “that the term ‘folds’ need not be construed at this time.” (ID, 12.)

To the extent that the Board decides to construe “folds,” Colibri agrees with Petitioners that the specification defines “folding” 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; Petition, 29-30.) As such, “folds” are defined by the ’400 patent specification’s definition of “folding,” and thus are the “sharp lines or creases that partition 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.” (See EX1001, 12:61-64.)

Petitioners largely agrees with Colibri’s definition, but replaces the ’400 patent’s definition of “folding” as being “along a sharp line of folding or crease” with the much more general term “lines”, purportedly because “dry tissue is not a requirement in any of the Challenged Claims” and Petitioners believe that hydrated material will create “lines,” but not “sharp lines or creases” when folded. (See Petition, 30.) However, Colibri disagrees with Petitioners that the ’400 patent specification’s definition of “folding” is limited to the “context of folding dry tissue.” (See Petition, 29.) The definitional section of the ’400 specification contains no such limitation. (See EX1001, 12:61-64.) Rather, Petitioners improperly import this limitation from an example given in the ’400 patent’s specification regarding how “folds” behave in one particular context:

[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.

(Compare Petition, 30 with EX1001, 10:10-19.) And it is black letter law that it is improper to import additional limitations into claim terms from outside the

lexicography portion of the specification, particularly when those additional limitations derive from an example that the specification provides, as is the case here. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1323 (Fed. Cir. 2005) (en banc).

**D. “Biocompatible Membrane [that] Does Not Comprise a Treated Tissue”**

Petitioners contend that the term “biocompatible membrane [that] does not comprise a treated tissue” “at least includes a biocompatible membrane made with a synthetic material.” (Petition, 30-31.) For purposes of this Response only, Colibri does not contest this construction.

**E. “Cusp,” “Cuff Wall,” “Cusp Wall,” “Frame,” “Mobile Leaflet Layer” or “Leaflet,” “Proximal,” “Non-Transverse,” “Plurality of...Leaflets”**

For purposes of this Response, Colibri agrees with the Board’s Institution Decision that these “terms are defined by the ’400 patent and these definitions control.” (ID, 12.)

**VII. THE PRIOR ART FAILS TO ANTICIPATE OR RENDER OBVIOUS EACH OF THE RECITED ELEMENTS OF THE CHALLENGED CLAIMS.**

**A. Grounds 1-3: Melsheimer alone, or in combination with Eberhardt or Pavcnik, does not anticipate or render obvious the Challenged Claims.**

**1. Petitioners failed to allege that Melsheimer anticipates or render obvious “leaflets attached to the lattice frame” as required by statute (Grounds 1-3, Claims 60-66, 79, 84).**

Claim 60 (and Challenged Claims 61-66, 79, and 84) recites “a plurality of non-rectangular polygonal mobile leaflets attached to the lattice frame”.

The Institution Decision states that the Board is “not convinced that simply because Petitioner did not explain in detail how Melsheimer discloses leaflets attached to the lattice frame that it does not do so.” (ID, 18.) Respectfully, Colibri’s argument is not that Petitioners did not *explain in detail* how Melsheimer discloses leaflets attached to the frame. Rather, Colibri’s argument is that Petitioners failed to allege *at all* that Melsheimer discloses leaflets attached to the frame, but instead alleged that a *different structure* within Melsheimer *separate from its leaflets* is attached to Melsheimer’s frame. “In an IPR, the petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable,” and by failing to allege that Melsheimer discloses leaflets attached to the frame, Petitioners failed to meet their statutory burden. *See Microsoft Corp. v. IPA Techs. Inc.*, No. 2021-1412, 2022 WL 989403, at \*6 (Fed. Cir. Apr. 1, 2022) (affirming Board’s conclusion “that Microsoft’s complete failure to address

the language differences and explain why they do not matter was a failure to meet the particularity requirements for what must be in the petition and cannot be left to be filled in on reply.”).

The Institution Decision additionally states that “the question of whether Melsheimer discloses this limitation hinges on the interpretation of the claim term ‘attached’...” (ID, 18.) For the reasons discussed in Section VI.A. above, a POSA would understand that the ’400 patent uses “attach” to mean ‘to fasten or join two or more components at the same location.’” (EX2001, ¶¶95-100, 141.) This would include, for example, “three components, A, B, and C, with all three components joined at the same location.” (EX2001, ¶¶115, 141.)

As discussed further in Section VI.A., above, the patent’s use of the term “attach” stands in contrast to the patent’s separately defined-term of “operably associated” which “refers to components that are linked to together in operable fashion.” (EX2001, ¶¶114-116, 142.) Unlike the narrower term “attach,” “operably associated” would encompass, for example, three components, D, E, and F, with D joined to E at one location and E joined to F at a different location.” (EX2001, ¶¶115-116, 142.)

Because the ’400 patent uses “attach” to mean ‘to fasten or join two or more components at the same location,’ to demonstrate disclosure of the claim element “leaflets attached to the lattice frame,” Petitioners were required to provide

evidence that Melsheimer’s leaflets and frame “are fastened or joined at the same location.” (EX2001, ¶143.) Petitioners failed to make any allegation about Melsheimer’s leaflets at all, much less that Melsheimer’s leaflets and frame “are fastened or joined at the same location.”

Specifically, in its analysis of this element, Petitioners rely on their analysis of claim 55, which differently recites “a plurality of substantially conical shaped *cusps* attached to the lattice frame.” (EX1001, 33:9-10; Petition, 42.) And indeed, in Petitioners’ referenced analysis, Petitioners made no allegations regarding whether Melsheimer discloses *leaflets* attached to the frame. Rather, Petitioners alleged in that analysis that Melsheimer has *cusps*—not leaflets—attached to the frame. (Petition, 33-34 (“Melsheimer discloses a plurality of substantially conical shaped cusps preferably formed from a folded sheet of material, each having a ‘receptacle’ and a ‘leaflet,’ wherein the *cusps are attached to the surrounding lattice frame.*”).)

Petitioners’ failure is particularly damaging in light of Petitioners’ repeated acknowledgment that Melsheimer’s alleged cusps include portions *other than* a leaflet, such that attachment to a cusp cannot be assumed to mean attachment to a leaflet. (*See id.* (“Melsheimer discloses a plurality of substantially conical shaped *cusps* preferably formed from a folded sheet of material, *each having a ‘receptacle’ and a ‘leaflet’*”); Petition, 43 (“[T]he entire structure shown in, *e.g.*,

Figures 4A-4C of Melsheimer makes up a single ‘cusp’ as claimed by the ’400 [p]atent”).)

Petitioners’ analysis of the “cusps attached to the lattice frame” element also does not help Petitioners’ case. Indeed, Petitioners rely on Melsheimer’s Figure 6, which Petitioners allege shows a “valve (1) and attachment area (60)”. (Petition, 34.) But Melsheimer actually *distinguishes* the attachment area from the leaflets, and so does nothing to show that Melsheimer’s *leaflets* are attached to the frame. (EX1003, ¶ [0072] (“Portions of the valve device 10 include, but are not limited to, *leaflets 16*, the receptacles 18, *the attachment area 60* and the frame 150.”).)

Because Petitioners failed to provide evidence that Melsheimer discloses “leaflets attached to the lattice frame” as Challenged Claims 60-66, 79, and 84 recite, Petitioners’ Grounds 1-3 fail as to these claims. *See Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016) (reiterating requirement that Petitioners “show with particularity why the patent [they] challenge[] is unpatentable.”). (EX2001, ¶147.)

**2. Petitioners failed to provide a construction of “attach” as required by 37 C.F.R. § 42.104(b)(3) (Grounds 1-3, Claims 60-66, 79, 84).**

The Institution Decision further states that “the question of whether Melsheimer discloses this limitation hinges on the interpretation of the claim term “attached” and neither Petitioner nor Patent Owner proposed claim construction for

this term.” (ID, 18.) Respectfully, if “the question of whether Melsheimer discloses this limitation hinges on the interpretation of the claim term “attached,” the Petition’s failure to explain how its allegation that Melsheimer discloses *cusps* attached to the frame should be construed as Melsheimer disclosing *leaflets* attached to the frame is fatal for failure to comply with 37 C.F.R. § 42.104(b)(3)’s requirement that a petition identify “[h]ow the challenged claim is to be construed.” See *MModal LLC v. Nuance Commc’ns, Inc.*, IPR2018-01355, Paper 45 at 23 (PTAB Feb. 5, 2020), *aff’d MModal LLC v. Nuance Commc’ns, Inc.*, 846 F. App’x 900, 906 (Fed. Cir. 2021) (Board holding that “Petition’s failure to address adequately” a claim element “is fatal....[W]e require a petition to identify ‘[h]ow the challenged claim is to be construed’ (37 C.F.R. § 42.104(b)(3)), as well as ‘[h]ow the construed claim is unpatentable’ (37 C.F.R. § 42.104(b)(4)). Because the Petition does not explain coherently how” the prior art discloses a claim element, “the Petition fails to comply with our rules. This is dispositive.”).

Nevertheless, as explained in Section VI.A. above, “attach” as used in the ’400 patent means “to fasten or join two or more components at the same location.” (EX2001, ¶¶95-116.) Because Petitioners’ allegation that Melsheimer’s *cusps*\_attached to the frame says nothing about Melsheimer disclosing “leaflets attached to the lattice frame” as Challenged Claims 60-66, 79, and 84 recite, Petitioners’ Grounds 1-3 fail as to these claims. (EX2001, ¶149.)

**3. Petitioners fail to allege that Melsheimer's *cusps*, as opposed to merely the *receptacles*, are "substantially conical" (Grounds 1-3, Claims 55-59, 78, 83).**

In view of the '400 patent's specification, Melsheimer does not disclose "substantially conical shaped cusps" as Challenged Claims 55-59, 78, and 83 recite. The Institution Decision states that "[e]ven assuming Patent Owner is correct that only Melsheimer's receptacles are substantially conical shaped cusps, this disclosure is sufficient to meet the limitation at issue as claim 55 does not preclude other structures. (ID, 20.) Respectfully, this is not what Colibri has argued, what the claims recite, or what the law requires.

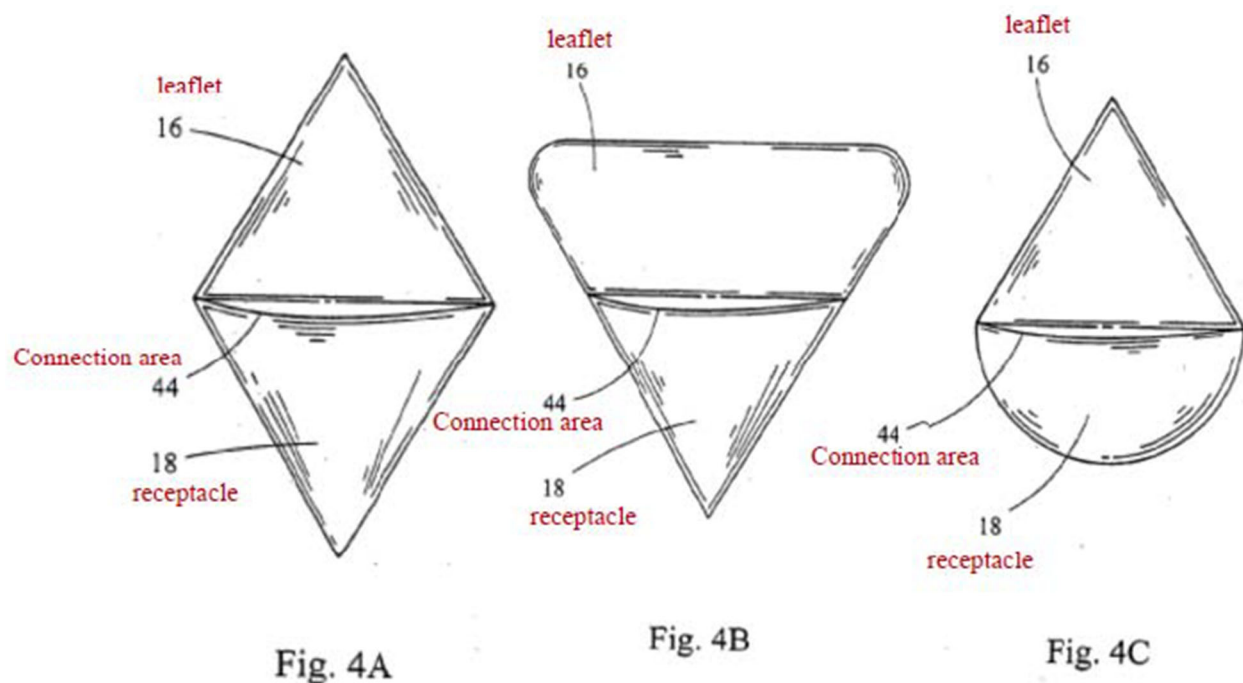
First, Colibri has never argued that "only Melsheimer's receptacles are substantially conical shaped cusps," to which additional structures may be added as the Institution Decision implies. Rather, as Colibri argues, and as a POSA would understand, Melsheimer's receptacles *cannot constitute* substantially conical-shaped cusps because they *are not cusps* and by themselves (without leaflets) do not operate to significantly restrict fluid flow in one direction as cusps do. (EX2001, ¶150-157.) Rather, by Petitioner's own admission, Melsheimer's receptacles form only a *portion* of a cusp and are therefore incapable of rendering Melsheimer's *cusps* into a "substantially conical shape." (EX2001, ¶158.) Indeed, the Petition never explains how Melsehimer allegedly discloses the recited "substantially conical shaped cusps," as it was required to do by statute. 37 C.F.R.



§ 42.104(b)(4)–(5) (requiring that Petition “specify where each element of the claim is found in the prior art patents or printed publication relied upon” and, regarding submitted evidence, state “the relevance of the evidence to the challenge raised, including identifying specific portions of the evidence that support the challenge”)).

Instead, Petitioners rely only on an unexplained quotation from Melsheimer about the receptacles extending proximally from the leaflets and expanding to form “a conically shaped *pocket*,” as opposed to “substantially conical shaped *cusps*,” as the claims recite. (Petition, 34; EX2002, 96:14-20 (Petitioner’s expert confirming that he relied on Melsheimer’s disclosure of “a conically shaped pocket” as allegedly disclosing the substantially conical-shaped cusps recited in the claims of the ’400 patent).) This is insufficient to meet Petitioners’ burden to provide “a detailed explanation of the significance” of Melsheimer’s disclosed “conically shaped pockets” to the claimed “substantially conical shaped cusps”—of which Melsheimer’s “pockets” are admittedly only a part. *See* 37 C.F.R. § 42.22(a)(2) (requiring in the Petition, among other things, “a detailed explanation of the significance of the evidence”).

Specifically, according to the Petition, “the entire structure shown in, *e.g.*, Figures 4A-4C [below] of Melsheimer makes up a single “cusp” as claimed by the ’400 [p]atent”.

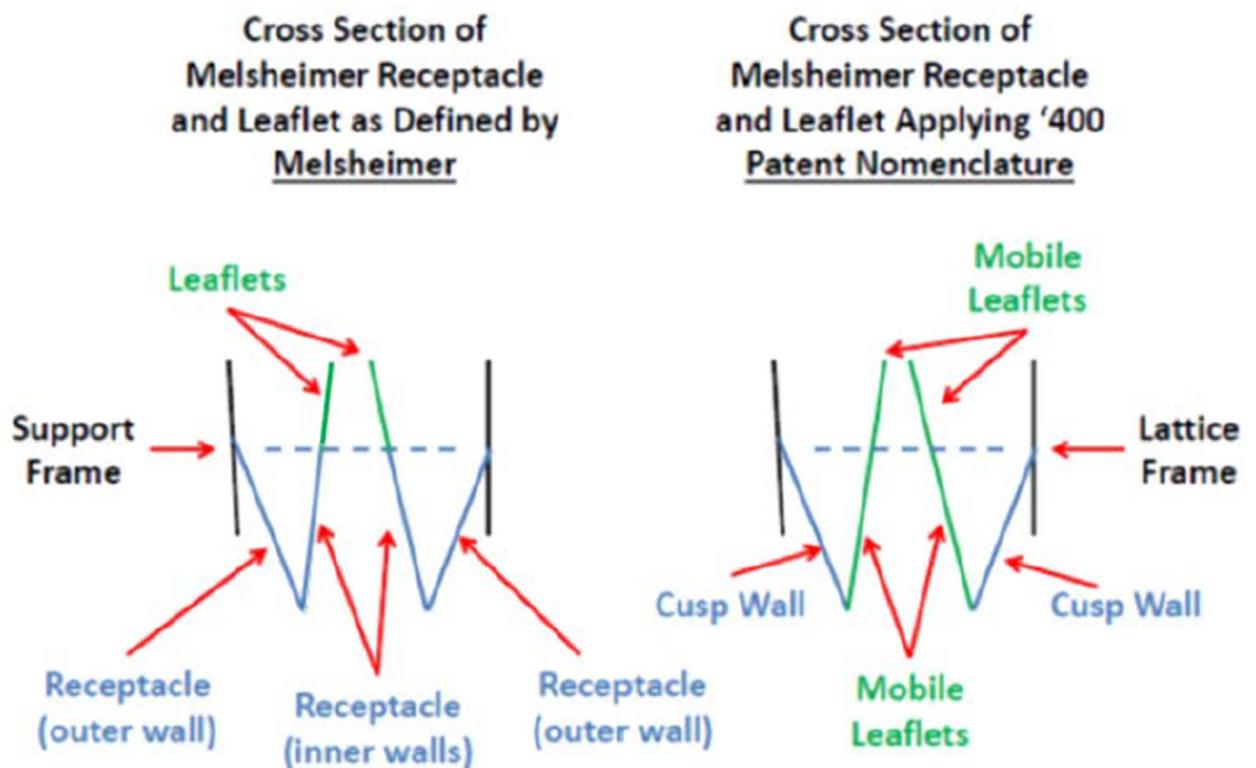


(Petition, 35.) However, Melsheimer makes clear that it is only the *receptacle*, and not the remaining portions of the structure shown in Figures 4A-4C that Petitioners allege constitute the claimed “cusp,” that forms Melsheimer’s disclosed “conically shaped pocket.” (EX1003, ¶ [0041] (“As shown in 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.”).) Thus, because Petitioners allege only that Melsheimer’s cusps are made up of the “conically shaped pocket” receptacle, in addition to other structures like the leaflet that a POSA would understand render Melsheimer’s *cusp* not “conically shaped” like its receptacle, Petitioners failed to meet their burden of demonstrating that Melsheimer anticipates, or even renders obvious, the “plurality of substantially conical shaped

cusps” that Challenged Claims 55-59, 78, and 83 recite, and so Petitioners’ Grounds 1-3 fail as to these claims. (EX2001, ¶¶159-161.)

The Institution Decision additionally states that claim 55 merely requires ‘substantially conical shaped cusps.’ It does not require the cusps *as a whole* be substantially conically shaped as argued by Patent Owner.” (ID, 20 (citation omitted, emphasis in original).) Respectfully, this impermissibly contradicts the definition of “cusp,” which both Petitioner and Colibri have agreed is “explicitly defined by the specification of the ’400 [p]atent” as “that structural portion of a valve related to a single leaflet that encompasses a space closed 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.” (EX1001, 12:4-11; Petition, 26-27; EX2001, ¶163.) *See Grace Instrument Indus., LLC v. Chandler Instruments Co., LLC*, No. 2021-2370, 2023 WL 163980 at \*6 (Fed. Cir. Jan. 12, 2023) (holding that the district court erred in contradicting the scope and meaning of a term that a POSA “would ascertain by reading the intrinsic record” because “[w]here the specification instructs as to the meaning of a claim term, ‘the inventor’s lexicography governs.’”).

The patent's definition of "cusp" is consistent with Petitioners' arguments that "the entire structure shown in, *e.g.*, Figures 4A-4C of Melsheimer," which includes a receptacle, leaflet, and connection area, "makes up a single 'cusp' as claimed by the '400 [p]atent." (Petition, 35.) Similarly, the patent's definition of "cusp" is also consistent with the below figure from the Petition, again showing that Melsheimer's "cusp" is "formed by the joined and/or continuous structures of the leaflet portion on the radially inner side and the cusp wall portion on the radially outer side."



(EX1001, 12:4-11; Petition, 36; EX2001, ¶164.) Thus, because the '400 patent defines a "cusp" as the "the joined and/or continuous structures of the mobile leaflet portion...and the cusp wall portion..." Petitioner cannot show that

Melsheimer’s “cusps” are “substantially conical” without showing that the “joined and/or continuous structures of the leaflet portion on the radially inner side and the cusp wall portion on the radially outer side” are substantially conical. Petitioners’ allegations limited to only one of these two “joined and/or continuous structures” that make up the “cusp” is insufficient to make any allegation about the shape of the “cusp,” whose shape is defined by **both** the leaflet portion and receptacle portion. (EX2001, ¶165.) *See Indus. Tech. Rsch. Inst. v. Int’l Trade Comm’n*, 567 F. App’x 914, 917–19 (Fed. Cir. 2014) (affirming the Commission’s construction because “[s]tarting with the claim language, the most natural reading of ‘structured arc sheet’ is that the entire sheet must be in the shape of an arc, **not that a part of the sheet** contains an ‘arc-like’ structure.”).

Additionally, a POSA would understand that the patent explicitly defines “substantially conical”—not to mean that only a substantial part of the cusp need be conical in shape (something that Petitioner still has never alleged)—but rather to mean that the cusp need not be in the shape of a perfect cone, since the cone is created by folding membrane sheets. (EX1002 ¶166.)

Finally, as discussed in Section VI.A., above, claims “must be interpreted in light of the teachings of the written description and purpose of the invention described therein.” *Apple*, 234 F.3d at 25. A POSA would have understood that to

achieve the goals of the inventions disclosed and claimed in the '400 patent, the geometry of the cusp—not merely a portion of the cusp is critical. (EX2001, ¶168.)

Specifically, the '400 patent enumerates two goals, the first of which is “to maximize effective orifice area and minimize opening pressure gradients through geometry that mimics the natural form of inflow into the valve—the tubular outflow tract of the heart pumping chamber.” (EX1001, 2:30-33.) A POSA would understand that to maximize the effective orifice area of the valve, a valve cusp that can lay flat against the inside wall of the cylindrical frame, helps achieve this goal. (EX2001, ¶169.) A POSA would further understand that a substantially conical-shaped cusp—rather than a substantially conical-shaped portion of a cusp—would be the way to accomplish this goal in the context of the patent. (EX2001, ¶169.)

This is because a POSA would understand that they could take a substantially conical-shaped cusp and fold it flat without any wrinkles or bulges. The POSA would also understand that this same substantially conical-shaped cusp, when placed inside a cylindrical surface with the long axis of the substantially conical-shaped cusp lined up with the long axis of the cylindrical surface, can also lay flat against the inside wall of the cylindrical surface. (EX2001, ¶170.) Finally, the POSA would understand that other structures—such as a cusp, only a portion of which is substantially conically-shaped—often bunch up to some degree, and so

do not lay flat and maximize the effective orifice area of the valve. (EX2001, ¶170.) Further, the POSA would understand that cusps of shapes that do not lay flat often produce some flow restrictions through the valve when open, and so do not have a “geometry that mimics the natural form of inflow into the valve” in accordance with the stated goal of the ’400 patent. (EX2001, ¶170.)

For these reasons, Petitioners failed to meet their burden of demonstrating that Melsheimer anticipates, or even renders obvious, the “plurality of substantially conical shaped cusps” that Challenged Claims 55-59, 78, and 83 recite, and so Petitioners’ Grounds 1-3 fail as to these claims. (EX2001, ¶171.)

**B. Ground 4: Braido in view of Eberhardt does not render obvious the Challenged Claims.**

**1. Braido in view of Eberhardt does not disclose or render obvious “mobile leaflets” “attached to the lattice frame” (Ground 4, Claims 60-72, 79, 84).**

Claim 60 (and Challenged Claims 61-66, 79, and 84) recites “a plurality of non-rectangular polygonal mobile leaflets attached to the lattice frame”.

The Institution Decision states that the Board is “not convinced that simply because Petitioner did not explain in detail how Braido discloses leaflets attached to the lattice frame that it does not do so.” (ID, 18.) For the same reasons as discussed in Section VII.A.1. above, this is contrary to the law, and by failing to allege that Braido discloses mobile leaflets attached to the frame, Petitioners failed to meet their statutory burden.

The Institution Decision additionally states that “Patent Owner’s argument is similar to the argument discussed in Section [VII.A.1.] above in that it hinges on the interpretation of the claim term ‘attached’...” (ID, 28.) For the reasons discussed in Section VI.A. above, a POSA would understand that the ’400 patent uses “attach” to mean ‘to fasten or join two or more components at the same location.’” (EX2001, ¶¶95-116.) And for the reasons discussed in Section VII.A.1. above, because the ’400 patent uses “attach” to mean ‘to fasten or join two or more components at the same location,’ to demonstrate disclosure of the claim element “leaflets attached to the lattice frame,” Petitioners were required to provide evidence that Braido’s mobile leaflets and frame “are fastened or joined at the same location.” (EX2001, ¶174.) Petitioners failed to make any allegation that about Braido’s mobile leaflets at all, much less that Braido’s mobile leaflets and frame “are fastened or joined at the same location.” (*See* Petition, 57-65.) And although Ground 4 also includes a combination with Eberhardt, Petitioners make no allegations concerning any form of attachment of the mobile leaflet with respect to Eberhardt. (*See* Petition, 57-65.)

Instead, the Petition merely alleges that Braido has *integrated cusps*—not mobile leaflets/folded biocompatible membrane sheets—attached to the frame. (Petition, 60 (“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.*, 61 (“Thus, it would have been obvious to a [POSA] 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”).) But as the Petition makes clear, Braido’s alleged “integrated cusp 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).” (Petition, 59.) Thus, attachment to an integrated cusp cannot be assumed to mean attachment to a mobile leaflet. (*See id.*) For this reason, Petitioners’ Ground 4 arguments as to Challenged Claims 60-66 and 79 fail. *See Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1369 (Fed. Cir. 2016). (EX2001, ¶¶176-180.)

**2. Braido in view of Eberhardt does not disclose or render obvious “at least two folded biocompatible membrane sheets attached to the lattice frame” (Ground 4, Claims 67-72, 80, and 85).**

Claims 67 (and Challenged Claims 68-72, 80, and 85) recites “at least two folded biocompatible membrane sheets attached to the lattice frame”. For this claim element, Petitioners merely refer to their failed argument for the claim 60 element reciting “a plurality of non-rectangular polygonal mobile leaflets attached to the lattice frame”. (Petition, 70.) But as discussed with respect to that claim 60 element, Petitioners’ only support for this claim element—a misleading citation to Braido, ¶ [0182]—affirmatively states that Braido’s membrane is *not* attached to the frame, and is instead attached to the valve’s cuff. (EX1004, ¶ [0182] (“[I]n FIG

74a[,] reference line 560a indicates the contour of one representative leaflet where it is ***attached*** near its bottom or upstream portion) ***to the cuff 80 of the valve.***”); *see* Section VIII.A.2.a., *supra.*)

Thus, because Petitioners have provided no evidence that Braido discloses or renders obvious “at least two folded biocompatible membrane sheets attached to the lattice frame” as Challenged Claims 67-72 and 80 recite, Petitioners’ Ground 4 arguments as to these claims fail for the same reasons as discussed in Section VII.B.2., above. (EX2001, ¶183.)

**C. Grounds 5-8: Moll in view of Paniagua, and in combination with Pavcnik, Melsheimer, or Eberhardt, does not render obvious the Challenged Claims.**

**1. Moll in combination with Paniagua (and/or Pavcnik for Ground 6 and Eberhardt for Ground 8) does not disclose or render obvious “substantially conical shaped cusps” (Grounds 5-6 and 8, Claims 55-59, 78, 83).**

Claim 55 (and Challenged Claims 56-59, 78, and 83) recites “a plurality of substantially conical shaped cusps”.

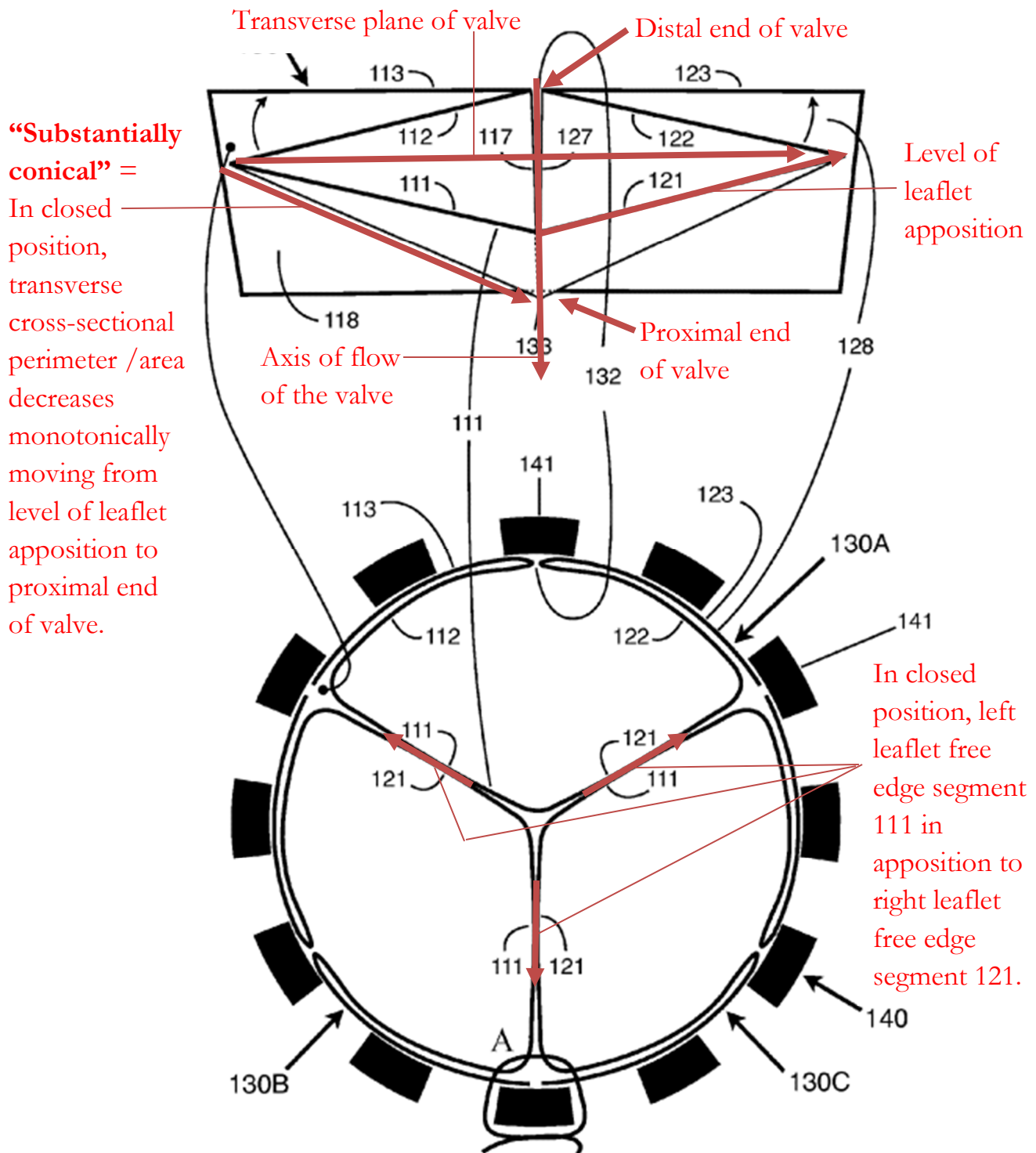
As the Parties and the Board agree, the ’400 patent defines “substantially conical,” as “resembling a cone or a portion thereof at some point in the practical use of the structure ***with the specific property that the transverse*** (that is, on a plane of section generally perpendicular to the axis of flow of the valve) ***cross-sectional perimeter or area of said structure in the operationally closed position decreases monotonically moving from the level of the leaflet apposition to the***

*proximal end of the valve.*” (EX1001, 12:47-54.) Additionally, the patent specifies that “at some point in the practical use of the structure” refers to the fact that the cusps are “substantially conical shaped” when in the closed position (when stopping blood from flowing), but not necessarily in the open position (when allowing blood to flow through). (See EX1001, 3:7-20 (“employing conical rather than spherical cusp geometry...with near-elliptical leaflet cross-section that progressively decreases moving proximal to the plane of leaflet apposition while being readily conformed on outward radial compression in the valve opening phase into a substantially flat folded construct against the interior tubular walls of the containing frame....In the closed position, the free edges of the separate leaflets of the conical cusps meet in apposition, each cone acting as an independent valve”).)

The '400 patent's figures provide helpful illustrations of these substantially conical-shaped cusps, an example of which is shown below:

**Figure 1G**

Suture attachments omitted for clarity.



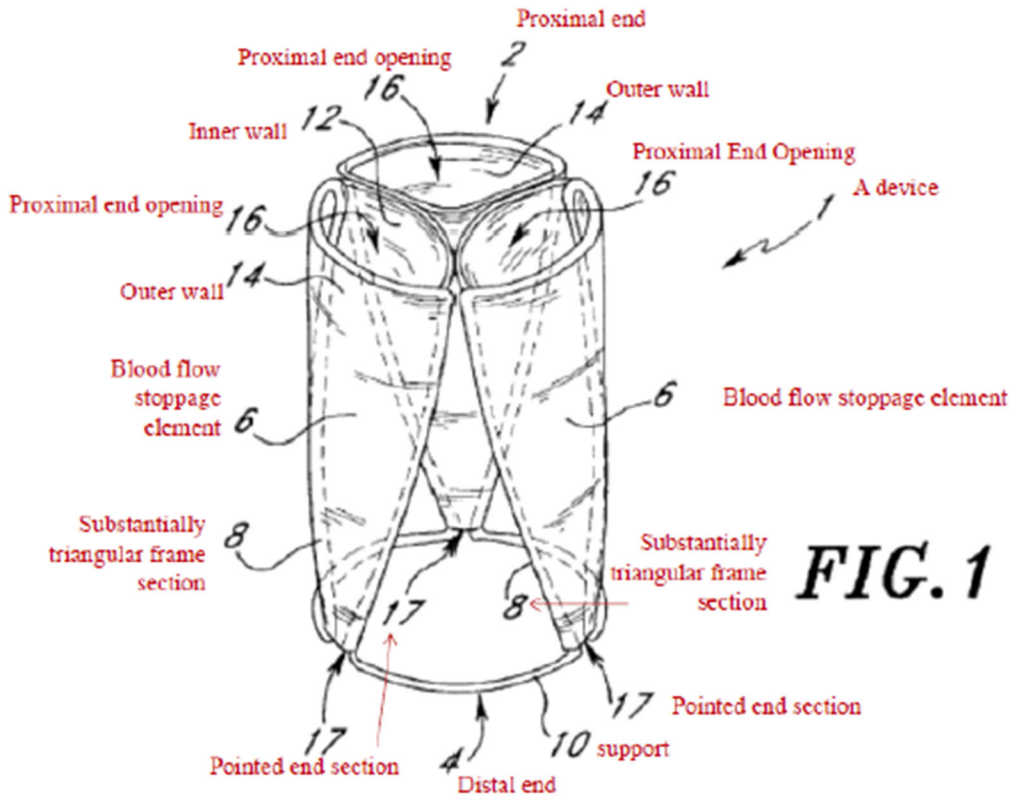
(EX1001, Figure 1G (annotated); *see id.*, 16:13-22.)

Petitioners assert that the Moll reference alone discloses “a plurality of substantially conical shaped cusps” within the meaning of the ’400 patent’s claims. (Petition, 78; EX1001, 12:47-54.) Like Petitioners, the Institution Decision matched Moll’s characterization of “its blood ‘flow stoppage element’ as ‘substantially conical in shape when occupying the blood flow stoppage configuration,’” with “the definition of the claim term ‘substantially conical’[, which] includes elements resembling a portion of a cone *at some point* in the practical use of the structure.” (ID, 35 (emphasis in original) (quotation omitted).) However, this analysis omits the second part of the patent’s 2-part definition of “substantially conical.”

Specifically, the patent defines “substantially conical as “[1] resembling a cone or a portion thereof at some point in the practical use of the structure [2] ***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 decreases monotonically moving from the level of the leaflet apposition to the proximal end of the valve.***” (EX1001, 12:47-54.) While Petitioners alleged that Moll meets the first portion of this definition, Petitioners failed to provide evidence that Moll meets the second portion of the patent’s definition of “substantially conical”—having “***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 decreases monotonically moving from the level of the leaflet apposition to the proximal end of the valve.” (EX1001, 12:47-54.)  
*See Nestle USA, Inc. v. Steuben Foods, Inc.*, 686 F. App’x 917, 919 (Fed. Cir. 2017) (Reversing the Board’s construction that was contrary to the specification provided in the patent, which is “binding lexicography.”).

Specifically, while the ’400 patent defines “substantially conical” as decreasing in perimeter or area “from the level of the leaflet apposition *to the proximal end of the valve*,” Petitioners have only provided evidence showing Moll’s disclosure of blood flow stoppage elements with a flared *proximal* end and a decreasing perimeter or area moving to the *distal* end of the valve in their annotation of Moll’s Figure 1, copied below:

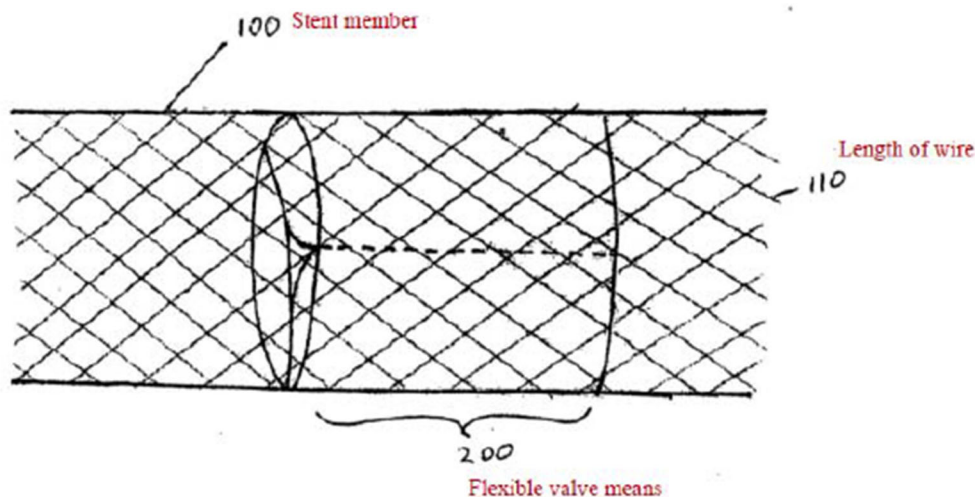


(Petition, 75.)

Because Petitioners failed to provide the required evidence that Moll’s disclosed blood stoppage element discloses “substantially conical shaped cusps” as recited by claim 55 (and Challenged Claims 56-59), Petitioners’ Ground 5 challenge fails as to those claims. (EX2001, ¶192.) *See Harmonic*, 815 F.3d at 1363. Additionally, because Petitioner’s Grounds 6 and 8 rely only on Moll for the “substantially conical shaped cusps” element of dependent claims 78 and 83, Petitioners’ Grounds 6 and 8 challenges fail as to those claims as well. (*See* Petition, 91-93, 95-97.) (EX2001, ¶193.)

**2. Moll in combination with Paniagua (and/or Pavcnik for Ground 6, Melsheimer for Ground 7, and Eberhardt for Ground 8) does not disclose a lattice frame (Grounds 5-8, all Challenged Claims).**

Each of the Challenged claims recites a “lattice frame.” A POSA would understand that Moll does not disclose a lattice frame. (EX2001, ¶195.) Indeed, the evidence Petitioners themselves provided with the Petition makes clear that a lattice frame in the context of vascular system implants conforms to the common usage of the term, which requires a stacked, multi-layered, repeating pattern with closed cell structures. (EX1002, ¶195.) For example, Petitioners allege that “Paniagua discloses a transcatheter valve that includes a folded valve and ***lattice frame***,” with reference to the figure copied below:

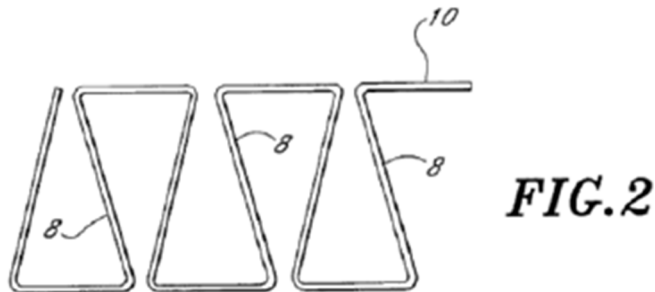


(Petition, 76-77.)

In contrast, for all Challenged Claims in Grounds 5-8, Petitioners rely on the frame in Moll, which a POSA would understand is *not* a lattice frame, as is evident



from the image of Moll's three-triangle *single layer* frame that Petitioners provide, copied below:



(Petition, 76; EX1002, ¶196.) Rather, a POSA would agree that a lattice structure is consistent with that found in dictionary definitions of the term, which include “[a]n open framework made of strips of metal, wood, or similar material overlapped or overlaid in a regular, usually crisscross pattern.” (EX1002, ¶197.)

Indeed, Petitioners were unable to even allege with a straight face that Moll discloses the recited “lattice frame,” and instead hedge around the issue, stating that Moll’s “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.” (Petition, 76.) But Applicants did not challenge the Examiner’s identification of Drasler’s disclosure of a lattice frame because Drasler *does* disclose a lattice frame, as is evident from numerous figures from Drasler, including at least Drasler’s Figure 19, copied below:

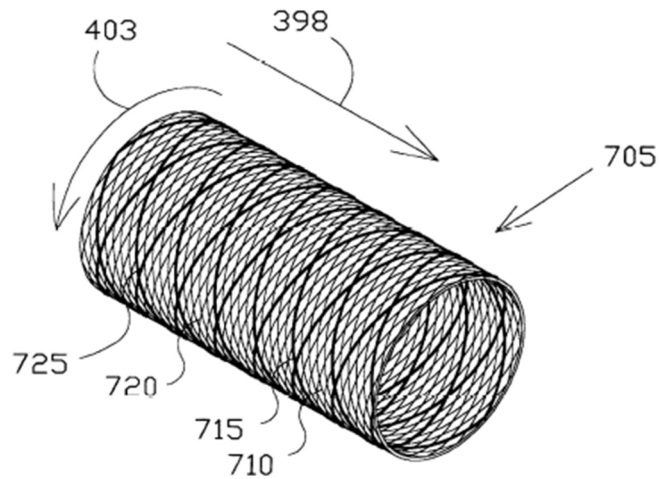
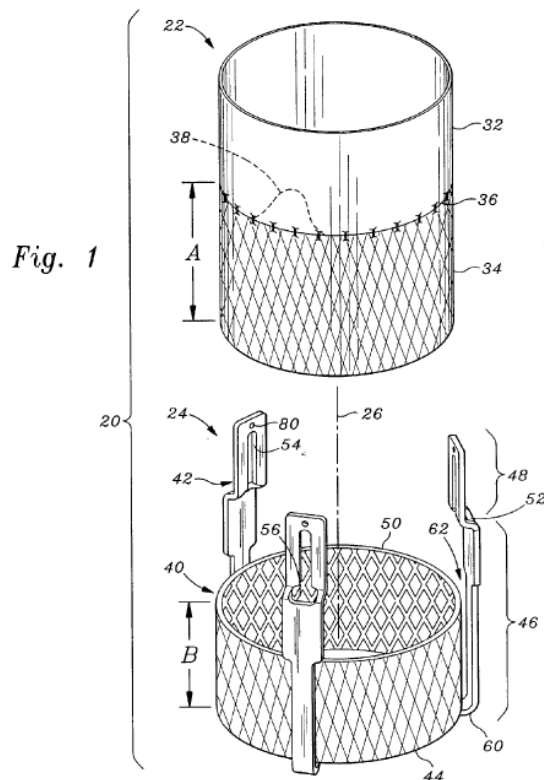


Fig 19

(EX1015, 59, Figure 19.) Further, the Examiner actually withdrew their rejection in view of Drasler, characterizing it as “moot,” and subsequently issued a different rejection arguing that Figure 1 from Schreck, copied below, discloses the recited “lattice frame”:

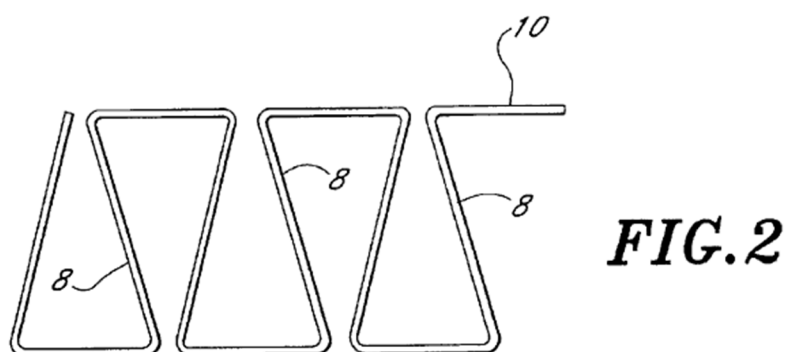
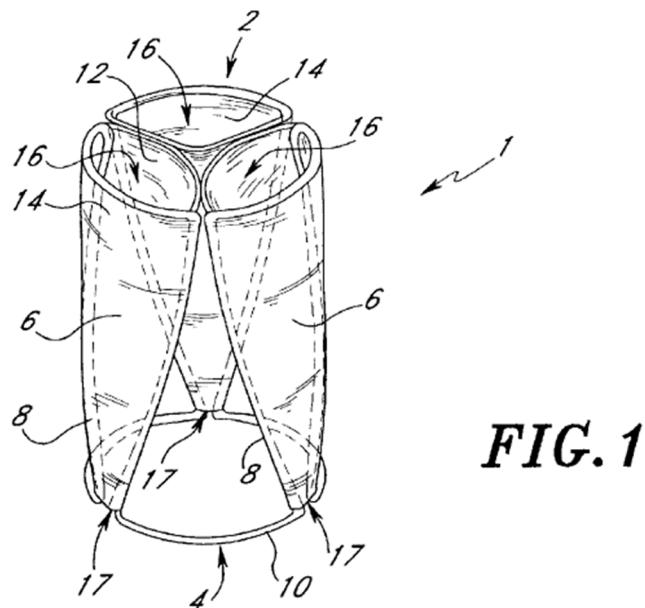


(EX1002, 3829; EX1019, 2, Figure 1.) This is again consistent with the common usage of the term “lattice frame”—which is not what Moll discloses.

Recognizing that Moll does not, in fact, disclose the recited “lattice frame,” Petitioners next allege, for all Challenged Claims in each of Grounds 5-8, that “[i]t 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.” (Petition, 77.) Notably, Petitioners did not allege that Moll’s own frame is not “readily collapsible and expandable and sufficiently strong to maintain a semi-rigid patent channel in the

vascular system.” (*See id.*) *See Winner Int’l Royalty Corp. v. Wang*, 202 F.3d 1340, 1349-50 (Fed. Cir. 2000) (affirming finding of nonobviousness where “there was no apparent disadvantage” to the prior art mechanism). Rather, Petitioners’ only alleged motivation to combine Moll’s “undulating structure” with Paniagua’s frame is the purported ability “to provide a number of alternative frame structures.” (*Id.*) This does not constitute a motivation to combine. *See BMW of North America, LLC v. Carrum Techs., LLC*, IPR2019-00904, Paper 10 at 14 (PTAB Oct. 18, 2019) (no motivation to combine because when “[one prior art reference] discloses methods for identifying when a vehicle has entered a curve..., it is not evident why [a POSA] would have looked to [a second prior art reference] to obtain additional methods of determining curve entry.”).

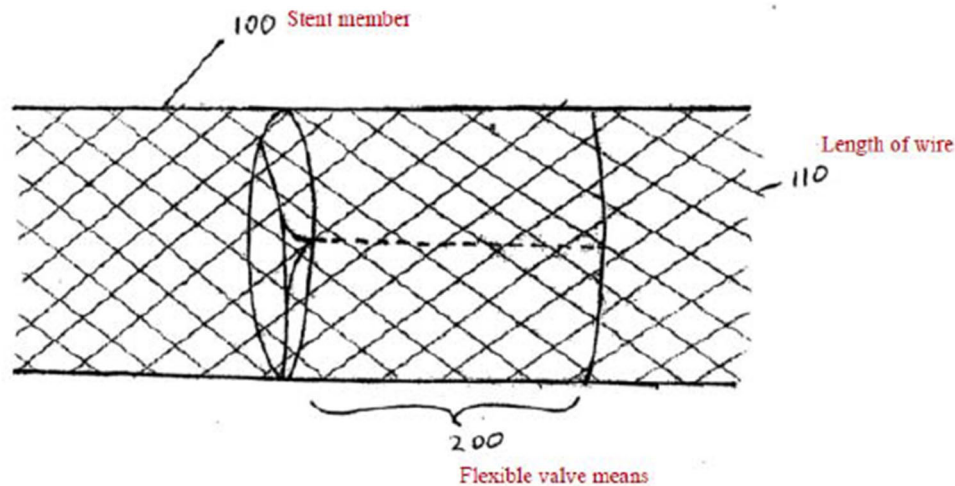
Petitioners have not explained why a POSA would have wanted to have “alternative frame structures” for use with Moll’s blood “flow stoppage element.” Indeed, a POSA would not have been motivated to have “alternative frame structures in light of Moll’s disclosure that its frame was specifically designed for its blood “flow stoppage elements.” (EX1002, ¶¶202-203.) Namely, Moll teaches that “[i]n order to yield a very effective valve working, the support preferably comprises ***substantially separate frame sections*** for each of the one or more fluid passage stoppage elements.” (EX1005, 2:34-37.) Moll provides examples of its ideal frame in its Figures 1 and 2, which are copied below:



(EX1005, Figures 1, 2; *id.*, 3:25-28 (“The support 10 is preferably made of a continuous length of memory metal, having, *as shown in FIG. 1 and 2, three substantially separate frame sections 8 for supporting each valve element.*”).)

As is evident from a comparison of the images of Moll’s ideal frame above with the image of Paniagua’s lattice frame below, it would have been clear to a POSA that Paniagua’s frame—with its lattice pattern consisting of a multitude of small diamond shapes—would not satisfy the ideal frame set forth in Moll, which

consists of “three substantially separate frame sections” for supporting each of Moll’s three blood “flow stoppage elements.” (EX1002, ¶204.)



(Petition, 77.) Indeed, a POSA would have had absolutely no motivation to replace the frame described in Moll with a lattice frame. (EX1002, ¶205.) This is because a POSA would understand that the valve described by Moll could possibly use an interesting method to attach/secure the frame (10) to the valve elements (6), in which the valve elements can potentially slide over the frame and be secured with minimal suturing of the valve elements to the frame. (EX1002, ¶205.) And while a POSA would understand that this method may work well for a bent/wire or open form support frame like Moll’s, replacing Moll’s described frame with a lattice type frame would be incredibly difficult to accomplish while keeping the remainder of the Moll concept. (EX1002, ¶205.) See *Plas-Pak Indus., Inc. v. Sulzer Mixpac AG*, 600 F. App’x 755, 757–60 (Fed. Cir. 2015) (affirming Board rejection of obviousness argument where “the prior art combinations would either alter

Fukuta’s ‘principle of operation’ or render Jacobsen ‘inoperable for its intended purpose,’” because “combinations that change the ‘basic principles under which the [prior art] was designed to operate,’ or that render the prior art “inoperable for its intended purpose,” may fail to support a conclusion of obviousness.” (quotation omitted)).

Petitioners also fail to provide the legally required explanation as to how Paniagua’s lattice frame would work in Moll, particularly in light of Moll’s expressed preference for a frame *unlike* Paniagua’s lattice frame. (*See* Petition, 77-78 (including only boilerplate language alleging that a POSA “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” POSA.).) *See Pers. Web Techs., LLC v. Apple, Inc.*, 848 F.3d 987, 994 (Fed. Cir. 2017) (reversing Board where “the Board nowhere clearly explained, or cited evidence showing, how the combination of the two references was supposed to work,” because “a clear, evidence-supported account of the contemplated workings of the combination is a prerequisite to adequately explaining and supporting a conclusion that a [POSA] would have been motivated to make the combination and reasonably expect success in doing so.”).

Moreover, a POSA would understand that Petitioners’ Ground 5 arguments stating “[i]t 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” contradict Petitioners’ Ground 8 arguments that it would have been obvious to a POSA *to use “the stent structure depicted in Figure 2 of Moll.”* (EX1002 ¶207; *Compare* Petition, 77 *with* Petition, 95-97.) Petitioners’ Grounds 5-8 “lattice frame” arguments fail for this reason as well as to all Challenged Claims. (EX2001, ¶207.) *See ZTE (USA) Inc. v. Fundamental Innovation Sys. Int’l LLC*, IPR2018-00274, Paper 17 at 17 (PTAB Aug. 29, 2018) (“Petitioner fail[ed] to establish that the [claimed] combination renders obvious” a claim limitation “because, inter alia, the combination deviates from standard USB signaling, thus contradicting Petitioner’s reasoning” elsewhere in the Petition).

Because Moll does not disclose the “lattice frame” recited in all Challenged Claims, and Petitioners failed to provide a motivation to combine Moll with Paniagua’s lattice frame, Petitioners’ Grounds 5-8 challenges fail as to all Challenged Claims. (EX2001, ¶208.)

**3. Moll in combination with Paniagua (and/or Pavcnik for Ground 6, Melsheimer for Ground 7, and Eberhardt for Ground 8) does not disclose that the leaflet-containing membrane is “attached to the lattice frame” (Grounds 5-8, all Challenged Claims).**

Each of the Challenged Claims recites an attachment of the leaflets and/or leaflet-containing membrane “to the lattice frame.” Specifically, claim 55 (and



Challenged Claims 56-59, 78, and 83) recites “a plurality of substantially conical shaped cusps attached to the lattice frame”. Similarly, claim 60 (and Challenged Claims 61-66, 79, and 84) recites “a plurality of non-rectangular polygonal mobile leaflets attached to the lattice frame”. Additionally, claim 67 (and Challenged Claims 68-72, 80, and 85) recites “at least two folded biocompatible membrane sheets attached to the lattice frame”. For all Challenged Claims in Grounds 5-8, Petitioners rely exclusively on Moll as disclosing the “attached to the lattice frame” element. (Petition, 78, 84-85, 89, 91-97.)

**a. Claims 55-59, 78, and 83 (Grounds 5-6 and 8)**

Claim 55 (and Challenged Claims 56-59, 78, and 83) recites “a plurality of substantially conical shaped cusps attached to the lattice frame”. For this claim element, Petitioners failed to allege that what Petitioner argues are “a plurality of substantially conical shaped cusps” in Moll (they are not, as discussed above), are “attached to the lattice frame.” (Petition, 78.) Instead, Petitioners merely allege that “Moll discloses a plurality of substantially conical shaped cusps.” (*Id.*) Full stop.

Although the Institution Decision “agree[s] that such an explicit statement is not made by Petitioner in reference to claim 55,” it states that the challenge does not fail “because of this oversight as it is clear from the remainder of the challenge that Petitioner’s position is that Moll discloses such an attachment. (ID, 36.) But for the same reasons as discussed in Section VII.A.1., above, this is contrary to the

law, and by failing to allege that Moll discloses “a plurality of substantially conical shaped cusps attached to the lattice frame,” Petitioners failed to meet their statutory burden.

Additionally, the Institution Decision’s analysis of this claim element fails to apply the Federal Circuit’s edict that “[d]ifferent claim terms are presumed to have different meanings.” *Bd. of Regents of the Univ. of Texas Sys. v. BENQ Am. Corp.*, 533 F.3d 1362, 1371 (Fed. Cir. 2008). This is evident in that the Institution Decision reasons that “it appears that although Petitioner inadvertently failed to state that Moll discloses *cusps* attached to the lattice frame as claimed in claim 55, its position is that Moll discloses such an attachment” simply because, “in its discussion of independent claim 60, Petitioner asserts that ‘Moll discloses a plurality of non-rectangular polygonal *mobile leaflets* attached to the lattice frame,’” and “for independent claim 67, Petitioner asserts that ‘Moll discloses the use of at least two *folded biocompatible membrane sheets*...attached to the lattice frame.’” (ID, 36-37.) But the Federal Circuit has made clear that there is a presumption that cusps are not the same as mobile leaflets or folded biocompatible membrane sheets, so Petitioner’s allegations of the latter two do not equate to an allegation of the former.

The Institution Decision’s failure to require that Petitioner prove its prima facie case in its Petition—as required by statute—is a hallmark due process

violation. *See Abbott Labs v. Cordis Corp.*, 710 F.3d 1318, 1327-28 (Fed. Cir. 2013) (“a patent is a property right protected by the Due Process Clause,” and “[t]he *indispensable ingredients of due process are notice* and an opportunity to be heard by a disinterested decision-maker.”). This is because although the Board has said that it believes that Petitioners’ “position is that Moll discloses such an attachment,” Colibri must now respond to a challenge to its patent’s validity, without even knowing what evidence Petitioners might assert as a basis for that challenge. In other words, Colibri has not been given proper notice of Petitioners’ allegations against it. *See Intelligent Bio-Sys.*, 821 F.3d at 1369 (“It is of the *utmost importance that petitioners in the IPR proceedings adhere to the requirement that the initial petition identify ‘with particularity’ the ‘evidence that supports the grounds for the challenge to each claim...*[The *expedited nature of IPRs bring[s] with it an obligation for petitioners to make their case in their petition to institute*. While the Board’s requirements are strict ones, they are *requirements of which petitioners are aware when they seek to institute an IPR.*”). Notably, Colibri’s lack of notice as to Petitioners’ arguments (if any) regarding attachment of Moll’s cusps to the frame is particularly problematic here, where many of Colibri’s arguments have centered around Petitioners’ failure to disclose that certain claim elements are attached to the frame. (*See* Section VII.A.1., B.1., B.2., above)

Because Petitioners failed to even allege that Moll discloses or renders obvious “a plurality of substantially conical shaped *cusps* attached to the lattice frame”, Petitioners’ Grounds 5-6 and 8 arguments as to Challenged Claims 55-59, 78, and 83 fail. (EX2001, ¶214.) *See Harmonic*, 815 F.3d at 1363.

**b. Claims 60-66, 79, and 84 (Grounds 5-6, 8)**

Claim 60 (and Challenged Claims 61-66, 79, and 84) recites “a plurality of non-rectangular polygonal mobile leaflets attached to the lattice frame”.

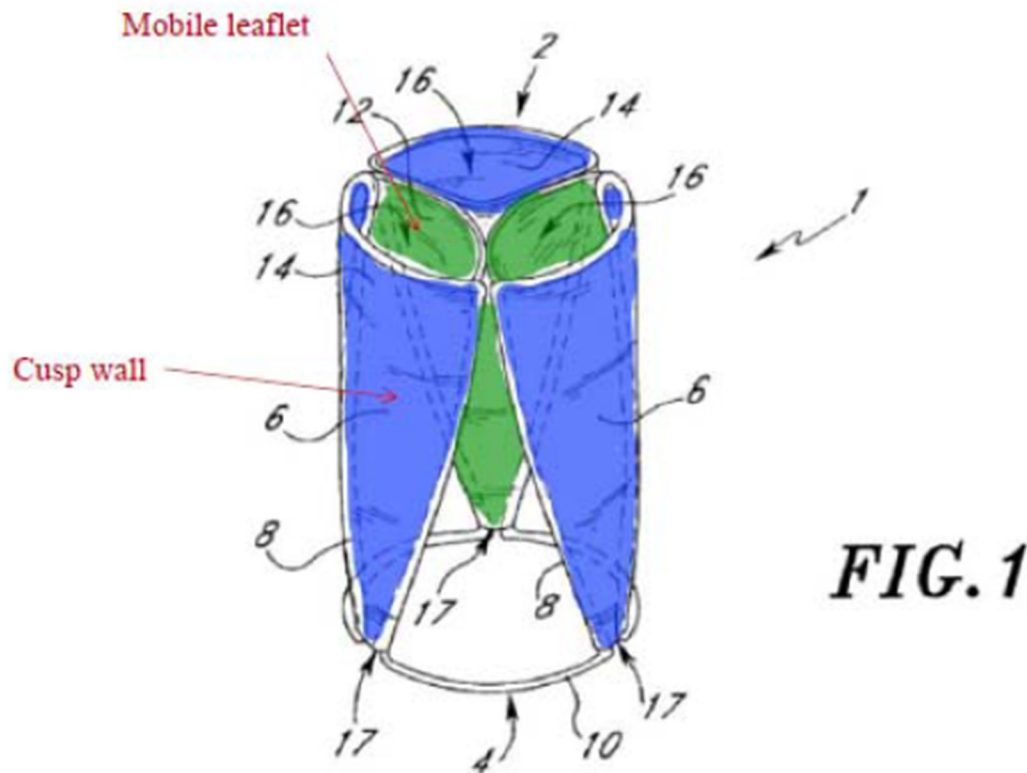
The Institution Decision states that the Board is “not convinced that simply because Petitioner did not explain in detail how Moll discloses leaflets attached to the lattice frame that it does not do so.” (ID, 37.) For the same reasons as discussed in Section VII.A.1. above, this is contrary to the law, and by failing to allege that Moll discloses mobile leaflets attached to the frame, Petitioners failed to meet their statutory burden.

The Institution Decision additionally states that “this argument hinges on the interpretation of the claim term ‘attached’...” (ID, 37.) For the reasons discussed in Section VI.A. above, a POSA would understand that the ’400 patent uses “attach” to mean ‘to fasten or join two or more components at the same location.’” (EX2001, ¶¶95-116.) And for the reasons discussed in Section VII.A.1. above, because the ’400 patent uses “attach” to mean ‘to fasten or join two or more components at the same location,’ to demonstrate disclosure of the claim element

“mobile leaflets attached to the lattice frame,” Petitioners were required to provide evidence that Moll’s mobile leaflets and frame “are fastened or joined at the same location.” (EX2001, ¶217.) Petitioners failed to make any allegation that about Moll’s mobile leaflets at all, much less that Moll’s mobile leaflets and frame “are fastened or joined at the same location.” (See Petition, 57-65.)

Specifically, instead of alleging that Moll discloses “*mobile leaflets* attached to the lattice frame,” Petitioners instead allege that it is the separate *cusp wall* that is attached to the frame in Moll:

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*:



(Petition, 84-85.)

Because claim 60 (and Challenged Claims 61-66, 79, and 84) recites “a plurality of non-rectangular polygonal *mobile leaflets* attached to the lattice frame,” and Petitioners have alleged that it is *not* Moll’s mobile leaflets, but instead Moll’s *cusp wall* that is attached to the frame in Moll, Petitioners’ Grounds 5-6 and 8 arguments as to Challenged Claims 60-66, 79, and 84 fail. (EX2001, ¶221; *compare* EX1001, 33:29-30 *with* Petition, 84-85.)

**c. Claims 67-72, 80, and 85 (Grounds 5-8)**

Claim 67 (and Challenged Claims 68-72, 80, and 85) recites “at least two folded biocompatible membrane sheets attached to the lattice frame”. For this claim element, Petitioners provide a bare conclusion—with no analysis or evidence

that actually supports this allegation—that “Moll discloses the use of at least two folded biocompatible membrane sheets (‘blood flow stoppage elements’) attached to the lattice frame.” (Petition, 89.) In support of this conclusion—which merely parrots the claim language for this element—Petitioners provide a total of three citations, each of which does nothing to support Petitioners’ allegation. (Petition, 89.)

Petitioners’ first citation states that “[b]lood flow stoppage elements 6, having the form of flexible hollow cones, *are each supported on a substantially triangular frame* section 8 of a support 10, see also FIG. 2.” (Petition, 89; EX1005, 3:18-20.) But as discussed above, not only does this text (nor any other disclosure in Moll, for that matter) contain no disclosure as to *how* Moll’s “flow stoppage elements” are “supported on [Moll’s] substantially triangular frame section 8 of a support 10,” it further contains no disclosure as to *whether* any portion of Moll’s “flow stoppage elements” are attached to Moll’s frame—as opposed to being attached to some other tissue or structure as was the case in Braido, discussed in Sections VII.B.1. and 2., above. (See EX1005, 3:18-20.) And Petitioners have not provided any analysis—beyond their misleading citations—that a POSA would have had any understanding as to whether any portion of Moll’s “flow stoppage elements” are attached to Moll’s frame. (See Petition, 89.)

The second of Petitioners' citations for this claim element does not even mention Moll's frame at all, much less whether Moll's "flow stoppage elements" are attached to Moll's frame. (Petition, 89.)

And the third of Petitioners' citations for this claim element is to Petitioners' expert declaration, which merely repeats—without providing any further analysis or support—the allegations in the Petition. (Petition, 89.) As the law makes clear, this is insufficient for Petitioners to meet their burden of demonstrating obviousness in their Petition. *See Initiative for Medicines, Access & Knowledge (I-MAK), Inc. v. Gilead Pharmasset LLC*, IPR2018-00390, Paper 7 at 14-15 (PTAB July 29, 2018).

Because Petitioners failed to provide *any* evidence supporting their bare allegation that Moll discloses or renders obvious "at least two folded biocompatible membrane sheets attached to the lattice frame" as claim 67 (and Challenged Claims 68-72, 80, and 85) recites, Petitioners' Grounds 5-8 challenges fail as to these claims. (EX2001, ¶227.) *See Aqua Prods., Inc. v. Matal*, 872 F.3d 1290, 1309 (Fed. Cir. 2017) ("Section 312 sets forth the various statutory requirements to which each petition challenging the validity of a patent ***must conform*** before the PTO may institute an inter partes review. The petition must identify, 'in writing and with particularity, each claim challenged, the grounds on



which the challenge to each claim is based, and the evidence that supports the grounds for the challenge to each claim....”).

4. **Moll in combination with Paniagua (and/or Pavcnik for Ground 6, Melsheimer for Ground 7, and Eberhardt for Ground 8) does not disclose that the leaflet-containing membrane includes non-transverse diagonally oriented folds that are angled relative to an axial flow direction (Grounds 5-8, all Challenged Claims).**
  - a. **Moll in combination with Paniagua (and/or Pavcnik for Ground 6, Melsheimer for Ground 7, and Eberhardt for Ground 8) does not disclose that the leaflet-containing membrane contains “folds” (Grounds 5-8, all Challenged Claims).**

Each of the Challenged Claims recites that the leaflets and/or leaflet-containing membranes contain “folds.” Specifically, claim 55 (and Challenged Claims 56-59, 78, and 83) recites that “each of the plurality of substantially conical shaped cusps include non-transverse diagonally oriented folds that are angled relative to an axial flow direction”. Similarly, claim 60 (and Challenged Claims 61-66, 79, and 84) recites 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”. Additionally, claim 67 (and Challenged Claims 68-72, 80, and 85) recites that “the at least two folded biocompatible membrane sheets has been formed to include a non-rectangular polygonal mobile leaflet, wherein each of the non-rectangular polygonal mobile leaflets include non-transverse diagonally oriented folds that are angled relative to an axial flow

direction.” For all Challenged Claims in Grounds 5-8, Petitioners rely exclusively on Moll in view of Paniagua as disclosing the Challenged Claims’ various recited “fold” elements. (Petition, 79-81, 85-86, 89-90, 91-97.) And for each of the Challenged Claims, Petitioners reference their analysis of the Challenged Claims’ recited “fold” elements in claim 55. (Petition, 79-80, 85-86, 89-97.)

For claim 55, Petitioners acknowledge that “Moll does not explicitly state that the sidewalls of the conical shaped flow stoppage elements have folds”. (Petition, 79.) This is correct. However, Petitioners go on to argue that “it is inherent in Moll’s teachings that the flow stoppage elements have folds as claimed by the ’400 [p]atent” because a POSA “would recognize that a ‘substantially flattened’ configuration wherein ‘one or more sidewalls lie substantially flat adjacent to each other’ would form ‘non-transverse diagonally oriented folds that are angled relative to an axial flow direction’ as claimed.” (Petition, 79 (citation omitted).) Petitioners’ argument fails for at least two reasons.

**First**, Petitioners’ argument, even if true (it is not), does not cause Moll’s “flow stoppage elements” to have “folds” or be “folded,” as all Challenged Claims require. Specifically, even under Petitioners’ proposed definition, “‘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.” (Petition, 30.) What Petitioners allege that Moll discloses are not “lines that

partition a flat-sheet section of material into subsections,” but rather lines that allegedly *partition a cone-shaped section of material* into subsections when “the flow of blood forces the inner walls 12 of the stoppage elements 6 against the outer walls 14” into “a substantially flattened configuration wherein one or more sidewalls lie substantially flat adjacent to each other.” (Petition, 79 (internal quotations omitted); *see* EX1005, 3:8-19 (“Blood flow stoppage elements 6, having the form of flexible *hollow cones*”).) Petitioners never allege that Moll’s “one or more sidewalls [that] lie substantially flat adjacent to each other” (the only potentially flat-sheet sections of material discussed in Moll) contain “lines that partition a flat-sheet section of material into subsections”—as would be required under Petitioners’ proposed construction of the term “folds.” For this reason, Petitioners’ arguments as to the “folds” claim element in Grounds 5-8 fail for all Challenged Claims. (EX2001, ¶230.)

**Second**, Petitioners’ argument contains a fatal assumption—that Moll’s “flow stoppage elements” are created with *one piece of membrane* that the flow of blood is capable of flattening until the membrane contains folds (even though, as discussed above, these would not be “folds” within the meaning of the construction Petitioners have proposed). (*See*, Petition, 79-81.) This assumption is apparent from the fact that if Moll’s “flow stoppage elements” used separate pieces of membrane for the two sidewalls, then Moll’s disclosure of these sidewalls lying

“substantially flat adjacent to each other” would not create folds, but instead would just bend at the seams joining the sidewalls.

But Moll contains no disclosure that its “flow stoppage elements” are created with a single piece of membrane, and neither Petitioners nor Petitioners’ expert attempt to provide any rationale for this assumption. (*See id.*) Indeed, in Ground 7, Petitioners acknowledge that Moll does not disclose the number of membrane sheets used to create Moll’s “flow stoppage elements.” (Petition, 94 (“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.”).)

By contrast, Moll discloses that its “inner walls 12 and the outer walls 14 are *joined together* at the distal end 4 of the device”. (EX1005, 4:5-6; *see id.*, 3:21-24 (“valve elements 6 have an inner wall 12 and an outer wall 14 extending from a proximal end (2) opening 16 in the ‘flared configuration’ to *join together* and terminate in the form of a pointed end section 17 at the distal end 4.”).) The implication of the inner and outer walls *joining together* is that these walls are made from two separate pieces of membrane, rather than a single piece of membrane that is flattened until the membrane contains folds, as Petitioners allege. (*See* Petition, 79-80.) This interpretation of Moll is also consistent with Petitioners’ allegation in Ground 7 that, although “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,” “[i]t would have been obvious to a [POSA] 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.” (Petition, 94.)

Because Petitioners have not shown that Moll discloses or renders obvious making its “flow stoppage elements” out of a single piece of membrane—a prerequisite for Petitioners’ arguments for the recited “folds” claim element that Petitioners completely ignore—Petitioners’ arguments as to this “folds” claim element in Grounds 5-8 fail for all Challenged Claims. (EX2001, ¶234.)

Put simply, Petitioners cannot have it both ways. Petitioners’ allegations in Ground 7 cannot be squared with Petitioners’ allegations that it is “inherent in Moll’s teachings that the flow stoppage elements have folds”—which, even under Petitioners’ proposed construction of “folds,” requires that the “flow stoppage elements” be made of only *one piece of membrane*—as Petitioners allege in Ground 5. (*Compare* Petition, 79-81 *with* Petition, 94-95.) Conversely, Petitioners’ allegations of inherency in Ground 5 cannot be squared with Petitioners’ admission that it is possible that each of Moll’s “flow stoppage elements” “comprises two or more pieces of biocompatible membrane material,” and in any event, it is obvious

for a POSA “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”—as Petitioners allege in Ground 7. (*Id.*) Because Petitioners’ allegations in Ground 5—upon which each of Petitioners’ Grounds 5-8 are based for the recited “folds” claim element—contradict Petitioner’s reasoning in Ground 7, each of Petitioner’s Grounds 5-8 fail as to all Challenged Claims. (EX2001, ¶236.) *See ZTE*, IPR2018-00274, Paper 17 at 17.

- b. Moll in combination with Paniagua (and/or Pavcnik for Ground 6, Melsheimer for Ground 7, and Eberhardt for Ground 8) does not render obvious forming in the leaflet-containing membrane non-transverse diagonally oriented folds that are angled relative to an axial flow direction (Grounds 5-8, all Challenged Claims).**

Petitioners argue that, “even if not inherent in Moll, it would have been obvious to a [POSA] to form non-transverse diagonally oriented folds along the flow stoppage elements of Moll in view of the teachings of Paniagua.” (Petition, 80.) This is false for at least three reasons.

**First**, the Petition alleges that a POSA would have been motivated “to modify Moll to include folds along the conical flow stoppage elements” in view of Paniagua’s teaching of “the use of folds in a valve structure for ‘improved resistance to tearing at the suture lines,’ and to aid in the patterned movement of the valve.” (Petition, 80.) This says nothing about a motivation to further include

*folds that are “non-transverse,” “diagonally oriented,” and “angled relative to an axial flow direction”* as each of the Challenged Claims recites. For this reason alone, Petitioner failed to meet its burden to demonstrate that it would have been obvious for a POSA to modify Moll to form in the leaflet-containing membrane non-transverse diagonally oriented folds that are angled relative to an axial flow direction.” *See Harmonic*, 815 F.3d at 1363.

**Second**, Petitioners fail to provide the legally required explanation as to how a POSA would create a valve structure including folds that are “non-transverse,” “diagonally oriented,” and “angled relative to an axial flow direction”—none of which Petitioner alleges are disclosed in Paniagua—and then include in Moll. *See Metalcraft of Mayville, Inc. v. The Toro Co.*, 848 F.3d 1358, 1367 (Fed. Cir. 2017) (affirming no motivation to combine because “[w]ithout any explanation as to how or why the references would be combined to arrive at the claimed invention, we are left with only hindsight bias that KSR warns against...we cannot allow hindsight bias to be the thread that stitches together prior art patches into something that is the claimed invention.”).

**Third**, a POSA would understand that folds by themselves do not improve the durability of a valve. (EX2001, ¶240.) Rather, the reason folds in a valve structure allow for improved resistance to tearing at suture lines is that folds allow suture lines to be located on the valve structure where there is less stress, which

leads to improved resistance to tearing. (EX2001, ¶240.) However, because Moll teaches very little about the details of adding the valve leaflets the frame—and specifically does not teach that sutures are used to assemble its various pieces—a POSA reading Moll would not be concerned with tearing at suture lines in Moll, and so would not be motivated to include folds in Moll to improve resistance to tearing at suture lines. (EX2001, ¶240.)

Moreover, a POSA reading Moll would not understand where folds could be added within Moll—and Petitioners fail to provide this required detail. (EX2001, ¶241.) *See Metalcraft*, 848 F.3d at 1367. Specifically, a POSA would understand that Moll discloses an inner layer of material and outer layer of material, which together form a pocket that acts as the valve to restrict flow in one direction. (EX2001, ¶241.) Based on this disclosure, a POSA would understand that more components—not described in the Petition—would have to be added to Moll to create folds that could improve the flow stoppage elements. (EX2001, ¶241.)

Finally, although a POSA reading Paniagua would understand that folds improve resistance to tearing at suture lines, Paniagua teaches very little about how to construct valve leaflets that include creating folds as recited in the ’400 patent’s claims, that then produce a durable valve. (EX2001, ¶242.) Without such a teaching, a POSA would know how to create a folded valve structure and then apply it to Moll. (EX2001, ¶242.)



For these additional reasons, Petitioners’ arguments as to the “non-transverse diagonally oriented folds that are angled relative to an axial flow direction” claim element in Grounds 5-8 fail for all Challenged Claims. (EX2001, ¶243.)

## **VIII. CONCLUSION**

For the reasons discussed above, Petitioners fail to meet their burden of demonstrating that any of claims 55-72, 78-80, and 83-85 are invalid. Therefore, Colibri respectfully requests the Board confirm that all Challenged Claims of the ’400 patent are patentable.

Dated: January 31, 2023

Respectfully Submitted,

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### **CERTIFICATE OF WORD COUNT**

Under the provisions of 37 CFR § 42.24(d), the undersigned hereby certifies that the Microsoft Office word count for the foregoing Patent Owner's Response under 37 C.F.R. § 42.120, excluding the table of contents, table of authorities, claim listing, certificate of word count, and certificate of service, totals 13,881 words, which is less than the 14,000 words allowed under 37 C.F.R. § 42.24(b)(2).

Dated: January 31, 2023

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## **CERTIFICATE OF SERVICE**

Pursuant to 37 C.F.R. § 42.6(e), I certify that I caused to be served on the counsel for Petitioner a true and correct copy of the foregoing Patent Owner's Response under 37 C.F.R. § 42.120, by electronic means on January 31, 2023 at the following addresses of record:

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