

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

EDWARDS LIFESCIENCES CORPORATION and
EDWARDS LIFESCIENCES LLC,
Petitioner,

v.

COLIBRI HEART VALVE LLC,
Patent Owner.

IPR2022-00878
Patent 9,737,400 B2

Before JEFFREY N. FREDMAN, LYNNE H. BROWNE, and
ERIC C. JESCHKE, *Administrative Patent Judges*.

BROWNE, *Administrative Patent Judge*.

DECISION
Granting Institution of *Inter Partes* Review
35 U.S.C. § 314

I. INTRODUCTION

Petitioner, Edwards Lifesciences Corp. and Edwards Lifesciences, LLC, filed a Petition (Paper 2, “Pet.”) requesting *inter partes* review of claims 55–72, 78–80, and 83–85 of U.S. Patent No. 9,737,400 B2 (Ex. 1001, “the ’400 patent”). Patent Owner, Colibri Heart Valve LLC, filed a Preliminary Response (Paper 6, “Prelim. Resp.”).

Having considered the arguments and evidence of record, for the reasons explained below, we grant institution of *inter partes* review.

A. *Real Parties in Interest*

Petitioner states that “Edwards Lifesciences Corporation and Edwards Lifesciences LLC are the real parties-in-interest.” Pet. 99. Patent Owner states that it, Colibri Heart Valve LLC, is the real party in interest. Paper 5, 1.

B. *Related Matters*

Petitioner states that it “is not aware of any other judicial or administrative matter involving the ’400 Patent that would affect, or be affected by, a decision in this proceeding.” Pet. 99. Patent Owner agrees. Paper 5, 1.

C. *The ’400 patent*

The ’400 patent relates to percutaneously deliverable heart valves. Ex. 1001, 1:15–17. The ’400 patent discloses numerous challenges to percutaneously replacing native heart valves, particularly the aortic valve. *Id.* at 1:21–27, 2:10–19. For example, it may be difficult to seat the percutaneous stent-mounted heart valve (“PHV”) in a diseased native valve. *Id.* at 1:59–65. Additionally, the diseased native valve leaflets “may themselves form a barrier separating the [aortic] sinuses of Valsalva from the leaflets of the PHV then disrupting the native closing geometry of the

valve so that the sinuses are no longer continuous with the pressurized space above the PHV leaflets.” *Id.* at 2:4–9. Accordingly, the ’400 patent describes a need for PHV devices that achieve two goals:

(1) . . . 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) . . . 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. at 2:29–40.

The ’400 patent purports to achieve these goals by “employing conical rather than spherical cusp geometry.” Ex. 1001, 3:6–7. The conical geometry provides a large effective orifice area and low transvalvular energy losses. *Id.* at 3:15–17. “Further, the conical cusps are particularly suited for compression and containment within a collapsible frame for transcatheter delivery.” *Id.* at 3:23–25. For example, the conical cusps are formed from a flat sheet of “tissue membrane that is folded into a substantially conical shape according to a flat folding pattern, the substantially conical shape is further formed by joining opposing sides of the substantially conical shape along a seam that is oriented along a longitudinal axis of the substantially conical shape.” *Id.* at 3:30–36, 6:45. The flat sheet includes “two diagonal folds separating a mobile leaflet layer from a cusp wall layer of the integrated cusp and leaflet folded structure” in which the two diagonal folds are angled from the axial flow direction of the valve. *Id.* at 6:39–59. In “at least one embodiment, the two diagonal folds are angled at between about 10 to 80 degrees from the axial flow direction.” *Id.* at 6:51–53. The flat sheet

is mounted an interior portion of a lattice frame along an axial flow direction of the valve. *Id.* at 3:26–42.

Figure 1A depicts the flat sheet and is reproduced below.

Figure 1A

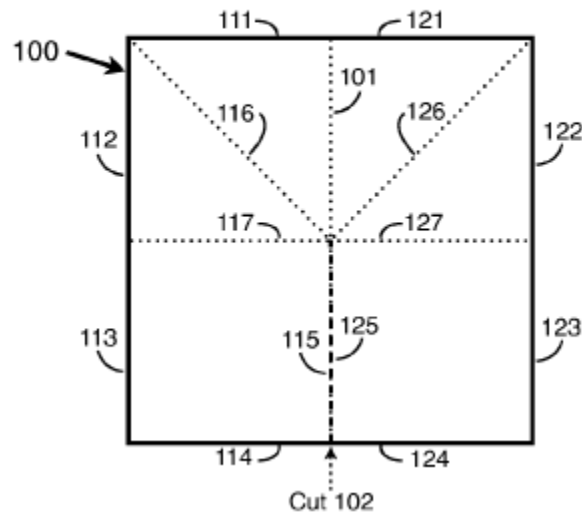
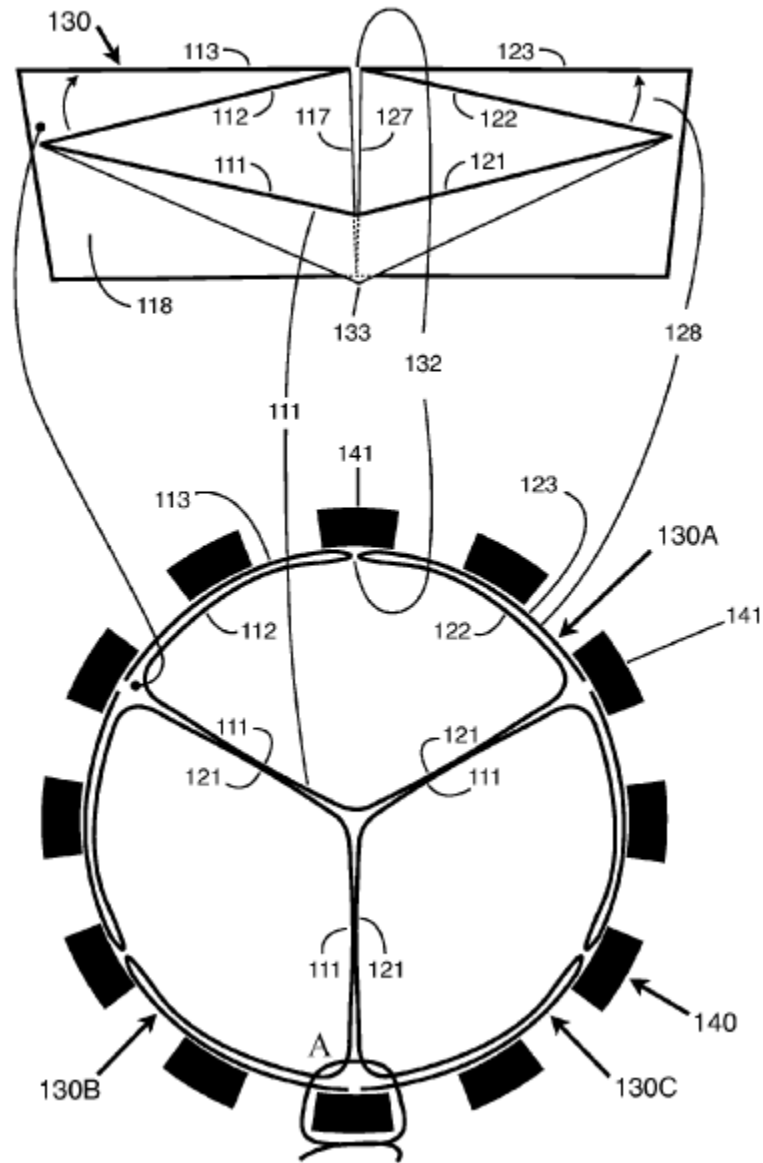


Figure 1A illustrates a square flat sheet 100 with dotted fold lines. Vertical fold line 101 divides the upper half of sheet 100 into two vertical halves. Vertical cut-line 102, shown as a dashed line, divides the lower half of sheet 100 into two vertical halves. Cutting at line 102 creates opposing edges 115 and 125. A horizontal fold line spans sheet 100 at the vertical center of the sheet, and is divided into left fold line 117 and right fold line 127, which meet at the center of sheet 100. Diagonal fold lines extend from the center of sheet 100 to the upper corners, with left diagonal fold line 116 extending to the upper left corner and right diagonal fold line 126 extending to the upper right corner of sheet 100.

Figure 1B depicts the sheet in its folded configuration and is reproduced below.

Figure 1G

Suture attachments omitted for clarity.



The top of Figure 1G illustrates leaflet structure 130. Leaflet structure 130 includes “seam 132 formed by the apposition of folds 117 and 127, thus forming a generally conical cusp and sinus space 131.” *Id.* at 15:22–25. “The triangular corners formed at the distal ends of folds 116 and 126 are opposed to and attached to the cuff wall sections 118 and 128, respectively.” *Id.* at 15:25–28. The bottom of Figure 1G is a top (distal) cross-sectional view of three leaflet structures 130A, 130B, and 130C circularly oriented

within multiple frame members 140 and 141. *Id.* at 15:52–67. Specifically, outer axial seam 132 of leaflet 130 “is aligned with one or more frame members 141 . . . to permit the attachment of the folds 117 to 127, and to the coincident frame member by the same attachment.” *Id.* at 15:63–66. Lines from the top of Figure 1G connect to the leaflets at the bottom of figure to show the configuration of the folded leaflets. Specifically:

- (1) the left leaflet free edge segment 111 is in each case apposed to the right leaflet free edge segment 121 of the adjacent leaflet; (2) the portions of the leaflets just proximal to the free edges, thus, are also apposed to form the contact seal that enables effective closing operation, thereby preventing valvular regurgitation; and (3) the distal edges 112 and 122 of the cusp wall sections are apposed to the distal edges of the cuff wall sections 113 and 123, respectively.

Id. at 16:13–24.

Figure 7A depicts a leaflet with a more complex fold pattern and is reproduced below.

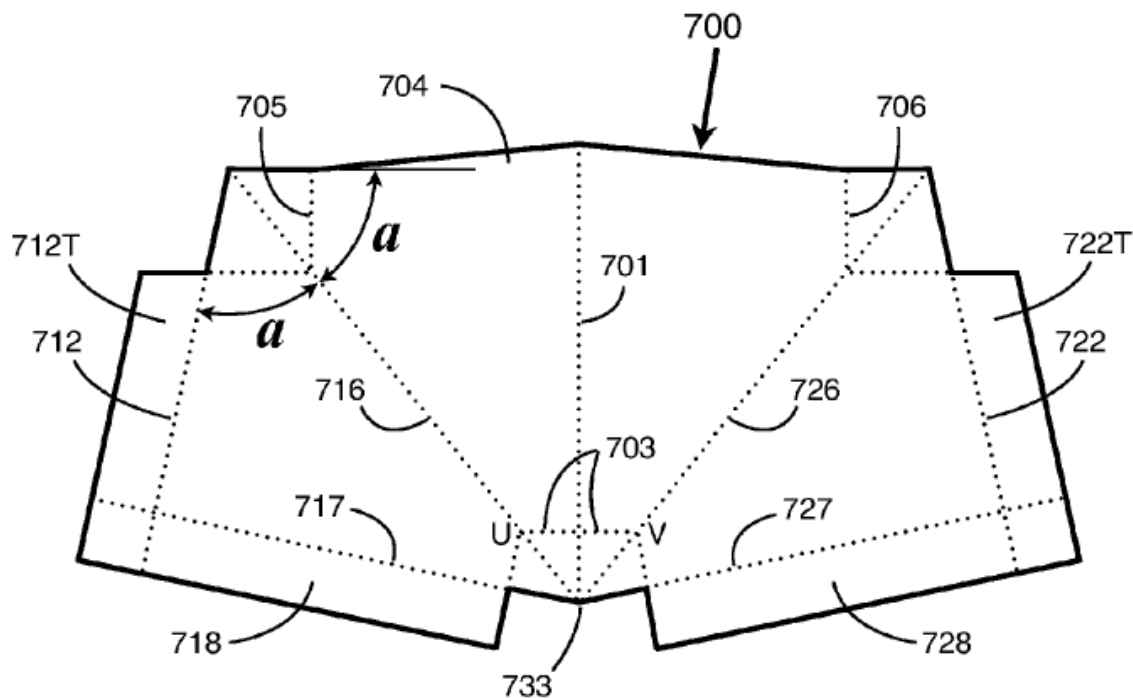


Figure 7A illustrates template 700 with principal folds 701, 716, 726, 717, 727, optional folds 712 and 722, and corner folds 705 and 706. *Id.* at 20:50–60. The folds converge at apex 733 to form an “overlapping two-layer triangular apex.” *Id.* at 20:63–66. “Folding along 717 and 727 acts to position the extension sections 718 and 728 outward of the cusp wall.” *Id.* at 21:9–10. Folding at “716 and 726 . . . forms triangular two-layer sections, 762 and 772, respectively.” *Id.* at 21:22–24.

D. Illustrative Claims

Petitioner challenges claims 55–72, 78–80, and 83–85. Pet. 1. Claims 55, 60, and 67 are independent. Ex. 1001, 33:7–15, 33:27–36, 33:58–67.

Representative claim 55, with Petitioner’s limitation numbering included, is reproduced below.¹ Pet. App. A.

[55[p]] A vascular system implant, comprising:

[55[a]] a lattice frame; and

[55[b]] a plurality of substantially conical shaped cusps attached to the lattice frame,

[55[c]] wherein each of the plurality of substantially conical shaped cusps includes a biocompatible membrane, and

[55[d]] 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.

Ex. 1001, 33:7–15.

E. Asserted Grounds of Unpatentability

Petitioner asserts the following grounds of unpatentability:

¹ We have reproduced each limitation as a separate paragraph to aid the reader.

Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
55, 56, 58–61, 63, 65, 66	102	Melsheimer ²
57, 64, 78, 79	103	Melsheimer
57, 64, 78, 79	103	Melsheimer, Eberhardt ³
62, 83, 84	103	Melsheimer, Pavcnik ⁴
60–72, 79, 80	103	Braido, ⁵ Eberhardt
55–61, 63–67, 69–72	103	Moll, ⁶ Paniagua ⁷
62, 83–85	103	Moll, Paniagua, Pavcnik
68	103	Moll, Paniagua, Melsheimer
78–80	103	Moll, Paniagua, Eberhardt

Pet. 31–97. In addition to the references listed above, Petitioner relies on the Declaration of Jonathan Rourke. Ex. 1026.

II. ANALYSIS

A. *Level of Ordinary Skill in the Art*

In determining the level of skill in the art, we consider the type of problems encountered in the art, the prior art solutions to those problems, the rapidity with which innovations are made, the sophistication of the technology, and the educational level of active workers in the field. *Custom Accessories, Inc. v. Jeffrey-Allan Indus. Inc.*, 807 F.2d 955, 962 (Fed. Cir.

² Melsheimer, U.S. Patent Publication No. 2007/0043431 A1, published February 22, 2007 (Ex. 1003) (“Melsheimer”).

³ Eberhardt et al., U.S. Patent Publication No. 2007/0233228 A1, published October 4, 2007 (Ex. 1006) (“Eberhardt”).

⁴ Pavcnik et al., U.S. Patent Publication No. 2004/0186558 A1, published September 23, 2004 (Ex. 1008) (“Pavcnik”).

⁵ Braido et al., International Publication No. WO 2009/042196 A2, published April 2, 2009 (Ex. 1004) (“Braido”).

⁶ Moll et al., U.S. Patent No. 6,287,334 B1, issued September 11, 2001 (Ex. 1005) (“Moll”).

⁷ Paniagua et al., U.S. Patent Publication No. 2005/0113910 A1, published May 26, 2005 (Ex. 1007) (“Paniagua”).

1986); *Orthopedic Equip. Co. v. United States*, 702 F.2d 1005, 1011 (Fed. Cir. 1983).

Petitioner proposes that a person of ordinary skill in the art would have been a mechanical engineer, medical device engineer, or an interventional cardiologist with a working knowledge of stent-based prostheses for use in a patient's heart or vasculature to replace and/or repair a diseased valve, intravascular delivery systems for the delivery of such prostheses, and methods associated with the delivery and implantation of such prostheses in a patient.

Pet. 31 (citing Ex. 1026 ¶ 27). Patent Owner “does not dispute Petitioners’ definition of a person of ordinary skill in the art.” Prelim. Resp. 3 (citing Pet. 31).

For purposes of this Decision, we adopt Petitioner’s proposal as reasonable and consistent with the prior art. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (the prior art may reflect an appropriate level of skill in the art).

B. Claim Construction

In *inter partes* reviews, the Board interprets claim language using the same claim construction standard that would be used in a civil action under 35 U.S.C. § 282(b), as described in *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (en banc). *See* 37 C.F.R. § 42.100(b). Under that standard, we generally give claim terms their ordinary and customary meaning, as would be understood by a person of ordinary skill in the art at the time of the invention, in light of the language of the claims, the specification, and the prosecution history. *See Phillips*, 415 F.3d at 1313–14. Although extrinsic evidence, when available, may also be useful when construing claim terms under this standard, extrinsic evidence should be considered in the context of the intrinsic evidence. *See id.* at 1317–19.

Petitioner that asserts that “[t]he ’400 Patent is somewhat unique given the sheer number of terms the Applicant defined in the specification and thus acted as its own lexicographer.” Pet. 26 (citing Ex. 1026 ¶ 81). Petitioner reproduces those terms that it characterizes as pertaining “to claim terms in the Challenged Claims.” *Id.* Petitioner does not, however, assert that the meaning of these terms is in controversy in the instant proceeding. *See id.* at 26–29.

Petitioner asserts that “[a] claim term that is not explicitly defined by the specification but requires construction is ‘folds.’” Pet. 29. For the term “folds,” Petitioner asserts that “‘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.” *Id.* at 30 (citing Ex. 1026 ¶ 83). In addition, Petitioner asserts that “a biocompatible membrane that ‘does not comprise a treated tissue’” also requires construction. *Id.* According to Petitioner, a person of ordinary skill in the art “would understand a biocompatible membrane that ‘does not comprise a treated tissue’ at least includes a biocompatible membrane made with a synthetic material.” *Id.* at 30–31 (citing Ex. 1026 ¶ 84).

Patent Owner agrees with Petitioner that the ’400 patent defines many of the terms included in the challenged claims. *See* Prelim. Resp. 16–19. Patent Owner disagrees with Petitioner that the claim term “folds” must be construed. *Id.* at 19. Patent Owner “submits that ‘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.’” *Id.* (citing Ex. 1001, 12:61–64). Patent Owner “disagrees with Petitioners that the ’400 patent

specification's definition of 'folding' is limited to the 'context of folding dry tissue,'" because "[t]he definitional section of the '400 specification contains no such limitation." *Id.* at 20 (citing Pet. 29; Ex. 1001, 12:61–64). Patent Owner contends that "Petitioners improperly import this limitation from an example given in the '400 patent's specification regarding how 'folds' behave in one particular context." *Id.* (comparing Pet. 30, with Ex. 1001, 10:10–19).

In addition, Patent Owner further does not contest Petitioner's contention that "the term 'biocompatible membrane [that] does not comprise a treated tissue' 'at least includes a biocompatible membrane made with a synthetic material.'" Prelim. Resp. 21 (citing Pet. 30–31).

On the record before us, we agree with Patent Owner that the term "folds" need not be construed at this time. We further agree with both parties that many claim terms are defined by the '400 patent and these definitions control. Pet. 26; Prelim. Resp. 16. The meaning of the claim term "substantially conical" is central to our analysis of Grounds 5–8. Accordingly, we reproduce the definition of this term from the Specification of the '400 patent below:

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.

Ex. 1001, 12:47–54. We agree with Patent Owner and Petitioner that this definition of "substantially conical" applies to the claims at issue in this proceeding.

In addition, we find the definition of the claim term “attached” to be at issue in this proceeding for at least some of the challenges presented by Petitioner as will be discussed in Sections II.D–II.H below. As, however, construction of this claim term is not required for our institution decision, we invite the parties to brief this issue in their respective responses to this decision.

C. Discretionary Denial Under 35 U.S.C. § 325(d)

Patent Owner contends that “the Board should deny Grounds 1–4 under 35 U.S.C. § 325(d) under the two-part framework set forth in *Advanced Bionics, LLC v. Med-El Elektromedizinische Geräte GMBH*, IPR2019-01469, Paper 6 at 8–9 (PTAB Feb. 13, 2020) (precedential).” Prelim. Resp. 74. Patent Owner does not make similar contentions regarding Grounds 5–8. Prelim. Resp. 74–77. Pursuant to § 325(d), in determining whether to institute a post-grant review, “the Director may take into account whether, and reject the petition or request because, the same or substantially the same prior art or arguments previously were presented to the Office.” The Board evaluates two issues in addressing § 325(d):

(1) whether the same or substantially the same art previously was presented to the Office or whether the same or substantially the same arguments previously were presented to the Office; and

(2) if either condition of [the] first part of the framework is satisfied, whether the petitioner has demonstrated that the Office erred in a manner material to the patentability of challenged claims.

Advanced Bionics, LLC v. MED-EL Elektromedizinische Geräte GmbH, IPR2019-01469, Paper 6 at 8 (PTAB Feb. 13, 2020) (precedential)

(“*Advanced Bionics*”). With respect to the first issue, previously “presented” art includes, among other things, “art provided to the Office by

an applicant, such as on an Information Disclosure Statement (IDS), in the prosecution history of the challenged patent.” *Id.* at 7–8. With respect to the second issue, institution generally will be denied if a “petitioner fails to make a showing of material error,” and “[i]f reasonable minds can disagree regarding the purported treatment of the art or arguments, it cannot be said that the Office erred in a manner material to patentability.” *Id.* at 8–9. “[T]his framework reflects a commitment to defer to previous Office evaluations of the evidence of record unless material error is shown.” *Id.* at 9.

Petitioner asserts eight grounds of unpatentability against the ’400 patent. Pet. 31–97. Grounds 1–3 rely primarily on Melsheimer, Ground 4 relies on Braido in combination with Eberhardt, and Grounds 5–8 rely primarily on Moll in combination with Paniagua. *Id.*

Regarding Grounds 1–4, Patent Owner argues that “all but one of the references upon which Petitioners base their Grounds ‘was presented to the Office’ during prosecution.” Prelim. Resp. 75 (citing Ex. 1001, 3 (listing U.S. Patent No. 7,604,661 to Pavcnik et al, which is a continuation of the Pavcnik found in Ex. 1008, and so contains the same specification)); *id.* at 4 (listing Patent Pub. No. US 2005/0113910 to Paniagua (Ex. 1007), US 2007/0043431 to Melsheimer (Ex. 1003), and US 2007/0233228 to Eberhardt (Ex. 1006)); *id.* at 5 (listing Patent Pub. No. US 2010/0185277 to Braido, which is the U.S. Publication of PCT/US2008/011153, published as WO 2009/042196 (Ex. 1004)).

Petitioner contends “that the art relied on in this Petition, as well as the prior art combinations, are not the same or substantially the same as what was considered by the Examiner—*i.e.* art raised here was never substantively considered and is uniquely situated over other prior art

references relied upon during prosecution.” Pet. 98–99. For Grounds 1–4, however, the references relied are the same or substantially the same as art presented to the Office. Prelim. Resp. 75.⁸ We thus determine under the first part of the *Advanced Bionics* framework that these references were previously presented to the Office.

Accordingly, we proceed to the second part of the *Advanced Bionics* framework and consider whether Petitioner has demonstrated that the Office erred in a manner material to the patentability of the challenged claims. *See Advanced Bionics*, Paper 6 at 10 (“[I]f the record of the Office’s previous consideration of the art is not well developed or silent, then a petitioner may show the Office erred by overlooking something”). In Grounds 1–4, Petitioner explains how references meet the limitations of the claims at issue. Pet. 31–75. For the reasons discussed in Section II.D–II.G below, we find that Petitioner demonstrates that the Examiner erred by overlooking the specific teachings in the relevant prior art such that the error by the Office was material to the patentability of the challenged claims. *See Advanced Bionics*, Paper 6 at 21. Thus, with respect to Grounds 1–4, on this record, we determine that the totality of the evidence favors declining to exercise our discretion under § 325(d) to deny institution.

Further, Petitioner’s demonstration of a reasonable likelihood of prevailing in showing that at least some of the claims challenged in Grounds

⁸ As noted above, under *Advanced Bionics*, the mere listing of a reference on an IDS is generally deemed to be sufficient to show that the reference was “presented” to the Office; there is no need to show that the reference was actually considered substantively. *See, e.g., Palo Alto Networks, Inc. v. Centripetal Networks, Inc.*, IPR2021-01149, Paper 10 at 14 (PTAB Feb. 22, 2022); *Advanced Bionics*, Paper 6 at 7–8 (“Previously presented art includes . . . art provided to the Office by an applicant, such as on an [IDS].”).

5–8 are unpatentable weighs in favor of declining to exercise our discretion under § 325(d) to deny institution.

D. Ground One: Anticipation of Claims 55, 56, 58–61, 63, 65, and 66 by Melsheimer

Petitioner asserts that claims 55, 56, 58–61, 63, 65, and 66 are anticipated by Melsheimer. Pet. 31. We begin our analysis of this challenge with an overview of Melsheimer. Then we consider the three arguments raised by Patent Owner. Prelim. Resp. 23–36. For this ground, the first argument only pertains to claims 60, 61, 63, 65, and 66. *Id.* at 23. The second and third arguments for this ground only pertain to claims 55, 56, 58, and 59. *Id.* at 25, 34. Having determined that Petitioner has made a sufficient showing for the uncontested limitations of the challenged claims, we focus our discussion for Ground 1 on these three arguments.

1. Overview of Melsheimer

Melsheimer “relates to medical devices, and in particular to prosthetic valve devices, methods of making such devices, and methods of deploying such devices within a body site.” Ex. 1003 ¶ 2. Melsheimer’s prosthetic valve includes at least one flexible member (having a proximal portion and a distal portion) movable between a first position that permits fluid flow in a first direction and a second position that substantially prevents fluid flow in a second direction. *Id.* ¶ 11. “The valve includes a receptacle operatively connected to the proximal portion of flexible member” and “[t]he receptacle has an expanded position adapted to receive fluid flowing in the second direction and a contracted position adapted to allow fluid flow through the valve in the first direction.” *Id.* “The valve further includes an attachment portion operably connected to the receptacle for attaching the valve to the body site.” *Id.*

Melsheimer's Figures 4A–4C (reproduced below) show the shape of a leaflet and receptacle in alternative embodiments of Melsheimer's valve.

Ex. 1003 ¶¶ 21–23.

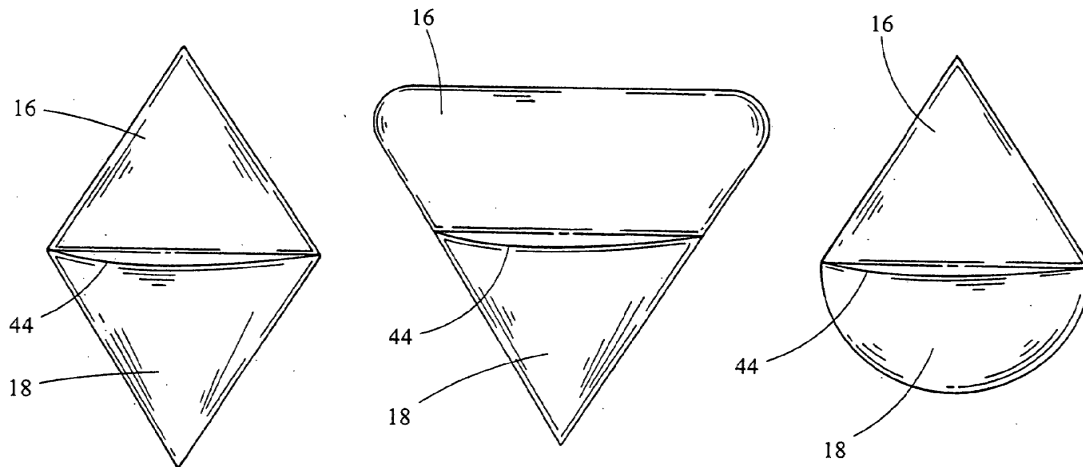


Fig. 4A

Fig. 4B

Fig. 4C

Id. Figs 4A–4C. “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.” *Id.* ¶ 41. “The shape of the leaflet 16 may be the same as the shape of the receptacle 18 or different.”

Id. Leaflet 16 and receptacle 18 may be integrally connected, formed by unitary construction from the same material or leaflet 16 may be formed separately from the receptacle 18 and operably connected after formation at a connection area 44. *Id.* ¶ 42.

2. *First Argument: Melsheimer Doesn't Disclose Leaflets Attached to the Lattice Frame*

Claim 60 requires “a plurality of non-rectangular polygonal mobile leaflets attached to the lattice frame.” Ex. 1001, 33:29–30. As discussed above, the '400 patent doesn't define the claim term “attached.” *See*

generally Ex. 1001. Petitioner asserts that “Melsheimer discloses a plurality of leaflets attached to the lattice frame.” Pet. 42 (citing *id.* at 33–34).

Patent Owner contends that “[i]n 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.’” Prelim. Resp. 23. According to Patent Owner, “Petitioners made no allegations regarding whether Melsheimer discloses *leaflets* attached to the lattice frame.” *Id.* Thus, Patent Owner contends that because Petitioner failed to provide evidence that Melsheimer discloses “leaflets attached to the lattice frame” as required by claim 60, this challenge fails.

On the record before us we are 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. 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.

3. *Second Argument: Melsheimer Doesn’t Disclose Substantially Conical Shaped Cusps*

Claim 55 requires “a plurality of substantially conical shaped cusps.” Ex. 1001, 33:9. As noted by Patent Owner, the ’400 patent states that “‘cone’ or ‘conical’ means resembling a cone or portion thereof at some point in the practical use of the structure” and that

“substantially conical” means 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.*

Prelim. Resp. 25 (citing Ex. 1001, 12:47–54). The '400 patent also states that

a “cusp” means 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.

Ex. 1001, 12:4–11. Given the explicit definitions of the claim terms “cusp,” “cone or conical,” and “substantially conical” set forth in the '400 patent, it is clear that Patent Owner has acted as its own lexicographer and the statements quoted above define these claim terms. *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). With these definitions in mind, we consider the parties’ positions summarized below.

Petitioner asserts that “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.” Pet. 33–34 (citing Ex. 1003 ¶¶ 38, 48–53, Fig. 6; Ex. 1026 ¶¶ 90–94). Specifically, Petitioner asserts that

the shape of the leaflets 16 and chambers 18 may be triangular, curvilinear, or any shape that will allow the leaflets 16 to form a contact region and the receptacle 18 to form a pocket for receiving fluid in the second direction 22. The shape of the leaflet 16 may be the same as the shape of the receptacle 18 or different.

Id. (citing Ex. 1003 ¶ 41). Petitioner asserts further that “the entire structure shown in, *e.g.*, Figures 4A–4C of Melsheimer makes up a single ‘cusp’ as claimed by the '400 Patent, which, in turn, comprises ‘cusp wall’ and

‘mobile leaflet’ portions as claimed by the ‘400 Patent.” *Id.* at 35 (citing Ex. 1026 ¶ 93). Based on this assertion, Petitioner opines that “there is no structural difference between the ‘400 Patent’s ‘leaflet’ and Melsheimer’s ‘inner wall’/‘leaflet’ combination” and that “[i]t is a difference only in nomenclature.” *Id.*

Patent Owner contends that “Melsheimer does not disclose ‘substantially conical shaped cusps’ as Challenged Claims 55–59, 78, and 83 recite.” Prelim. Resp. 29. According to Patent Owner, “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.’” *Id.* at 30 (quoting Ex. 1003 ¶ 41). Patent Owner contends that “because Petitioners allege that Melsheimer’s cusps consist of structures in addition to the receptacle, Petitioners’ reliance on Melsheimer’s disclosure of ‘a conically shaped pocket’—which is formed *only by the receptacle*—says nothing about whether Melsheimer’s *cusps* as a whole are ‘substantially conical shaped’” as required by claims 55–59, 78, and 83. *Id.* at 30–31.

On the record before us, Petitioner has adequately demonstrated that Melsheimer discloses “a plurality of substantially conical shaped cusps” as required by claim 55. Even 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. Moreover, claim 55 merely requires “substantially conical shaped cusps.” Ex. 1001, 33:9. It does not require the cusps *as a whole* be substantially conically shaped as argued by Patent Owner. Prelim. Resp. 30–31.

4. *Third Argument: Melsheimer Doesn't Disclose Substantially Conical Cusps and Non-transverse Diagonally Oriented Folds*

Claim 55 requires 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.” Ex. 1001, 33:12–15. Petitioner asserts that Melsheimer discloses substantially conical cusps as discussed in the previous Section. Pet. 33–36. Petitioner further asserts that “the plurality of substantially conical cusps of Melsheimer comprise non-transverse diagonally oriented folds angled relative to an axial flow direction.” *Id.* at 38–39 (citing Ex. 1026 ¶¶ 97–99). Petitioner references a paper model of Melsheimer’s valve to demonstrate where these folds are located and how they are non-transverse diagonally oriented folds that are angled relative to an axial flow direction. *Id.* at 38–40.

Patent Owner contends that “Petitioners have improperly relied [on] a single structure within Melsheimer’s alleged cusps as disclosing two separate claim elements.” Prelim. Resp. 34. According to Patent Owner, “Petitioners have relied on the ‘folded edges’ of the Melsheimer receptacles, both (1) as disclosing the recited element of ‘non-transverse diagonally oriented folds that are angled relative to an axial flow direction,’ and (2) as defining the Melsheimer receptacles (not cusps, as discussed above) as ‘substantially conical.’” *Id.* at 34–35 (citing Ex. 1003, Fig. 1A; Pet. 38, 40).

We note that as quoted above, in claim 55, the folds are included in (i.e., part of) the cusps. Thus, Patent Owner’s argument that the claim requires two separate claim elements to meet the limitation pertaining to the folds is unavailing. Further, on the record before, we find that Petitioner has

adequately demonstrated for purposes of institution that Melsheimer discloses non-transverse diagonally oriented folds as claimed.

5. *Conclusion For Ground 1*

On the record before us, we find that Petitioner has demonstrated a reasonable likelihood of prevailing in showing that claims 55, 56, 58–61, 63, 65, and 66 are anticipated by Melsheimer.

E. Ground 2: Obviousness of Claims 57, 64, 78, and 79 Based on Melsheimer Alone or in Combination with Eberhardt

Petitioner asserts that claims 57, 64, 78, and 79 are unpatentable over Melsheimer alone or in combination with Eberhardt. Pet. 48–54. We begin our analysis of this challenge with an overview of Eberhardt.

1. *Overview of Eberhardt*

Eberhardt relates to an implantable heart valve. *See* Ex. 1006 ¶ 2. In particular, Eberhardt discloses a biocompatible membrane made of processed mammalian (i.e., porcine) pericardial tissue. *Id.* ¶ 38.

2. *Claims 57 and 78*

For claim 57, Petitioner asserts that a person of ordinary skill in the art “would understand that Melsheimer’s broad disclosure of pericardium includes processed mammalian pericardium given that mammalian pericardium was the only type of pericardium used in prosthetic heart valves as of the priority date of the ’400 Patent.” Pet. 48 (citing Ex. 1026 ¶¶ 123–126; Ex. 1027, 230, 233; Ex. 1032, 1–2). For claim 78, Petitioner asserts that it would have been apparent to a person of ordinary skill in the art “from the folding instructions provided for the exemplary Figure 8 embodiment” “that the angle of the folds relative to the axial flow direction fall approximately in the middle of the claimed range of 10–80 degrees.” *Id.* at 50–51 (citing Ex. 1003 ¶¶ 106–109).

Patent Owner does not contest Petitioner’s assertions for these claims. *See generally* Prelim. Resp. Rather, Patent Owner argues these claims (which depend from claim 55) with claim 55. *Id.* at 25–36. For the reasons discussed in Section II.D.3–4 above, Patent Owner’s arguments are unconvincing.

3. *Claims 64 and 79*

Claims 64 and 79 depend from claim 60. As discussed in Section II.D.2 above, the question of whether Melsheimer anticipates claim 60 hinges on the interpretation of the claim term “attached” and neither Petitioner nor Patent Owner proposed claim construction for this term. Due to their dependence from claim 60, the question of whether Melsheimer alone or in combination renders claims 64 and 79 unpatentable also hinges on this issue.

4. *Conclusion Re Ground 2*

On the record before us, we find that Petitioner has demonstrated a reasonable likelihood of prevailing in showing that claims 57, 64, 78, and 79 are unpatentable over Melsheimer alone or in combination with Eberhardt.

F. Ground 3: Obviousness of Claims 62, 83, and 84 Based on Melsheimer in Combination with Pavcnik

Petitioner asserts that claims 62, 83, and 84 are unpatentable over the combined teachings of Melsheimer and Pavcnik. Pet. 54–56. We begin our analysis of this challenge with an overview of Pavcnik.

1. *Overview of Pavcnik*

Pavcnik relates to “medical devices, more particularly, to intraluminal devices.” Ex. 1008 ¶ 2. In particular, Pavcnik discloses valve cusps that include a vertex forming a proximal, upstream tip that can be folded over in

a radially outward direction and attached to the lattice frame to form a “corner flap.” *Id.* ¶ 104.

2. *Claim 83*

Claim 83 depends from claim 55. Ex. 1001, 34:58. Petitioner asserts that “it would have been obvious to modify Melsheimer in view of Pavcnik by taking the vertex forming a proximal, upstream tip of Melsheimer and folding it over in a radially outward direction and attaching it to the lattice frame.” Pet. 57 (citing *id.* at 54–56).

Patent Owner does not contest Petitioner’s assertions for this claim. *See generally* Prelim. Resp. Rather, Patent Owner argues this claim with claim 55. *Id.* at 25–36. For the reasons discussed in Section II.D.3–4 above, Patent Owner’s arguments are unconvincing.

3. *Claims 62 and 84*

Claim 62 depends from claim 61, which depends from claim 60, and claim 84 depends from claim 62. Ex. 1001, 33:42, 34:63. Thus, both claims depend indirectly from claim 60. As discussed in Section II.D.2 above, the question of whether Melsheimer anticipates claim 60 hinges on the interpretation of the claim term “attached” and neither Petitioner nor Patent Owner proposed claim construction for this term. Due to their dependence from claim 60, the question of whether the combined teachings of Melsheimer and Pavcnik render claims 62 and 84 unpatentable also hinges on this issue.

4. *Conclusion Re Ground 3*

On the record before us, we find that Petitioner has demonstrated a reasonable likelihood of prevailing in showing that claims 62, 83, and 84 are unpatentable over the combined teachings of Melsheimer and Pavcnik.

G. Ground 4: Obviousness of Claims 60–72, 79, and 80 Based on Braido and Eberhardt

Petitioner asserts that claims 60–72, 79, and 80 are unpatentable over the combined teachings of Braido and Eberhardt. Pet. 57–75. We begin our analysis of this challenge with an overview of Braido. Then we consider the three arguments made by Patent Owner. Prelim. Resp. 37–44. Having determined that Petitioner has made a sufficient showing for the uncontested limitations of the challenged claims, we focus our discussion for Ground 4 on these three arguments.

1. Overview of Braido

Braido relates to collapsible prosthetic heart valves including a sheet-like, flexible, leaflet member mounted inside a supporting structure.

Ex. 1004 ¶¶ 3–4. The leaflet includes a free edge portion that forms a flexible chord across the interior of the supporting structure. *Id.* ¶ 4. Figure 10 depicts a single leaflet design and is reproduced below.

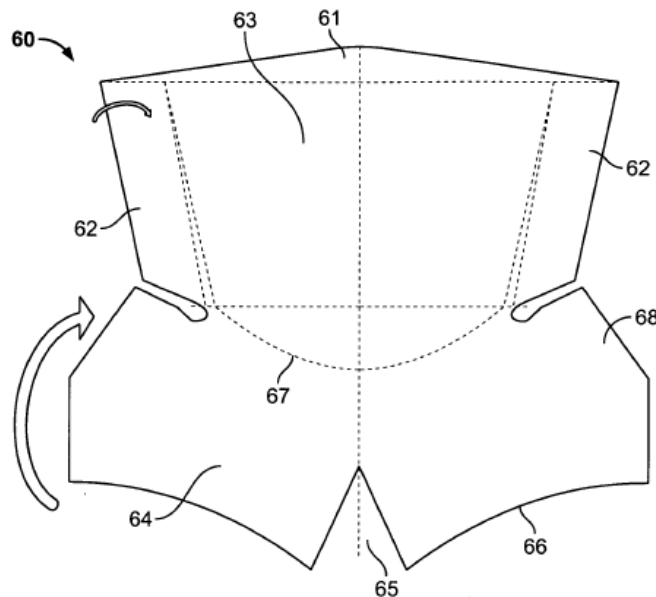


FIG. 10

Figure 10 illustrates leaflet 60 that including a belly-shaped contour 63 in the center of the leaflet body, shown as dotted lines. *Id.* ¶ 120. Dotted curve 67 at the bottom of contour 63 shows where the leaflet material may be sutured to form a “natural belly shape for the leaflet.” *Id.* Above belly shape 63 is located material 61 used “for redundant coaptation where all three leaflets 60a–c [(see Figure 11 below)] meet under back-pressure.” *Id.* To the left and right sides of belly shape 63 are located side flaps 62, which wrap around commissure posts of the support. *Id.* Below belly shape 63 is located bottom flap 64 that includes a triangular cut-out in the middle that “allows for flexible movement of the edge and actually will meet when wrapped, while the rounded lower edge sections 66 will meet to form one continuous circular path around the stent.” *Id.* Braido further discloses alternative embodiments, that include a straight lower portion rather than a contour. *See id.* ¶ 182, Figures 74A, 75.

Figure 11 depicts three leaflets 60a–c attached to a stent as is reproduced below.

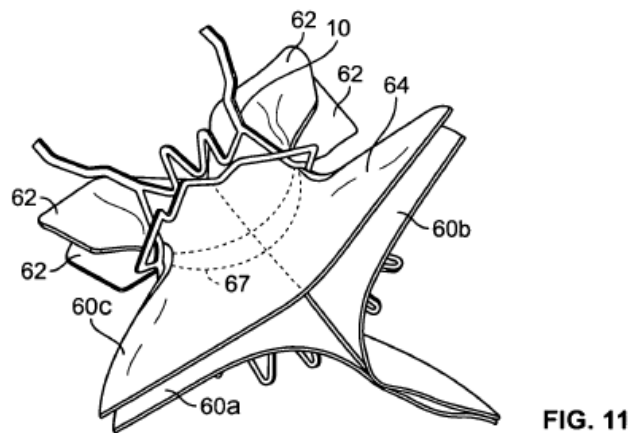


Figure 11 illustrates stent 10 surrounding three single leaflets 60a–c, which are attached to the stent. Ex. 1004 ¶ 121. The leaflets include side flaps 62

and bottom flaps 62 which protrude from the interior of the stent and are then attached to the stent. *See id.*

Figure 43 depicts the leaflets in a stent that “more closely mimics the contour shape of a native valve,” as reproduced below.

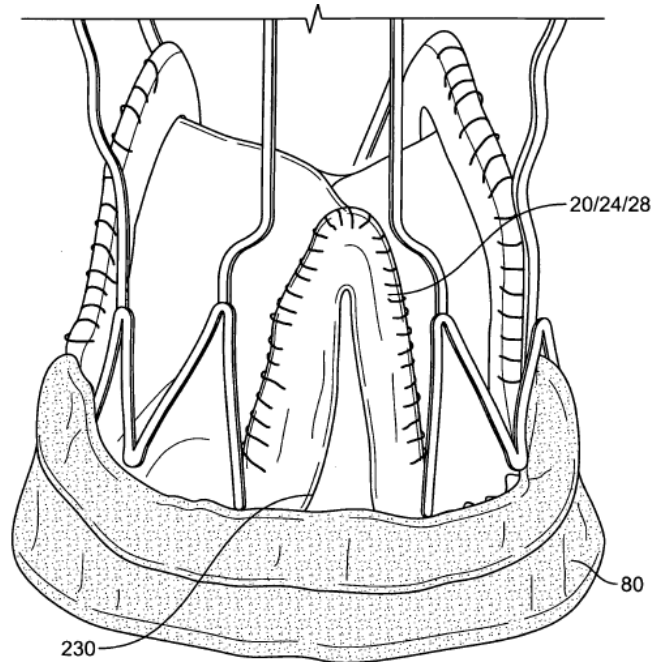


FIG. 43

Figure 43 illustrates a stent with patch 230 sutured through eyelets 22 and around the base of stent 10. *Id.* ¶ 154. The bottom of stent 10 is covered by a double layer of cuff material 80 “to aid in better sealing and tissue in-growth when pushed against native aortic root tissue.” *Id.*

2. *First Argument: Braido in View of Eberhardt Fails to Disclose or Suggest Mobile Leaflets Attached to the Lattice Frame*

Claim 60 requires “a plurality of non-rectangular polygonal mobile leaflets attached to the lattice frame.” Ex. 1001, 33:29–30. Patent Owner asserts that “Petitioners have failed to make any showing that Braido contains such a disclosure.” Prelim. Resp. 37 (citing Pet. 57–65). Patent Owner asserts further that “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.” *Id.* According to Patent Owner, “the Petition merely alleges Braido has *integrated cusps*—not mobile leaflets—attached to the lattice frame.” *Id.* (quoting Pet. 60–61).

Patent Owner’s argument is similar to the argument discussed in Section II.D.2 above in that it hinges on the interpretation of the claim term “attached” and neither Petitioner nor Patent Owner proposed claim construction for this term. On the record before us we are 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.

3. *Second Argument: Braido in View of Eberhardt Fails to Disclose or Suggest At Least Two Folded Biocompatible Membrane Sheets Attached to the Lattice Frame*

Claim 67 requires “at least two folded biocompatible membrane sheets attached to the lattice frame.” Ex. 1001, 33:60–61. Patent Owner asserts that for this limitation “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.’” Prelim. Resp. 40–41 (citing Pet. 70).

Patent Owner’s argument is essentially the same as its argument in the prior section and is unpersuasive for the same reason.

4. *Third Argument: Reliance on Multiple Embodiments of Braido Without Articulated Reasoning for Combining These Embodiments*

For the limitations in claims 60 and 67 pertaining to attachment to a lattice frame, Petitioner asserts that “[i]n a number of Braido’s embodiments, dotted lines outline the artificial divide that forms the mobile leaflet portion of the integrated cusp” and that the mobile leaflets include a

curved lower edge. Pet. 60 (citing Ex. 1004 ¶ 120). Petitioner asserts that “[i]n further embodiments, Braido also discloses that this curved lower edge can instead be a horizontal straight edge depending on how the integrated cusp is attached to the lattice frame.” *Id.* According to Petitioner, “it would have been obvious to a POSITA⁹ 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.” *Id.* at 61 (citing Ex. 1026 ¶ 149).

Patent Owner contends that “Petitioners rely on Braido’s Figure 74A (and its accompanying Figure 75 showing only a leaflet) for their failed attachment arguments” and that “Petitioners rely on these figures for their arguments relating to the recited ‘non-rectangular polygonal mobile leaflet’ claim element as well,” but “the stent disclosed for this set of figures does not include a *lattice* frame.” Prelim. Resp. 41–42 (citing Pet. 60–61, 70).

On the record before us, we determine that for purposes of institution Petitioner provides sufficient rationale in support of its reasoning that Braido renders the limitations pertaining to the attachment to the lattice frame.

5. *Conclusion Re Ground 4*

On the record before us, we find that Petitioner has demonstrated a reasonable likelihood of prevailing in showing that claims 60–72, 79, and 80 are unpatentable over the combined teachings of Braido and Eberhardt.

H. Grounds 5–8: Obviousness Based on the Combined Teachings of Moll and Paniagua Alone, or Further in View of Pavcnik, Melsheimer, or Eberhardt.

Each of Grounds 5–8 relies on the combined teachings of Moll and Paniagua alone, or in combination with Pavcnik (Ground 6), Melsheimer

⁹ Person of ordinary skill in the art.

(Ground 7), or Eberhardt (Ground 8). Pet. 75–97. We begin our analysis of this challenge with overviews of Moll and Paniagua. Then we consider the four arguments raised by Patent Owner. Prelim. Resp. 45–74. The first and second arguments pertain to Grounds 5, 6, and 8. *Id.* at 45–60. The third and fourth arguments pertain to Grounds 5–8. *Id.* at 60–74. Having determined that Petitioner has made a sufficient showing for the uncontested limitations of the challenged claims, we focus our discussion for Grounds 5–8 on these four arguments. Further, as Patent Owner argues independent claims 55, 60, and 67 together, we refer to Petitioner’s findings pertaining to representative claim 55 except where differences in claim language necessitate discussion of the findings pertaining to claims 60 and 67.

1. Overview of Moll

Moll discloses a valve prosthesis that is implantable within a blood vessel using a minimally-invasive surgical procedure. Ex. 1005, code (57). The valve includes a flow stoppage element with a flareable proximal end that changes from a flared stoppage configuration and a substantially flattened flow permitting configuration. *Id.* at 1:44–46. “When occupying the blood flow stoppage configuration, the flow stoppage element encloses a temporary blood storage area between its open proximal end and the closed distal end.” *Id.* at 1:62–65. “The stoppage element is preferably substantially conical in shape when occupying the blood flow stoppage configuration, the closed distal end being synonymous with the tip of the cone and the proximal end opening being synonymous with the flared base of the cone.” *Id.* at 2:13–17. The flow stoppage element is mounted on a support that is preferably adjustable between an introducing form and an expanded form suitable for supporting the stoppage element within a blood vessel. *Id.* at 2:8–10, 19–23.

Figure 1 depicts the flow stoppage element and is reproduced below.

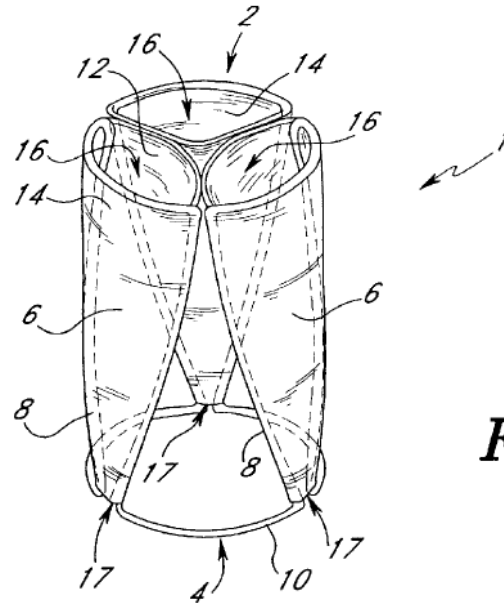


FIG. 1

Figure 1 illustrates device 1 including proximal end 2 and distal end 4. *Id.* at 3:16–17. Device 1 includes three valve/blood flow stoppage elements 6, in the form of three flexible hollow cones. *Id.* at 3:18–20. Valve elements 6 include inner wall 12 and outer wall 14 extending from proximal end opening 16 in the flared configuration to join together and terminate in the form of pointed end section 17 at distal end 4. *Id.* at 3:21–24. Valve elements 6 are supported on triangular support section 8 of circular support 10. *Id.* at 3:19–20. Support 10 is shown as a circle on at distal end 4, with three triangular support sections 8 extending to the proximal direction with valve elements 6 attached thereto. *Id.*

Figures 5 and 6 depict the flow of blood through the valve and are reproduced below.

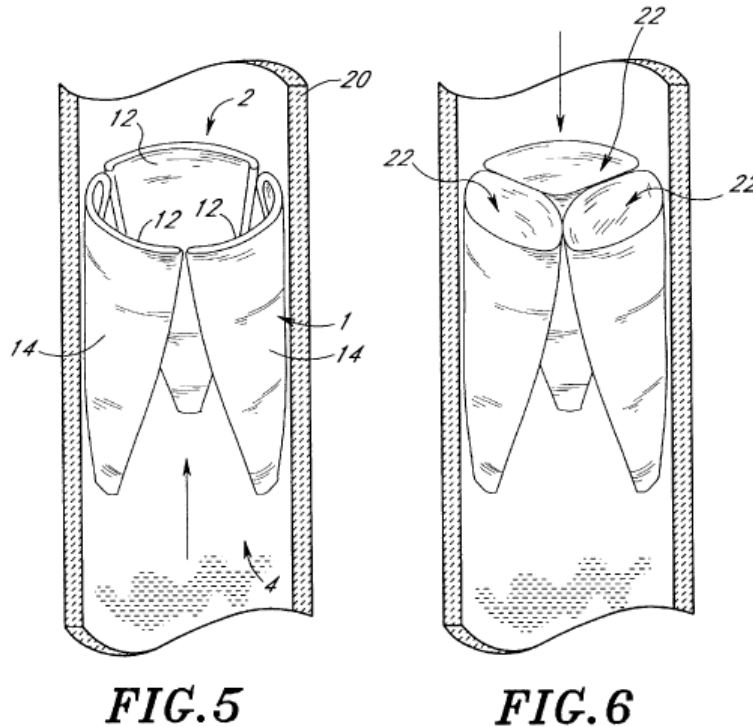


Figure 5, on the left, illustrates blood vessel 20 with device 1 implanted therein, device 1 including three stoppage elements 6, each with inner walls 12 and outer walls 14. Figure 5 includes an arrow, indicating blood flow, pointing up toward distal end 4 of device 1. *Id.* at 3:59–61. The flow of blood travels through distal end 4, forcing inner walls 12 of stoppage element (valve) 6 against outer walls 14 to effect blood through device 1. *Id.* at 3:62–65. Between heartbeats, blood may flow back toward proximal end 2 of device 1. *Id.* at 3:66–4:1. The back flow of blood forces inner walls 12 away from outer walls 14 of stoppage elements 6 to create opening 16 leading into temporary blood storage area 22, as shown in Figure 6 on the right. *Id.* at 4:1–8.

2. Overview of Paniagua

Paniagua “is directed to a percutaneously implantable replacement heart valve and method of making same.” Ex. 1007 ¶ 2. One type of

replacement heart valve is a tissue valve that is “constructed by sewing the leaflets of pig aortic valves to a stent to hold the leaflets in proper position, or by constructing valve leaflets from the pericardial sac of cows or pigs and sewing them to a stent.” *Id.* ¶ 17. However, “[t]he pericardium is a thin and very slippery [membrane], which makes it difficult for suturing in a millimetrically precise way.” *Id.* Paniagua purports to solve this problem in the making of a replacement heart valve that includes tissue by using a process to dry the pericardium in “such a way that makes it possible to handle and fold more easily.” *Id.*

Figure 5 of Paniagua depicts an exemplary replacement heart valve device and is reproduced below.

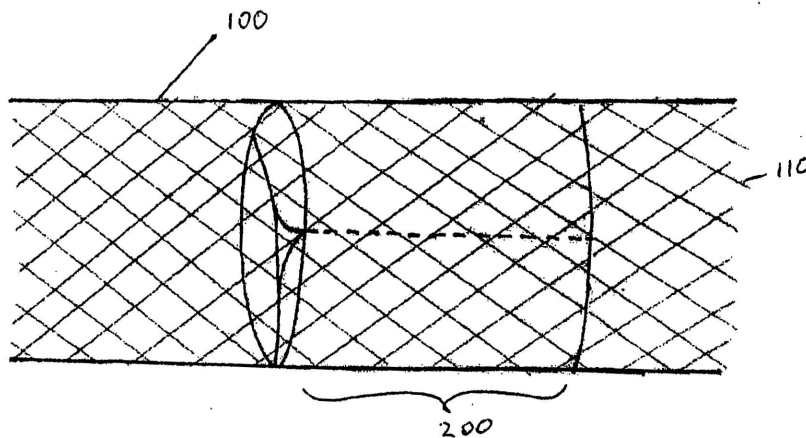


Fig. 5

Figure 5 shows a side view of a replacement heart valve device that includes a self-expanding stent in the expanded position. *Id.* ¶ 33. The replacement heart valve device comprises stent member 100 and flexible valve means 200. *Id.* ¶ 37. Stent member 100 includes wire 110 “formed in a closed zigzag configuration” and “is preferably self-expanding although balloon-expandable stents can be used as well, and has a first polygonal shape in its

compressed or collapsed configuration and a second, larger polygonal shape in its expanded configuration.” *Id.* ¶¶ 37, 40. Valve means 200 comprises generally tubular portion 210 and is preferably, “a peripheral upstanding cusp or leaflet portion 220” (shown in Figure 1). *Id.* ¶ 37. Valve means 200 is disposed within cylindrical stent member 100 with tubular portion 210 “transverse of and at some acute angle relative to the stent walls.” *Id.* The preferred material for valve means 200 is bovine “pericardium tissue.” *Id.* ¶ 46.

Paniagua discloses that in order to make the valve, the bovine pericardium “material is isolated and all the fat tissue and extra fibers are removed.” Ex 1007 ¶ 49. “Once the pericardium is completely clean, it is [placed in a solution of gluteraldehyde,] preferably at a concentration of about 0.07-25%” during 36 hours, then the pericardium is transferred to a solution of ethanol, preferably at a concentration of about 60% before making the valve. *Id.* Paniagua further discloses in order to make the pericardium material less slippery and easier to fold, “the pericardium is dried, preferably with artificial light using a 60-watt lamp with the pericardium [material placed in a] flat aluminum surface to dry it homogeneously.” *Id.* ¶ 51. “A photomechanical drying machine can also be used” and “[t]he final result is a homogeneous tissue that looks like plastic paper and makes it easy to manipulate to fold and suture the valve.” *Id.*

3. *First Argument: Moll Doesn’t Disclose Substantially Conical Shaped Cusps*

Petitioner asserts that “Moll discloses a plurality of substantially conical shaped cusps.” Pet. 78 (citing Ex. 1005, 3:18–20; Ex. 1026 ¶ 200). Patent Owner responds that “[w]hile Moll characterizes its blood ‘flow stoppage element’ as ‘substantially conical in shape when occupying the

blood flow stoppage configuration,’ Moll’s specification makes abundantly clear that Moll does not use ‘substantially conical in shape’ within the meaning explicitly set forth in the ’400 patent, and agreed upon by Petitioners.” Prelim. Resp. 47 (citing Ex. 1005, 2:13–17; *Nestle USA, Inc. v. Steuben Foods, Inc.*, 686 F. App’x 917, 919 (Fed. Cir. 2017); *Martek Biosciences Corp. v. Nutrinova, Inc.*, 579 F.3d 1363, 1380 (Fed. Cir. 2009)) (internal citations omitted).

As discussed in Section II.B above, the definition of the claim term “substantially conical” includes elements resembling a portion of a cone *at some point* in the practical use of the structure. Ex. 1001, 12:47–49. Here, Patent Owner concedes that “Moll characterizes its blood ‘flow stoppage element’ as ‘substantially conical in shape when occupying the blood flow stoppage configuration.’” Prelim. Resp. 47.

On the record before us, we determine that for purposes of institution Petitioner has sufficiently demonstrated that Moll discloses a plurality of substantially conical shaped cusps.

4. *Second Argument: Moll in Combination with Paniagua Doesn’t Disclose a Lattice Frame*

Petitioner asserts that Moll discloses a wire lattice made of a continuous length of memory metal having three substantially separate frame sections for supporting each valve element. Pet. 76 (citing Ex. 1005, 3:25–28, Fig. 2). Petitioner asserts further that “[t]o the extent it is argued that the stent structure in Figure 2 of Moll is not a ‘lattice frame’ as claimed, it would have been obvious to a POSITA to modify the stent structure of Moll accordingly.” *Id.* (citing Ex. 1026 ¶¶ 196–199). In support of this assertion Petitioner contends that Paniagua teaches such a lattice frame and provides reasoning in support of this proposed modification. *Id.* at 76–78.

Patent Owner responds that the frame in Moll is not a lattice frame. Prelim. Resp. 52. Patent Owner responds further that “Petitioners have not explained why a POSA¹⁰ would have wanted to have ‘alternative frame structures’ for use with Moll’s blood ‘flow stoppage element,’ particularly where Moll discloses that its frame was specifically designed for those particular elements.” *Id.* at 56. In other words, Patent Owner asserts that Petitioners have no articulated reasoning with rational underpinning in support of the proposed modification. *Id.*

On the record before us, we determine that for purposes of institution Petitioner has articulated adequate reasoning in support of the proposed modification.

5. *Third Argument: The Combined Teachings of Moll and Paniagua Don’t Render a Cusp or Leaflet Attached to the Lattice Frame Obvious*

For claim 55, Patent Owner contends that “Petitioners have simply failed to allege that what Petitioner argues are ‘a plurality of substantially conical shaped cusps’ in Moll . . . are ‘attached to the lattice frame.’” Prelim. Resp. 61. We agree that such an explicit statement is not made by Petitioner in reference to independent claim 55. We do not agree, however, that the challenge fails 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. For example, 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.” Pet. 84 (citing Ex. 1026 ¶¶ 219–220). Similarly, for independent claim 67, Petitioner asserts that “Moll discloses the use of at least two folded biocompatible

¹⁰ Person of skill in the art.

membrane sheets . . . attached to the lattice frame.” *Id.* at 89 (citing Ex. 1005, 3:18–20, 1:40–46; Ex. 1026 ¶ 235). Thus, 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.

Patent Owner further contends that instead of asserting that Moll’s leaflets are attached to the lattice frame, “Petitioners allege instead that it is the separate *cusp wall* that is attached to the frame in Moll.” Prelim. Resp. 62 (citing Pet. 85) (emphases omitted). Like the arguments discussed in numerous Sections above, this argument hinges on the interpretation of the claim term “attached” and neither Petitioner nor Patent Owner proposed claim construction for this term. On the record before us, we are 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.

6. *Fourth Argument: The Combined Teachings of Moll and Paniagua Don’t Render Folds Obvious*

Petitioner asserts that “[a]lthough Moll does not explicitly state that the sidewalls of the conical shaped flow stoppage elements have folds, it is inherent in Moll’s teachings that the flow stoppage elements have folds as claimed by the ’400 Patent.” Pet. 79. According to Petitioner, “a POSITA 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.’” *Id.* (citing Ex. 1005, 1:40–46, 1:58–61).

Alternatively, Petitioner asserts that “even if not inherent in Moll, it would have been obvious to a POSITA to form non-transverse diagonally oriented folds along the flow stoppage elements of Moll in view of the

teachings of Paniagua.” *Id.* at 80 (citing Ex. 1026 ¶ 204). Petitioner asserts that “Paniagua teaches the use of folds in a valve structure for ‘improved resistance to tearing at suture lines,’ and to aid in the patterned movement of the valve.” *Id.* (citing Ex. 1007 ¶ 24). According to Petitioner, “[b]oth of these benefits of a folded valve structure would have motivated a POSITA to modify Moll to include folds along the conical flow stoppage elements.” *Id.* (citing Ex. 1026 ¶ 204).

Patent Owner responds that “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.’”

Prelim. Resp. 71. Patent Owner responds further that “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.” *Id.* (citing Pet. 79–81).

According to Patent Owner, “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.” *Id.*

Patent Owner’s argument does not address Petitioner’s alternative basis for these grounds based on the combined teachings of Moll and Paniagua.

7. Conclusion Re Grounds 5–8

On the record before us, we determine that Petitioner has demonstrated a reasonable likelihood of prevailing in showing that claims 55–61, 63–67, and 69–72 are unpatentable over the combined teachings of Moll and Paniagua (Ground 5), claims 62 and 83–85 are unpatentable over

the combined teachings of Moll, Paniagua, and Pavcnik (Ground 6), claim 68 is unpatentable over the combined teachings of Moll, Paniagua, and Melsheimer (Ground 7), and claims 78–80 are unpatentable over the combined teachings of Moll, Paniagua, and Eberhardt (Ground 8).

III. CONCLUSION

After considering the evidence and arguments presented in the Petition and the Preliminary Response, we determine that Petitioner has demonstrated a reasonable likelihood of prevailing with respect to at least one of the challenged claims, and thus, we institute an *inter partes* review of all challenged claims on all presented challenges. 37 C.F.R. § 42.108(c); *SAS Inst. Inc. v. Iancu*, 138 S. Ct. 1348, 1359–60 (2018); *PGS Geophysical AS v. Iancu*, 891 F.3d 1354, 1360 (Fed. Cir. 2018) (interpreting the statute to require “a simple yes-or no institution choice respecting a petition, embracing all challenges included in the petition”).

At this stage of the proceeding, the Board has not made a final determination as to the patentability of any challenged claim or any underlying factual and legal issues.

IV. ORDER

In consideration of the foregoing, it is hereby

ORDERED that, pursuant to 35 U.S.C. § 314(a), an *inter partes* review of claims 55–72, 78–80, and 83–85 of U.S. Patent No. 9,737,400 B2 is instituted with respect to all the grounds set forth in the Petition; and

FURTHER ORDERED that, pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4(b), *inter partes* review of U.S. Patent No. 9,737,400 B2 shall commence on the entry date of this Order, and notice is hereby given of the institution of a trial.

IPR2022-00878
Patent 9,737,400 B2

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