

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*.

JUDGMENT
Determining Some Challenged Claims Unpatentable
35 U.S.C. § 318(a)

I. INTRODUCTION

We have authority to hear this *inter partes* review under 35 U.S.C. § 6. This Final Written Decision is issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73. For the reasons discussed below, we determine that Petitioner, Edwards Lifesciences Corp. and Edwards Lifesciences, LLC, has shown by a preponderance of the evidence that claims 55–72, 78–80, 83, and 84 of U.S. Patent No. 9,737,400 B2 (Ex. 1001, “the ’400 patent”) are unpatentable, but has not shown by a preponderance of the evidence that claim 85 is unpatentable. *See* 35 U.S.C. § 316(e) (2018); 37 C.F.R. § 42.1(d) (2019).

A. *Procedural History*

Petitioner requested *inter partes* review of claims 55–72, 78–80, and 83–85 of the ’400 patent (the “challenged claims”). Paper 2 (“Petition” or “Pet.”). Patent Owner, Colibri Heart Valve LLC, filed a Preliminary Response. Paper 6. Based upon the record at that time, we instituted *inter partes* review on all challenged claims on the grounds presented in the Petition. Paper 8 (“Institution Decision” or “Dec.”).

After institution, Patent Owner filed a Response (Paper 14, “PO Resp.”), Petitioner filed a Reply (Paper 17, “Pet. Reply”), and Patent Owner filed a Sur-reply (Paper 18, “PO Sur-reply”).

On July 17, 2023, an oral hearing was held. The transcript of the hearing (Paper 24) was entered in the record.

B. *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.

C. 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.

D. 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.

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

Figure 1A

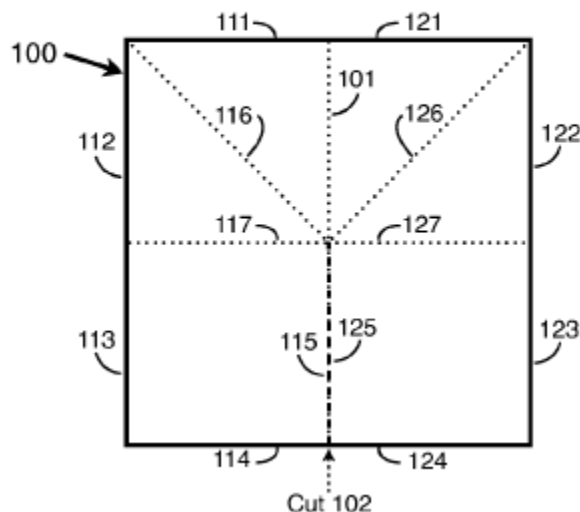


Figure 1A illustrates a square flat sheet 100 with dotted fold lines. Vertical fold line 101 divides the upper half of sheet 100 into two vertical halves. Vertical cut-line 102, shown as a dashed line, divides the lower half of sheet 100 into two vertical halves. Cutting at line 102 creates opposing 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 1B

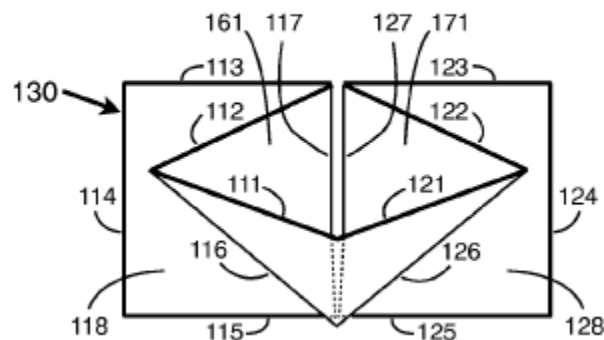


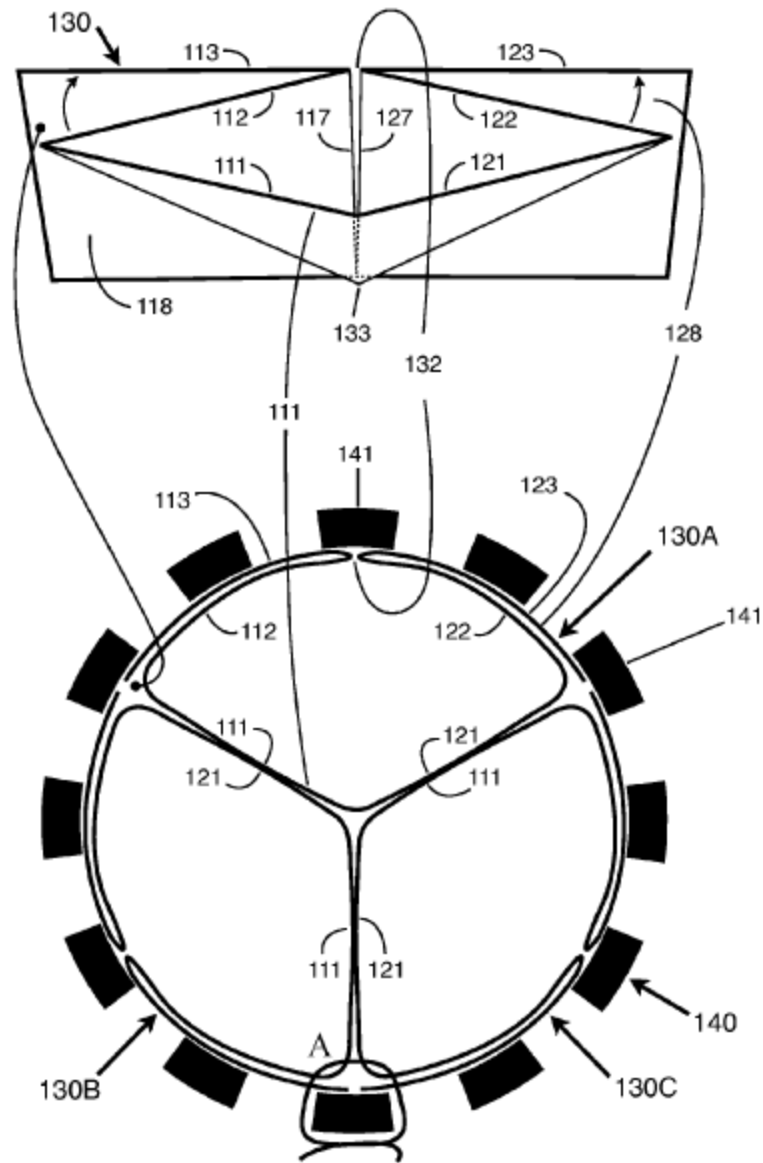
Figure 1B illustrates “substantially completed folded leaflet and cusp structure 130” depicting “the reoriented segments and sections of FIG. 1A after execution of the template foldings.” Ex. 1001, 14:21–25. Leaflet 130 includes left cuff wall section 118 and right cuff wall section 128; the cuff wall sections positioned next to the frame, and remain substantially immobile during operation of the valve. *Id.* at 12:25–31, 14:39–42. Left segment 111 and right segment 121 extend from the cuff walls to form “the

left and right halves of the distal free edge of the mobile operating portion of the leaflet.” *Id.* at 14:25–27. “Inward folding at 116 and 126 forms a second layer of membrane outward of the first, with segments 112 and 122 forming the distal free margin of the outer wall of the integrated cusp.” *Id.* at 14:27–30. “The left cusp wall section 161 is bounded by folds 116 and 117 and edge segment 112. The right cusp wall section 171 is bounded by folds 126 and 127 and edge segment 122.” *Id.* at 14:35–37.

Figure 1G depicts a leaflet structure residing within a lattice frame 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 the 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.

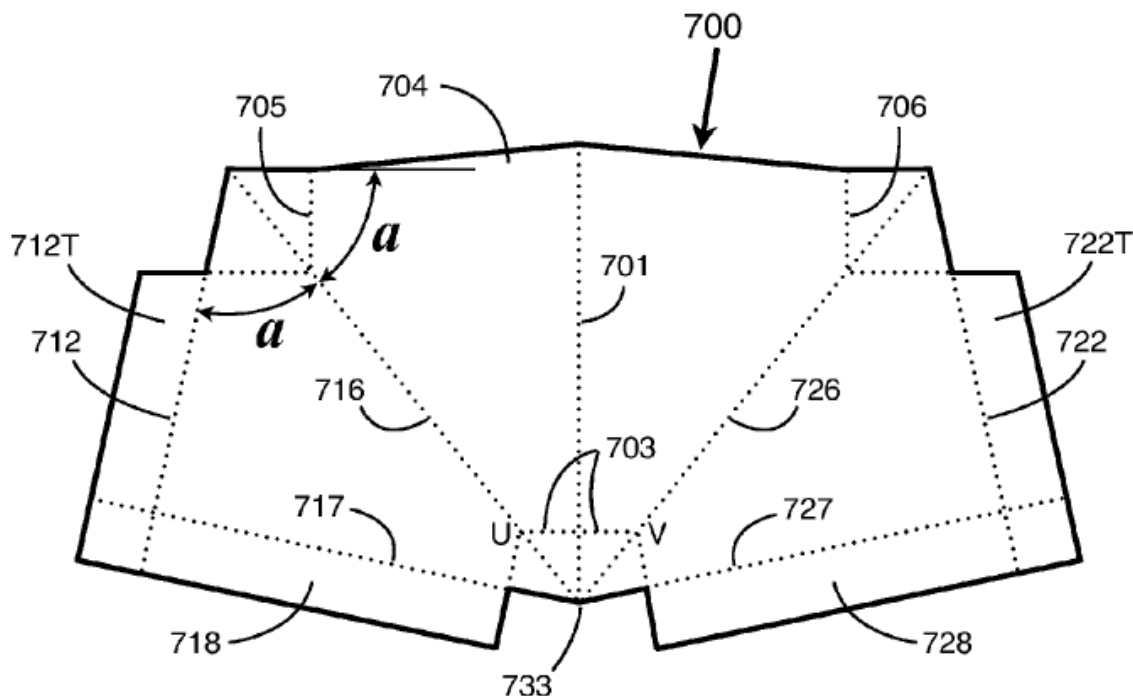


Figure 7A illustrates template 700 with principal folds 701, 716, 726, 717, 727, optional folds 712 and 722, and corner folds 705 and 706. *Id.* at 20:50–60. The folds converge at apex 733 to form an “overlapping two-layer triangular apex.” *Id.* at 20:63–66. “Folding along 717 and 727 acts to position 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.

E. Challenged 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.

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.

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

F. Asserted Grounds of Unpatentability

Petitioner asserts the following grounds of unpatentability:

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.

G. Supporting Declarations

Petitioner relies on the Declaration of Jonathan Rourke. Ex. 1026.
Patent Owner relies upon the declaration of Steven W. Opolski. Ex. 2001.
Based on the statements of qualifications and curricula vitae, we find
Petitioner’s declarant Jonathan Rourke qualified to provide technical
opinions from the perspective of a person of ordinary skill in the art in this
proceeding. See Ex. 1026 ¶¶ 5–17. Also based on the statements of

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”).

qualifications and curricula vitae, we find Patent Owner’s declarant Steven Opoloski qualified to provide technical opinions from the perspective of a person of ordinary skill in the art in this proceeding. See Ex. 2001 ¶¶ 7–20.

II. ANALYSIS

A. *Principles of Law*

“A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros., Inc. v. Union Oil Co. of Cal.*, 814 F.2d 628, 631 (Fed. Cir. 1987); *see also Finisar Corp. v. DirecTV Group, Inc.*, 523 F.3d 1323, 1334 (Fed. Cir. 2008) (to anticipate a patent claim under 35 U.S.C. § 102, “a single prior art reference must expressly or inherently disclose each claim limitation”). Moreover, “[b]ecause the hallmark of anticipation is prior invention, the prior art reference—in order to anticipate under 35 U.S.C. § 102—must not only disclose all elements of the claim within the four corners of the document, but must also disclose those elements ‘arranged as in the claim.’” *Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359, 1369 (Fed. Cir. 2008) (quoting *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 1548 (Fed. Cir. 1983)). Whether a reference anticipates is assessed from the perspective of one of ordinary skill in the art. *See Dayco Prods., Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1368–69 (Fed. Cir. 2003) (“‘[T]he dispositive question regarding anticipation [i]s whether *one skilled in the art* would reasonably understand or infer from the [prior art reference’s] teaching’ that every claim element was disclosed in that single reference.” (second and third alterations in original) (quoting *In re Baxter Travenol Labs.*, 952 F.2d 388, 390 (Fed. Cir. 1991))).

A patent claim is unpatentable under 35 U.S.C. § 103(a) if the differences between the claimed subject matter and the prior art are such that

the subject matter, as a whole, would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of skill in the art; and (4) any objective evidence of obviousness or non-obviousness.⁸ *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

B. Level of Ordinary Skill

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

Petitioner contends 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 Petitioner[’s] definition of a person of ordinary skill in the art.” PO Resp. 2.

⁸ The parties have not directed our attention to any objective evidence of obviousness or non-obviousness.

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).

C. Claim Construction

Pursuant to 37 C.F.R. § 42.100(b), we apply the claim construction standard as set forth in *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (en banc). Under *Phillips*, claim terms are generally given their ordinary and customary meaning as would be understood by one with ordinary skill in the art in the context of the specification, the prosecution history, other claims, and even extrinsic evidence including expert and inventor testimony, dictionaries, and learned treatises, although extrinsic evidence is less significant than the intrinsic record. *Phillips*, 415 F.3d at 1312–17. Usually, the specification is dispositive, and it is the single best guide to the meaning of a disputed term. *Id.* at 1315. Only terms that are in controversy need to be construed, and then only to the extent necessary to resolve the controversy. *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (in the context of an *inter partes* review, applying *Vivid Technologies, Inc. v. American Science & Engineering, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999)).

Petitioner proposes claim construction for the claim terms “folds” and “biocompatible membrane [that] does not comprise a treated tissue.” Pet. 29–31. In its Reply,⁹ Petitioner proposes claim construction for the claim term “attached.” Pet. Reply. 1–6. Petitioner also discusses the claim terms “cusp,” “cuff wall,” “cusp wall,” “frame,” “mobile leaflet layer,”

⁹ Upon our invitation. Dec. 13.

“mobile leaflet,” “proximal,” and “substantially conical” in the Petition. Pet. 26–28.

Patent Owner proposes claim construction for the claim term “attached.”¹⁰ PO Resp. 13–25. Patent Owner also discusses the claim terms “substantially conical,” “folds,” “biocompatible membrane [that] does not comprise a treated tissue,” “cusp,” “cuff wall,” “frame,” “mobile leaflet layer” or “mobile leaflet,” “proximal,” “non-transverse”, and “plurality of . . . leaflets.” *Id.* at 26–28. In its Sur-reply, Patent Owner reiterates its position regarding claim construction of the claim term “attached.” PO Sur-reply 1–13.

1. Terms Defined by the '400 Patent

Both parties discuss claim terms (“substantially conical,” “folds,” “biocompatible membrane [that] does not comprise a treated tissue,” “cusp,” “cuff wall,” “frame,” “mobile leaflet layer” or “mobile leaflet,” “proximal,” “non-transverse”, and “plurality of . . . leaflets”) which are defined by the ’400 patent’s explicit definition of these terms or its explicit definition of a related term (e.g., definition of “folding” also defines claim term “folds”). Pet. 26–28; PO Resp. 26–28. Both parties assert that the definitions in the ’400 patent define these claim terms. *Id.* We agree. For the claim terms defined by the ’400 patent, Patent Owner has acted as its own lexicographer by setting out the definitions of these claims terms in the specification of the ’400 patent. *Thorner v. Sony Comput. Ent. Am., LLC*, 669 F.3d 1362, 1365

¹⁰ We note that throughout its claim construction arguments, Patent Owner refers to the claim construction of the word “attach;” however, the claim term at issue is “attached.” We understand Patent Owner to be referring to this claim term and treat Patent Owner’s arguments as if they refer to the claim term “attached.”

(Fed. Cir. 2012). To the extent that these terms are in controversy as discussed in Sections D–F below, we construe these terms in accordance with their definitions set forth in the ’400 patent.

2. “Attached”

In our Institution Decision, we invited the parties to brief the claim construction of the claim term “attached.” Dec. 13. Petitioner asserts that “attached” should be given its plain and ordinary meaning. Pet. Reply 1–9. According to Petitioner, the plain and ordinary meaning of “attached” is “fastened, secured, or joined, directly or indirectly.” *Id.* at 1. Patent Owner disagrees. According to Patent Owner, “attached” should be construed to mean “to fasten or join two or more components at the same location.” PO Resp. 13; *see also* PO Sur-reply 1. In its Response, Patent Owner makes five arguments in support of its construction. We consider each of these arguments and Petitioner’s response thereto, in turn.

a) Allegation That Construing “Attached” as “to Fasten or Join Two or More Components at the Same Location” is Consistent with the Specification of the ’400 Patent

Patent Owner asserts that “[a]lthough the patent does not explicitly define ‘attach[ed],’ the patent uses the term with such frequency that a [person of skill in the art] can determine its meaning within the context of the patent.” PO Resp. 13. As an example, Patent Owner quotes the following passage of the ’400 patent, which describes 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 cusp 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 cusp 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 cusp wall sections 761A and 771B, respectively.

Id. at 13–15 (quoting Ex. 1001, 26:42–67).

Patent Owner contends that a person of ordinary skill in the art “reading the ’400 patent would view the patent’s definition of ‘attach[ed]’ as consistent with the definitions found in dictionaries, such as ‘to fasten, secure, or join,’” but “would realize that the patent uses ‘attach[ed]’ in [a] more specific manner than as used in common parlance.” PO Resp. 15 (citing Ex. 2001 ¶¶ 95–97); *see also* PO Sur-reply 10–12. Patent Owner contends further that a person of ordinary skill in the art reading the section quoted above would realize that the described components cannot be joined or attached in any manner, but must be attached at the same location. *Id.* at 15–16.

Petitioner replies that Patent Owner’s construction “required *direct* attachment”¹¹ and that Patent Owner “bases its construction on Figure 9D of the ’400 [Patent], which [its] expert admits does not provide support for PO’s construction.” Pet. Reply 1.

We agree with Petitioner that a person of skill in the art reading this description of Figure 9D would not conclude that the claim term “attached” requires attachment of the described components “at the same location.” Rather, we understand this portion of the ’400 patent to describe commissure tabs attached to the outer surface of the cusp and leaflet structure and to cusp wall sections. Ex. 1001, 26:59–37. Although, it is not shown in Figure 9D, we understand that in this embodiment the mobile leaflet constitutes the layer of the cusp and leaflet structure that does not abut the frame. *See id.*, Fig. 9E. The mobile leaflet is attached to the frame via the commissure tabs, and thus, is not necessarily “attached at the same location.” *See id.*, Figs. 9D–9E, 26:59–67.

¹¹ In response to Petitioner’s Reply, Patent Owner contends that it “*never* defined ‘attached’ as ‘requir[ing] *direct* attachment’ as Petitioners argue” contending that [t]his is evident from the definition itself—“to fasten or join **two or more components** at the same location”—which necessitates joining at least two of the components indirectly.” PO Sur-reply 1. Patent Owner replies further that it “explained that both direct and indirect attachment are encompassed by its definition: ‘For example, **as with “attach,”** “operably associated” may describe **three components, A, B, and C, with all three components joined at the same location.**’” *Id.* (citing PO Resp. 24–25) (footnote omitted). Thus, according to Patent Owner, “Petitioners’ Reply—which focuses on why ‘attached’ must include indirect attachment—is irrelevant to Colibri’s definition.” *Id.* We agree with both parties that the proper construction of “attached” includes both direct and indirect attachments and do not discuss this issue further.

*b) Allegation That the Definition of “Attached”
Applied by Petitioner’s Expert is Inconsistent with the
Specification of the ’400 Patent*

Patent Owner contends that the definition of “attached” applied by Petitioner’s expert is inconsistent with the specification of the ’400 patent. PO Resp. 17–21. As an example, Patent Owner contends that under Petitioner’s expert’s definition the portion of the description of Figure 9D pertaining to the commissure tabs is redundant. PO Resp. 18 (citing Ex. 2001 ¶ 103). Patent Owner contends further that

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[ed],” 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.

Id. (citing Ex. 2001 ¶ 104).

Petitioner replies that the ’400 patent “repeatedly uses ‘attached’ more generically than the ‘specific locations at which two or more structures are attached to each other.’” Pet. Reply 5 (quoting PO Resp. 16; citing Ex. 1001, 5:58–59, 6:16–20) (further citation omitted). We agree with Petitioner. Even the description of Figure 9D that Patent Owner relies upon in support of its claim construction uses “attached” more generically in that it describes both areas of attachment as well as individual attachments.

Further, we do not understand Petitioner’s expert’s claim construction to preclude additional attachments once two structures are described as being “attached.” To the extent that Patent Owner’s argument rests on the premise that the ’400 patent precludes a claim interpretation of “attached” that includes indirect joining or fastening of components, we note that Patent

Owner asserts that its claim construction encompasses indirect attachments.
See PO Sur-reply 1.

c) Allegation That Construing “Attached” 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

Patent Owner contends that a person of ordinary skill “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’” and that “Petitioners’ broad definition of ‘attach[ed]’ 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.” PO Resp. 21–22 (citing Ex. 2001 ¶ 107); *see also* PO Sur-reply 10. Patent Owner contends that its “location-specific definition of ‘attach[ed]’ captures these key features of the ’400 patent’s inventions.” *Id.* at 22 (citing Ex. 2001 ¶ 108).

Petitioner replies that “the Challenged Claims are not limited to specific folding patterns, nor do they say anything about *how* to attach valve components to the frame—they simply are ‘attached.’” Pet. Reply 8 (citing Pet. 22–23). Petitioner asserts further that Patent Owner’s “construction improperly imports limitations from specific embodiments into the claims.” *Id.* (citing *Personalized Media Commc’ns, LLC v. Apple Inc.*, 952 F.3d 1336, 1343 (Fed. Cir. 2020)).

We agree with Petitioner that the challenged claims are not limited to specific folding patterns. We also agree with Petitioner that the claims are not limited to the “key teachings” of the ’400 patent. The challenged claims do not recite “secure and atraumatic attachments” and we decline to construe

the claim language “attached” in a manner that precludes other types of attachments. *See* Patent Owner’s Expert Declaration, Ex. 1034, 61:9–11 (“The ’400 patent does not define attach. They define operably associated. But attach is not defined.”)

d) Allegation That Petitioner’s Expert’s Definition of “Attached” Impermissibly Renders Claim Terms Meaningless

Patent Owner contends that “applying Petitioners’ expert’s definition of ‘attach[ed]’ impermissibly renders claim terms meaningless.” PO Resp. 22 (citing *Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc.*, 520 F.3d 1358, 1362 (Fed. Cir. 2008)). As an example, Patent Owner contends that the recitation in claim 83 requiring “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” is rendered meaningless under Petitioner’s claim construction, because claim 55 (from which claim 83 depends) already requires “cusps attached to the lattice frame.” *Id.* at 22–23 (quoting Ex. 1001, 33:9–10, 34:59–62); *see also* PO Sur-reply 4–7.

Petitioner replies that “it is not ‘meaningless’ for Claim 83 to clarify that after being created, this ‘tip’ is ‘attached’ to the frame.” Pet. Reply 5, n.5. We agree with Petitioner. As discussed in Section II.C.2.b above, we do not understand the ordinary and customary meaning of “attached” to preclude a structure from being attached to another structure at more than one attachment point.

e) Allegation That Petitioner's Expert's Definition of "Attached" is Impermissibly Synonymous with a Different Term Defined in the '400 Patent

Patent Owner contends that “the definition of ‘attach[ed]’ applied by [Petitioner’s] expert matches a different term that the ’400 patent defines separately from—and more broadly than—its use of the term “attach[ed].” PO Resp. 24. Noting that “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,’” Patent Owner contends that “under the definition of ‘attach[ed]’ applied by Petitioners’ expert, ‘attach[ed]’ and ‘operably associated’ are one and the same.” *Id.* at 24–25 (citing Ex. 2001 ¶¶ 114–115); *see also* PO Sur-reply 8–9. Thus, according to Patent Owner, “the definition of ‘attach[ed]’ applied by Petitioners’ expert is incorrect.” PO Resp. 25 (citing *Horizon Pharma, Inc. v. Dr. Reddy’s Labs. Inc.*, 839 F. App’x 500, 504 (Fed. Cir. 2021)).

Petitioner replies that Patent Owner “offers no legal support for the proposition that an inventor acting as their own lexicographer for a particular term (*i.e.*, ‘operably associated’) alters the plain and ordinary meaning of other terms (e.g., ‘attached’) that are not specially defined.” Pet. Reply 6. Petitioner replies further that Patent Owner “ignores that ‘operably associated’ requires linking together ‘*in operable fashion*’ . . . an operability requirement beyond merely being ‘fastened, secured, or joined.’ Two components may be attached but not operably associated (e.g., two attached static components).” *Id.* (citing Ex. 1001, 7:9–15).

We agree with Petitioner that Patent Owner provides no legal support for its proposition that an explicit definition of a term in a patent precludes a different undefined term from having a similar meaning. We further agree with Petitioner that its “construction of ‘attached’ includes directly and indirectly attached elements but does not have operability requirements and thus, on its face, is of different scope than ‘operably associated’” as defined by the ’400 patent.

*f) Conclusion Re Claim Construction For
“Attached”*

We begin our analysis by reiterating that under the *Phillips* standard, claim terms are generally given their ordinary and customary meaning as would be understood by one with ordinary skill in the art in the context of the specification, the prosecution history, other claims, and even extrinsic evidence including expert and inventor testimony, dictionaries, and learned treatises, although extrinsic evidence is less significant than the intrinsic record. *Phillips*, 415 F.3d at 1312–17. When a patent owner wishes to employ a definition that is different from the ordinary and customary meaning of a claim term, it may do so by acting as its own lexicographer setting out the definition of that claim term in the specification of its patent. *Thorner*, 669 F.3d at 1365.

As discussed in Section II.C.1 above, Patent Owner has acted as its own lexicographer and defined numerous claim terms in the ’400 patent. *See Ex. 1001*, 11:41–13:18. Thus, it is readily apparent that when Patent Owner intended to employ a definition of a claim term that differed from the the ordinary and customary meaning of that claim term, Patent Owner provided such a definition. A person of ordinary skill in the art would infer

from this practice that undefined claim terms should be construed in accordance with their ordinary and customary meaning.

Having considered the full record before us including the evidence, testimony, and argument in support of the parties' positions, we agree with Petitioner that the claim term "attached" should be construed in accordance with its ordinary and customary meaning, which the parties agree is "fastened, secured, or joined, directly or indirectly."¹² Pet. Reply 1; PO Resp. 15. We do not find that the context of the '400 patent further narrows this term such that a person of ordinary skill in the art would have understood "attached" to require attachment "at the same location." Accordingly, we apply the ordinary and customary meaning of the claim term "attached" in considering the challenges set forth in the Petition discussed below.

D. Grounds 1–3: Anticipation of Claims 55, 56, 58–61, 63, 65, and 66 by Melsheimer, Obviousness of Claims 57, 64, 78, and 79 Based on the Combined Teachings of Melsheimer and Eberhardt, Obviousness of Claims 62, 83, and 84 Based on the Combined Teachings of Melsheimer and Pavcnik

Petitioner asserts that claims 55, 56, 58–61, 63, 65, and 66 are anticipated by Melsheimer. Pet. 31–47. Petitioner asserts further that claims 57, 64, 78, and 79 are unpatentable over the combined teachings of Melsheimer and Eberhardt and that claims 62, 83, and 84 are unpatentable over the combined teachings of Melsheimer and Pavcnik. *Id.* at 48–57. Patent Owner addresses all three of these grounds together. PO Resp. 29–41. We begin our analysis of this challenge with overviews of Melsheimer, Eberhardt, and Pavcnik.

¹² See n.10.

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. Figure 1B, reproduced below, shows a perspective view of an embodiment of Melsheimer’s valve in an open position. *See id.* ¶¶ 15–16.

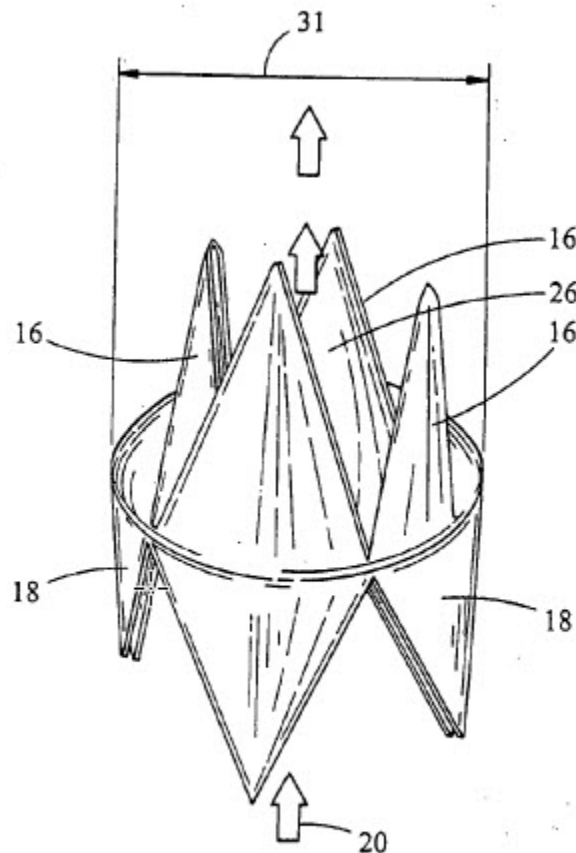


Fig. 1B

The embodiment of Figure 1B includes four leaflet 16 and receptacle 18 pairs. *Id.* Fig. 1B. Each pair includes a cone-shaped receptacle 18 with a triangular-shaped leaflet 16 extending from half of the upper edge of the cone-shaped receptacle 18. *Id.* In a flattened condition, the perimeter of each flexible member is rhombus- or diamond-shaped, with the long sides of

the rhombus extending vertically. *Id.* As shown in Figure 1B, the four pairs are arranged within a blood vessel, such that the upper edges of receptacles 18 that are not connected to leaflets 16 form a circular perimeter for attachment at attachment area 60 (not labeled) to the blood vessel. *Id.* Fig. 1B, ¶ 46. Each leaflet 16 and receptacle 18 pair is either integrally connected, formed by unitary construction from the same material, or leaflet 16 is formed separately from the receptacle 18 and operably connected after formation at a connection area 44 (not shown in Figure 1B). *Id.* ¶ 42.

In Figure 1B valve device 10 is shown in a vessel. Melsheimer discloses that attachment area 60 can include support frame 150 (i.e., lattice frame) to further support the valve device 10. Ex. 1003 ¶ 48. Melsheimer indicates that “[a]ny suitable support frame can be used as the support frame 150 in the valve device 10. The specific support frame chosen will depend on several considerations, including the size and configuration of the vessel at the implantation site and the size and nature of the valve device 10.” *Id.* ¶ 49.

2. *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.

3. *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.

4. Discussion

We have reviewed the full record before us including the evidence, testimony, and arguments in support of the parties' positions and determine that for each of the uncontested limitations of the challenged claims Petitioner has shown by a preponderance of the evidence that Melsheimer, either alone or in combination with Eberhardt or Pavcnik, discloses or suggests the limitations of the claims at issue. We focus our discussion on the three arguments raised by Patent Owner.

a) Alleged Failure of Melsheimer to Disclose or Suggest "Leaflets Attached to the Lattice Frame"

Patent Owner's first argument only pertains to claims 60–66, 79, and 84. PO Resp. 29. Claim 60 requires "a plurality of non-rectangular polygonal mobile leaflets attached to the lattice frame." Ex. 1001, 33:29–30. 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 "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." PO Resp. 29. According to Patent Owner, "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.'" *Id.* at 31 (citing Ex. 1001, 33:9–10; Pet. 42). Patent Owner asserts that "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." *Id.* (citing Pet. 33–34).

Patent Owner contends further that “Petitioners’ analysis of the ‘cusps attached to the lattice frame’ element also does not help Petitioners’ case.” PO Resp. 32. Noting that Petitioner relies on Melsheimer’s Figure 6 as allegedly showing “a ‘valve (1) and attachment area (60),” Patent Owner asserts that “Melsheimer actually *distinguishes* the attachment area from the leaflets, and so does nothing to show that Melsheimer’s *leaflets* are attached to the frame.” *Id.* (citing Ex. 1005 ¶ 72).

Petitioner replies that a person of ordinary skill in the art “reading the ’400 [patent] would understand attachment of the cusp includes ‘direct’ attachment of the mobile leaflet, the cusp wall, or both.” Pet. Reply 28 (citing *id.* at 25–28). Petitioner asserts that “Melsheimer’s frame is attached at portions of the valve structure where the leaflet and outer wall meet” and that “attachment at this portion of Melsheimer’s cusp is ‘direct’ attachment of the frame to both the mobile leaflet and cusp wall.” *Id.* at 29.

Patent Owner responds that “attachment to Melsheimer’s alleged ‘cusp,’ even at the point at which the leaflet and outer wall meet, is not evidence that attachment is to the leaflet (which needs to remain free enough to remain a *mobile* leaflet), rather than to the outer wall.” PO Sur-reply 17. Patent Owner responds further that “Melsheimer does not describe its ‘attachment area’ as attaching the alleged ‘cusp’ to the frame, but instead is ‘for attachment to the vessel wall.’” *Id.* (citing Ex. 1003 ¶ 46).

We agree with Petitioner that Melsheimer discloses mobile leaflets attached to the lattice frame as required by claim 60.¹³ Pet. 42–45.

¹³ We note that Petitioner addresses the mobile leaflets set forth in independent claim 60 in the Petition and does not simply rely on its discussion of claim 55 for the limitations pertaining to the mobile leaflets. Pet. 42–45.

Applying the claim construction of “attached” we adopted in Section II.C.2.f above (i.e., “fastened, secured, or joined, directly or indirectly”), we determine that Melsheimer’s leaflets 16 are attached to its frame directly at the bottom vertices of triangular-shaped leaflets 16 (i.e., “where the leaflet and outer wall meet”). Pet. 29. Leaflets 16 are also indirectly attached to the frame by virtue of being joined to receptacles 18 which are attached to the frame at attachment area 60.

In its Sur-Reply, Patent Owner alleges for the first time that Melsheimer doesn’t disclose that its leaflet 16 and receptacle 18 pairs (i.e., its “cusps”) are attached to a frame. PO Sur-reply 17. As discussed in Section II.D.1 above, Melsheimer discloses the use of a frame to further support valve device 10. Ex. 1003 ¶¶ 48. Melsheimer does not specify which embodiments include the frame. *Id.* However, it appears that this teaching is applicable to all of its embodiments. *See id.* ¶¶ 48–53. Accordingly, we understand Melsheimer to explicitly disclose attachment of its “cusps” to a frame. *Id.*

*b) Alleged Failure to Comply With 37 C.F.R.
§ 42.104(b)(3)*

Patent Owner’s second argument only pertains to claims 60–66, 79, and 84. PO Resp. 32. Patent Owner asserts that “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.” PO Resp. 33 (citing *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)).

The Petitioner, however, does explain how Melsheimer's leaflets are attached to the frame as discussed above. Pet. 42–45. Thus, the Petition complies with 37 C.F.R. § 42.104(b)(3).

c) Allegation that Petitioner Fails to Allege That Melsheimer's Cusps, as Opposed to its Receptables Are Substantially Conical

Patent Owner's third argument only pertains to claims 55–59, 78, and 83. PO Resp. 34. Independent claim 55 requires “a plurality of substantially conical shaped cusps.” Ex. 1001, 33:9. 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.

Ex. 1001, 12:47–54. The '400 patent also states that “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. 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’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.” PO Resp. 34 (citing Ex. 2001 ¶¶ 150–157). Rather, according to Patent Owner, “Melsheimer’s receptacles form only a **portion** of a cusp and are therefore incapable of rendering Melsheimer’s **cusps** into a ‘substantially conical shape.’” *Id.* (citing Ex. 2001 ¶ 158). Patent Owner contends further that the Melsheimer’s disclosure of “a conically shaped pocket” does not meet the requirement for “substantially conical shaped cusps” “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 [person of ordinary skill]

would understand render Melsheimer's *cusp* not 'conically shaped' like its receptacle." *Id.* at 35–36 (citing Pet. 34; Ex. 2002, 96:14–20).

Petitioner replies that Patent Owner's arguments are not based on the definition of "substantially conical" set forth in the '400 patent and rely on "its expert's *ipse dixit*" redefinition of "'substantially conical' as 'not . . . a *perfect* cone.'" Pet. Reply 30 (citing PO Resp. 39; Ex. 1034, 58:15–59:10).

Patent Owner responds by reiterating its arguments set forth in its Response. PO Sur-reply 14–16. Patent Owner further contends that it did not redefine the claim term "substantially conical" in its Response. *Id.* at 16.

Having reviewed the full record before us including the evidence, testimony, and arguments in support of both parties' positions, we agree with Petitioner that Melsheimer's cusps are substantially conical as required by independent claim 55.

The definition of "substantially conical" set forth in the '400 patent does not require that every part of the structure in question resemble a cone. Ex. 1001, 12:47–54. Rather, it requires a structure that "resembles a cone or portion thereof at some point in the practical use of the structure" and a "cross-sectional perimeter or *area of the structure* in the operationally closed position that decreases moving from the level of the leaflet apposition to the proximal end of the valve." *Id.* (emphasis added). Melsheimer discloses receptacles 18 that are cone-shaped. Ex. 1003, Fig. 4A. Although, Melsheimer's leaflet 16 and receptacle 18 pairs are not entirely cone-shaped, they do still resemble a cone. Further, Melsheimer's receptacles 18 have the required cross-sectional perimeter. *See id.* Accordingly, we determine that these pairs (i.e., Melsheimer's cusps) are "substantially conical" in accordance with the definition set forth in the '400 patent.

5. *Conclusion For Grounds 1–3*

Having considered the full record before us including the evidence, testimony, and arguments of both parties, we determine that Petitioner shows by a preponderance of the evidence that claims 55, 56, 58, 59–61, 63, 65, and 66 are anticipated by Melsheimer (Ground 1). We further determine that claims 57, 64, 78, and 79 are unpatentable over Melsheimer alone or in combination with Eberhardt (Ground 2) and that claims 62, 83, and 84 are unpatentable over Melsheimer alone or in combination with Pavcnik (Ground 3).

E. Ground 4: Obviousness of Claims 60–72, 79 and 80 Based on the Combined Teachings of Braido and Eberhardt

Petitioner asserts that claims 60–72, 79, and 80 are unpatentable over Braido and Eberhardt. Pet. 57–75. We begin our analysis of this challenge with an overview of Braido.

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.

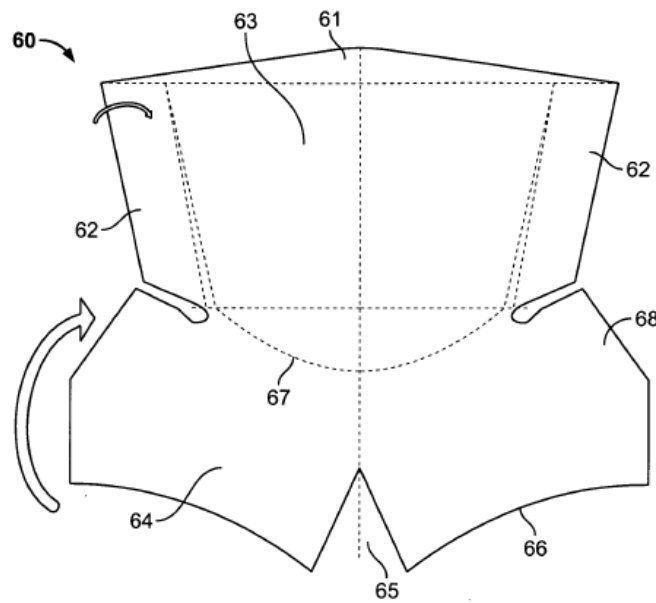


FIG. 10

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.

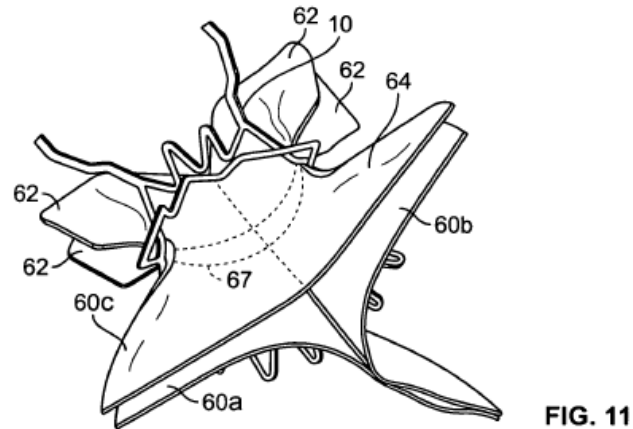


Figure 11 illustrates stent 10 surrounding three single leaflets 60a–c, which are attached to the stent. Ex. 1004 ¶ 121. The leaflets include side flaps 62 and bottom flaps 62, which protrude from the interior of the stent and are then attached to the stent. *See id.*

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

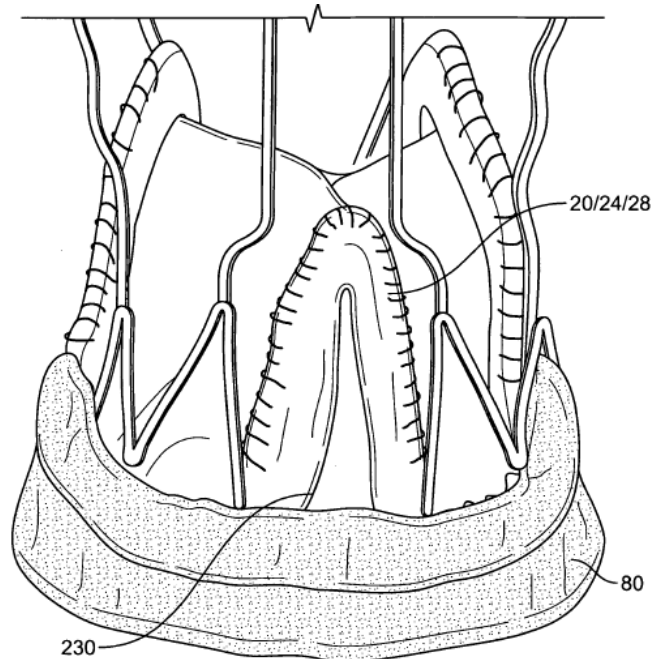


Figure 43 illustrates a stent with patch 230 sutured through eyelets 22 and around the base of stent 10. *Id.* ¶ 154. The bottom of stent 10 is covered by a double layer of cuff material 80 “to aid in better sealing and tissue in-growth when pushed against native aortic root tissue.” *Id.*

2. Discussion

We have reviewed the full record before us including the evidence, testimony, and arguments in support of the parties’ positions and determine that for each of the uncontested limitations of the challenged claims Petitioner has shown by a preponderance of the evidence that the combined teachings of Braido and Eberhardt disclose or suggest the limitation. We focus our discussion on the two arguments raised by Patent Owner.

a) Allegation that Braido in View of Eberhardt Fails to Disclose or Suggest Mobile Leaflets Attached to the Lattice Frame

Patent Owner’s first argument pertains only to claims 60–66, 79, and 84. PO Resp. 41.¹⁴ 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 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.’” PO Resp. 42 (citing Pet. 57–65); *see also* PO Sur-reply 18. 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 that Braido has *integrated cusps*—not mobile

¹⁴ We note that the Header VII.B.1 also refers to claims 67–72, however, these claims do not recite mobile leaflets. PO Resp. 41.

leaflets—attached to the lattice frame.” *Id.* at 42–43 (citing Pet. 60–61); *see also* PO Sur-reply 18.

Petitioner replies that Patent Owner “ignores statements in the Petition that the Braido leaflet is directly attached to the frame.” Pet. Reply 26. According to Petitioner, “Braido teaches: ‘Reference line 560a in FIG. 74a shows the lower portion of the leaflet attached straight across from the bottom eyelet 22 of one commissure post 20 to the next commissure post 20.’” *Id.* at 26–27 (quoting Ex. 1004 ¶ 192; citing Pet. 60–61) (emphasis omitted).

We agree with Petitioner that it has asserted that Braido’s leaflets are attached to the frame. Although the Petition does not explicitly state that Braido’s leaflets are attached to the frame, it is clear from the context and annotated drawings on pages 60–61 of the Petition that it asserts that the lower edges of Braido’s leaflets are attached directly to the frame. Pet. 60–61. Specifically, the Petition discusses embodiments wherein the leaflets have a horizontal straight edge for their lower edge and refers to attachment of the cusp along this edge. *Id.* It is clear from this discussion that the Petition asserts that the horizontal straight lower edge of the leaflets is attached to the frame.

Further, we agree with Petitioner that Braido’s leaflets are attached to the frame. For example, in paragraph 183 in reference to Braido’s Figure 74b, Braido states “a typical leaflet 60 is attached part of the way up the posts 20, and the belly section of the leaflet gradually contours (curves) toward the stent base below the posts.” Ex. 1004 ¶ 183 (citing *id.* at Figs. 76a–b). As another example, in paragraph 184 in reference to Braido’s Figure 74c, Braido states “a typical leaflet 60 in this case is attached near the bottom of the posts 20, and the leaflet belly section gradually contours

toward the stent base, at which point it can be attached to the base of the stent, cuff 80, and features like those shown in FIGS. 66-68.” *Id.* ¶ 184.

b) Alleged Failure of Braid to Disclose or Suggest At Least Two Folded Biocompatible Membrane Sheets Attached to the Lattice Frame

This argument pertains only to claims 67–72 and 80. PO Resp. 43.¹⁵ 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.’” PO Resp. 43 (citing Pet. 70).

Patent Owner then refers to an alleged prior argument regarding claim 60 pertaining to “a misleading citation to Braid.” *Id.* We do not discern where such an argument is made in reference to claim 60, however, we consider Patent Owner’s argument. According to Patent Owner, Braid “affirmatively states that Braid’s membrane is *not* attached to the frame, and is instead attached to the valve’s cuff.” *Id.* at 43–44 (citing Ex. 1004 ¶ 182); *see also* PO Sur-reply 18–19. Thus, according to Patent Owner, “because Petitioners have provided no evidence that Braid 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.” *Id.* at 44 (citing Ex. 2001 ¶ 183). As best understood, Patent Owner is arguing that because Braid’s leaflets

¹⁵ Although, claim 85 is listed in Header VII.B.2, claim 85 is not contested in this challenge.

are not attached to the lattice frame, it does not disclose two folded biocompatible membrane sheets as claimed.

Paragraph 182 of Braidó states:

FIGS. 74a-c show several illustrative variations on what is shown in FIG. 65. For example, in 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. (Apart from reference line 560a, FIG. 74a omits leaflets 60 and does not attempt to show the rear of the structure. Reference line 560a is shown primarily for purposes of explanation. This line does not itself depict structure, but rather is primarily just for geometric reference. The same is true for reference lines 560b and 560c in later FIGS.) FIG. 74a may show a balloon-expandable valve with a fabric cuff 80 and a porcine tissue buffer layer (hidden on the inside diameter ('ID') of fabric 80) attached to about 75% of the height of the annulus portion 40 of the stent (i.e., the lower 75% of the annulus portion 40 height) [] (Stent portion 40 may be called the annulus portion because it is typically implanted in or near the annulus of the patient's native heart valve annulus.) Reference line 560a in FIG. 74a shows the lower portion of the leaflet attached straight across from the bottom eyelet 22 of one commissure post 20 to the next commissure post 20. See also FIG. 75, which shows an example of such a leaflet 60 with reference line 560a superimposed on it.

Ex. 1004 ¶ 182. Patent Owner does not explain how this paragraph precludes attachment of Braidó's two folded biocompatible membrane sheets to the frame. It is not readily apparent how Braidó's disclosure that one representative leaflet is attached to cuff 80 precludes that leaflet from also being attached to the frame. *Id.* Further this paragraph explicitly states that "FIG. 74a shows the lower portion of the leaflet *attached* straight across from the bottom eyelet 22 of one commissure post 20 to the next commissure post 20." *Id.* As Braidó's commissure posts 20 are part of its

lattice frame and Braido's leaflets constitute two folded biocompatible membrane sheets, this paragraph supports Petitioner's position. *See* Ex. 1004 ¶¶ 109, 120–121.

In its Sur-reply, Patent Owner contends that "Petitioners improperly rely on EX1004, ¶¶ [0122] and [0184] for the first time on reply." PO Sur-reply 19. Patent Owner further contends that "Petitioners' arguments on Reply cite to multiple different embodiments within Braido without providing the required motivation to combine these separate embodiments." *Id.* at 20. Petitioner, however, identifies paragraphs 122 and 184 as supporting its position in response to Patent Owner's arguments. Further, to the extent that Petitioner relies on different embodiments (Figs. 3a–b) in its Reply to show that Braido discloses contested limitations, we see no need for Petitioner to provide articulated reasoning (i.e., motivation) to combine these embodiments, because the embodiments in Braido are not disclosed as separate patently distinct embodiments. That is, the embodiments are not being combined together, but rather are being individually relied upon as providing evidentiary support showing attachment.

3. *Conclusion Re Ground 4*

Having considered the full record before us including the evidence, testimony, and arguments of both parties, we determine that Petitioner has shown by a preponderance of the evidence that claims 60–72, 79, and 80 are unpatentable over the combined teachings of Braido and Eberhardt.

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

Petitioner asserts that claims 55–61, 63–67, and 69–72 are unpatentable over the combined teachings of Moll and Paniagua. Pet. 75–

91. Petitioner also asserts that claims 62 and 83–85 are unpatentable over the combined teachings of Moll, Paniagua, and Pavcnik, that claim 68 is unpatentable over the combined teachings of Moll, Paniagua, and Melsheimer, and that claims 78–80 are unpatentable over the combined teachings of Moll, Paniagua, and Eberhardt. *Id.* at 91–98. Patent Owner addresses all three of these grounds together. PO Resp. 44–75. We begin our analysis of this challenge with overviews of Moll and Paniagua.

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, 2:19–23.

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

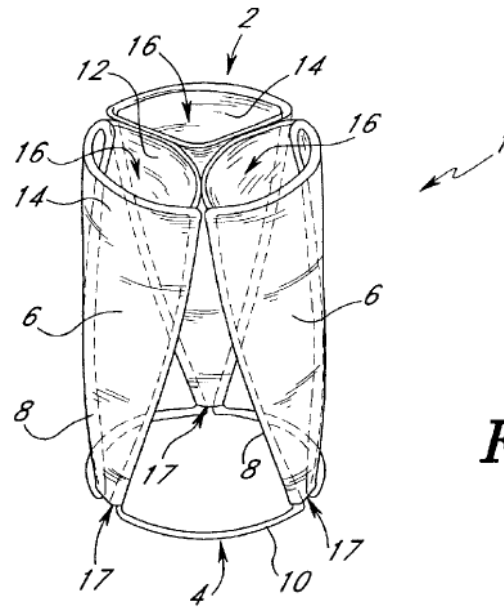


FIG. 1

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.

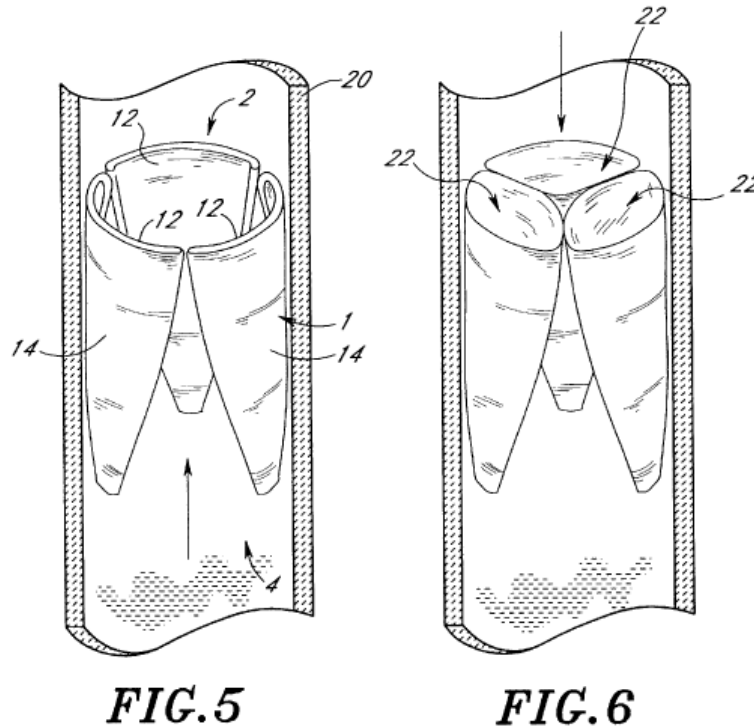


Figure 5, on the left, illustrates blood vessel 20 with device 1 implanted therein, device 1 including three stoppage elements 6, each with inner walls 12 and outer walls 14. Figure 5 includes an arrow, indicating blood flow, pointing up toward distal end 4 of device 1. *Id.* at 3:59–61. The flow of 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.

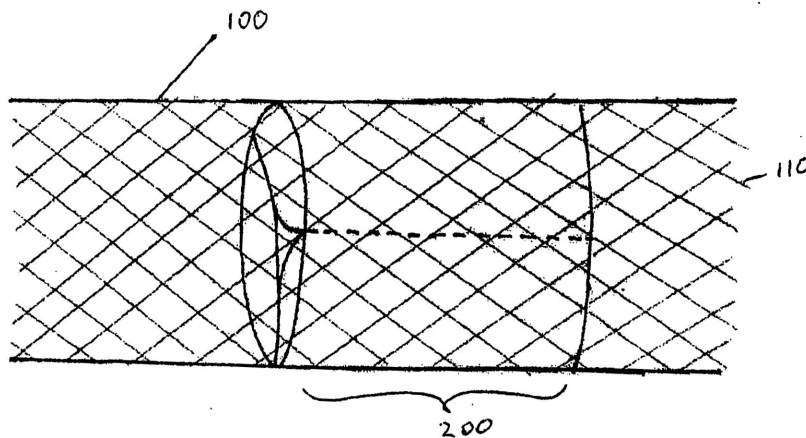


Fig. 5

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%” for 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. Discussion

We have reviewed the full record before us including the evidence, testimony, and arguments in support of the parties’ positions and determine that for Grounds 5–8, Patent Owner’s argument that the combined teachings of Moll and Paniagua, alone for further on combination with Pavcnik, Melsheimer, or Eberhardt fail to disclose non-transverse diagonally oriented

folds that are angled relative to an axial flow direction is dispositive. We focus our discussion on this argument.

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 contends that Moll does not disclose or suggest “non-transverse diagonally oriented folds that are angled relative to an axial flow direction” as required by each of the independent claims (i.e., claims 55, 60, and 67) at issue in this proceeding. PO Resp. 67–72. In particular, Patent Owner contends 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.* at 69. According to Patent Owner, “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.” *Id.* at 70.

Petitioner replies Moll inherently discloses the claimed folds. Pet. Reply 20. According to Petitioner, the ’400 patent “contemplates embodiments using folded membrane sheets made from multiple pieces of material.” *Id.* at 21 (citing Ex. 1001, 11:1–4, 11:55–56, 33:28–41). Although, these portions of the ’400 patent do contemplate multi-piece membrane sheets, the fact that Moll’s membranes may be made of multiple pieces does not necessitate the use of folds. Petitioner has not adequately demonstrated that flattening of Moll’s flow stoppage elements necessarily creates folds. For this reason, we agree with Patent Owner that Moll does not inherently disclose folds.

Turning to Patent Owners alternative position, Patent Owner contends that Petitioner’s reasoning for modifying Moll in view of Paniagua’s teachings regarding the use of folds “says nothing about a motivation to further include ***folds that are ‘non-transverse,’ ‘diagonally oriented,’ and ‘angled relative to an axial flow direction.’***” PO Resp. 72–73. Patent Owner asserts further that “Petitioners fail to provide the legally required explanation as to how a [person of skill in the art] 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.” *Id.* at 73 (citing *Metalcraft of Mayville, Inc. v. The Toro Co.*, 848 F.3d 1358, 1367 (Fed. Cir. 2017)).

Patent Owner’s arguments are inapposite in that they attack Paniagua’s teachings separately and do not consider the combined teachings of Moll and Paniagua. We understand the challenge to rely on Moll’s teachings of a valve structure including folds that are “non-transverse,” “diagonally oriented,” and “angled relative to an axial flow direction.” Pet. 79–81.

In addition, Patent Owner contends that a person of skill in the art “would understand that folds by themselves do not improve the durability of a valve.” PO Resp. 73 (citing Ex. 2001 ¶ 240). Patent Owner asserts further that

because Moll teaches very little about the details of adding the valve leaflets [to] the frame—and specifically does not teach that sutures are used to assemble its various pieces—a [person of skill in the art] 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.

PO Resp. 74 (citing Ex. 2001 ¶ 240). In addition, Patent Owner contends that a person of skill in the art “reading Moll would not understand where folds could be added within Moll—and Petitioners fail to provide this required detail.” *Id.* (citing Ex. 2001 ¶ 241; *Metalcraft*, 848 F.3d at 1367). Finally, Patent Owner asserts that “although a [person of skill in the art] 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,” “[w]ithout such a teaching, a [person of skill in the art] would [not] know how to create a folded valve structure and then apply it to Moll.” *Id.* (citing Ex. 2001 ¶ 242).

Petitioner replies that Patent Owner “does not dispute a [person of ordinary skill in the art] would be motivated to use folds to ‘aid in the patterned movement of the valve’” and that “[t]his alone is motivation to modify Moll.” Pet. Reply 24 (citing Pet. 80–81, 85–86, 90; Ex. 1007 ¶ 24). Petitioner replies further that Patent Owner admits that a person of ordinary skill in the art “knew sutures were used for valve attachment” and would have understood “the valve described by Moll . . . can potentially . . . be secured with minimal suturing.” *Id.* (citing Ex. 1012 ¶ 39; Ex. 1011, 12:58–63; Ex. 1034, 39:9–16; PO Resp. 56; Ex. 2001 ¶ 205).

In addition, Petitioner replies that Patent Owner’s argument “that ‘Paniagua teaches very little about how to construct valve leaflets that include creating folds’” and that a person of ordinary skill in the art “would not know how to create ‘a folded valve structure and then apply it to Moll’ . . . is (1) factually wrong, because Paniagua discloses and describes a specific folding pattern” and “(2) irrelevant because Petitioner’s argument is a [person of skill in the art] would modify Moll’s flow stoppage elements with folds along the ‘edges’ of the cones, based on Paniagua’s teaching of the advantages of folded valves; a POSITA does not need to create Paniagua’s valve in order to fold Moll.” Pet. Reply 24–25 (citing PO Resp. 74; Ex. 1007, Figs. 9A–9C, ¶ 47).

We agree with Patent Owner. As discussed above, Moll does not explicitly or inherently disclose folds. Although Paniagua teaches the use of folds, we agree with Patent Owner that Petitioner has not adequately explained why such folds would be incorporated in Moll in an orientation that is “non-transverse diagonally oriented” “at an angle relative to an axial flow direction.” In other words, Petitioner’s rationale relies on Moll having folds for inclusion of Paniagua’s folds in the correct orientation. But Moll

does not disclose folds for the reasons discussed above, and thus, Petitioner's reasoning in support of the proposed combination lacks rational underpinning.

4. *Conclusion Re Grounds 5–8*

Having considered the full record before us including the evidence, testimony, and arguments of both parties, we determine that Petitioner fails to show by a preponderance of the evidence that claims 55–61, 63–67, and 69–72 are unpatentable over the combined teachings of Moll and Paniagua (Ground 5), fails to show that claims 62 and 83–85 are unpatentable over the combined teachings of Moll, Paniagua, and Pavcnik (Ground 6), fails to show that claim 68 is unpatentable over the combined teachings of Moll, Paniagua, and Melsheimer (Ground 7), and fails to show that claims 78–80 are unpatentable over the combined teachings of Moll, Paniagua, and Eberhardt (Ground 8).

III. CONCLUSION

For the forgoing reasons, we determine that Petitioner has demonstrated by a preponderance of the evidence that claims 55–72, 78–80, and 83–85 are unpatentable on the bases set forth in the following table.¹⁶

¹⁶ Should Patent Owner wish to pursue amendment of the challenged claims in a reissue or reexamination proceeding subsequent to the issuance of this Final Decision, we draw Patent Owner's attention to the April 2019 *Notice Regarding Options for Amendments by Patent Owner Through Reissue or Reexamination During a Pending AIA Trial Proceeding*. See 84 Fed. Reg. 16,654 (Apr. 22, 2019). If Patent Owner chooses to file a reissue application or a request for reexamination of the challenged patent, we remind Patent Owner of its continuing obligation to notify the Board of any such related matters in updated mandatory notices. See 37 C.F.R. § 42.8(a)(3), (b)(2).

Claims	35 U.S.C. §	References	Claims Shown Unpatentable	Claims Not Shown Unpatentable
55, 56, 58–61, 63, 65, 66	102	Melsheimer	55, 56, 58–61, 63, 65, 66	
57, 64, 78, 79	103	Melsheimer	57, 64, 78, 79	
57, 64, 78, 79	103	Melsheimer, Eberhardt	57, 64, 78, 79	
62, 83, 84	103	Melsheimer, Pavcnik	62, 83, 84	
60–72, 79, 80	103	Braido, Pavcnik	50–72, 79, 80	
55–61, 63–67, 69–72	103	Moll, Paniagua		55–61, 63–67, 69–72
62, 83–85	103	Moll, Paniagua, Pavcnik		62, 83–85
68	103	Moll, Paniagua, Melsheimer		68
78–80	103	Moll, Paniagua, Eberhardt		78–80
Overall Outcome			50–72, 78–80, 83, 84	85

IV. ORDER

In consideration of the foregoing, it is hereby

ORDERED that Petitioner has demonstrated by a preponderance of the evidence that claims 50–72, 78–80, 83, 84 of U.S. Patent 9,737,400 B2 are unpatentable; and

FURTHER ORDERED that because this is a Final Written Decision, any party to the proceeding seeking judicial review of this Decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

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