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Paper 59
Entered: May 2, 2019

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ST. JUDE MEDICAL, LLC,
Petitioner,

v.

SNYDERS HEART VALVE LLC,
Patent Owner.

Case IPR2018-00105
Patent 6,540,782 B1

Before PATRICK R. SCANLON, MITCHELL G. WEATHERLY, and JAMES A. WORTH, *Administrative Patent Judges.*[1]

SCANLON, *Administrative Patent Judge.*

FINAL WRITTEN DECISION
35 U.S.C. § 318(a) and 37 C.F.R. § 42.73

[1] Director Andrei Iancu has taken no part in this Decision due to recusal.

I. INTRODUCTION

St. Jude Medical, LLC ("Petitioner") filed a Petition (Paper 3, "Pet.") requesting an *inter partes* review of claims 1, 2, 4–8, 10–13, 17–19, 21, 22, and 25–30 of U.S. Patent No. 6,540,782 B1 (Ex. 1001, "the '782 patent"). Snyders Heart Valve LLC ("Patent Owner") filed a Preliminary Response (Paper 10, "Prelim. Resp."). The Board instituted a trial as to claims 1, 2, 4–8, 10–13, 17–19, 21, 22, and 25–30 of the '782 patent. Paper 15 ("Institution Decision," "Dec.").

After institution of trial, Patent Owner filed a Patent Owner Response ("PO Resp.") to the Petition. Paper 30. Petitioner filed a Reply ("Reply") to the Patent Owner Response. Paper 38. Patent Owner filed a Sur-Reply ("Sur-Reply"). Paper 40. Petitioner relies on the Declaration of Lakshmi Prasad Dasi, Ph.D. (Ex. 1003) in support of its Petition, and Patent Owner relies on the Declaration of Dr. Nicolas Chronos (Ex. 2026) in support of its Response.

Petitioner filed a Motion to Exclude Evidence (Paper 45, "Mot. to Exclude") and a Motion to Strike (Paper 46, "Mot. To Strike"). Patent Owner filed an Opposition to the Motion to Exclude (Paper 48, "Opp. Mot. to Exclude") and an Opposition to the Motion to Strike (Paper 49, "Opp. Mot. To Strike"). Petitioner filed a Reply to the Opposition to the Motion to Exclude. Paper 52 ("Mot. to Exclude Reply").

An oral hearing was held on January 30, 2019, and the record contains a transcript of this hearing. Paper 58 ("Tr.").

We have jurisdiction 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 that follow, we determine that Petitioner has not shown by a preponderance of the evidence that claims 1, 2, 4–8, 10–13, 17–19, 21, 22, and 25–30 of the ’782 patent are unpatentable. Petitioner’s Motion to Exclude Evidence and Motion to Strike are both dismissed as moot.

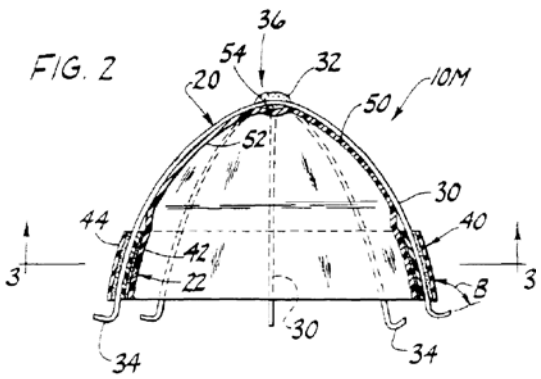
II. BACKGROUND

A. Related Matters

The parties indicate that the ’782 patent is at issue in *Snyders Heart Valve LLC v. St. Jude Medical SC, Inc.*, No. 4:16-cv-00812 (E.D. Tex.). Pet. 1; Paper 5, 2. Related *inter partes* review proceeding IPR2018-00106 also involves the ’782 patent. In addition, U.S. Patent No. 6,821,297 B2, which is related to the ’782 patent, is the subject of related *inter partes* review proceedings IPR2018-00107 and IPR2018-00109.

B. The ’782 patent

The ’782 patent, titled “Artificial Heart Valve,” issued April 1, 2003, with claims 1–30. Ex. 1001, (54), (45), 10:22–16:39. The ’782 patent is directed to “artificial heart valves for repairing damaged heart valves.” *Id.* at 1:11–12. Figures 2 and 3 of the ’782 patent are reproduced below.



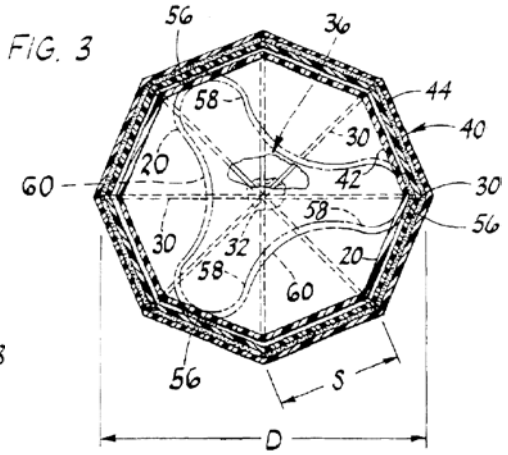


Figure 2 depicts "a vertical cross section of an artificial valve," and Figure 3 depicts "a cross section of the valve taken in the plane of line 3–3 of FIG. 2." *Id.* at 4:8–10. Artificial valve 10M shown in Figures 2 and 3 "is specifically configured for repairing a damaged mitral valve," although the '782 patent also discloses an artificial valve configured to repair a damaged pulmonary heart valve. *Id.* at 4:30–33.

Artificial valve 10M comprises flexibly resilient external frame 20 and flexible valve element 22. *Id.* at 4:48–50. Frame 20 includes U-shaped stenting elements 30 that are joined together generally midway between their respective ends at junction 32. *Id.* at 4:51–58. U-shaped elements 30 are sufficiently compressible to allow valve 10M to be compressed into a configuration for implantation and sufficiently resilient to hold valve 10M in position between the cusps of a native heart valve after implantation while holding the cusps open. *Id.* at 4:61–5:2. Peripheral anchors 34 are formed at each end of the U-shaped elements to attach frame 20 in position between an upstream region and a downstream region. *Id.* at 5:13–17. Frame 20 further includes central portion 36 located between peripheral anchors 34. *Id.* at 5:26–29.

Artificial valve 10M also comprises band 40 that extends around frame 20 between U-shaped frame elements 30 to limit maximum spacing between the frame elements, but permit the frame elements to be pushed together so flexibly resilient frame 20 can be collapsed to a collapsed configuration. *Id.* at 5:30–37. Band 40 preferably includes internal strip 42 and external strip 44 joined in face-to-face relation. *Id.* at 6:5–7.

Flexible valve element 22 is attached to central portion 36 of frame 20 and has convex upstream side 50 facing an upstream region and concave downstream side 52 facing a downstream region. *Id.* at 6:24–32. With this arrangement, "valve element 22 moves in response to differences between fluid pressure in the upstream region and the downstream region between an open position (as shown in phantom lines in FIG. 3) and a closed position (as shown in solid lines in FIG. 3)." *Id.* at 6:35–39. Flexible valve element 22 permits flow between the upstream and downstream regions when in its open position and blocks flow between the upstream and downstream regions when in its closed position. *Id.* at 6:39–43.

More specifically, apex 54 of upstream side 50 is attached to junction 32 of frame 20. *Id.* at 7:1–3. As shown in Figure 3, flexible valve element 22 also is attached to band 40 at several attachment points 56, such that flexible valve element 22 defines flaps 58 between adjacent attachment points. *Id.* at 7:10–14. Flaps 58 and corresponding portions of band 40 define openings 60 when valve element 22 moves to its open position. *Id.* at 7:14–17.

Figure 4 of the '782 patent is reproduced below.

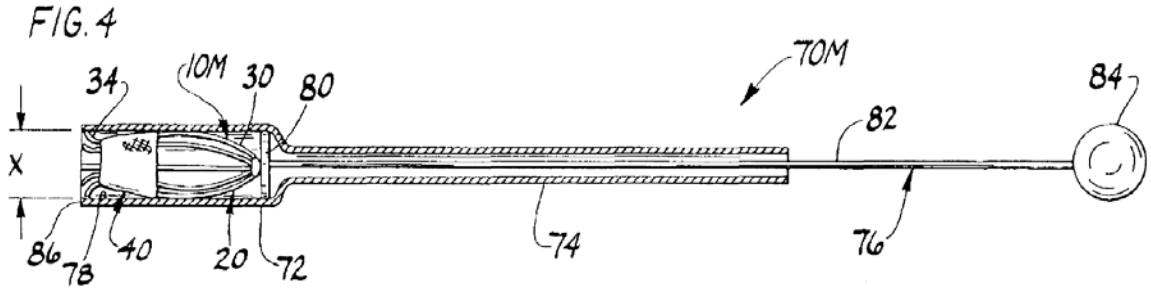


Figure 4 depicts "a vertical cross section of an instrument for implanting a valve using an endothoracoscopic procedure." *Id.* at 4:11–13. The instrument of Figure 4 includes tubular holder 72 and elongate tubular

manipulator 74 attached to the holder for manipulating the holder into position. *Id.* at 7:34–36. The instrument further includes ejector 76 that is positioned in the hollow interior of holder 72 for ejecting an artificial heart valve from the holder. *Id.* at 7:36–39.

C. Challenged Claims

As noted above, Petitioner challenges claims 1, 2, 4–8, 10–13, 17–19, 21, 22, and 25–30 of the '782 patent. Claims 1, 10, 17, 18, 28, 29, and 30 are independent. Claims 2 and 4–8 depend, directly or indirectly, from independent claim 1, and claims 19, 21, 22, and 25–27 depend, directly or indirectly, from independent claim 18. Independent claim 1 is reproduced below:

> 1. An artificial valve for repairing a damaged heart valve having a plurality of cusps separating an upstream region from a downstream region, said artificial valve comprising:
>
> a flexibly resilient frame sized and shaped for insertion in a position between the upstream region and the downstream region, the frame having a plurality of peripheral anchors for anchoring the frame in the position between the upstream region and the downstream region and a central portion located between the plurality of peripheral anchors;
>
> a band attached to the frame limiting spacing between adjacent anchors of said plurality of peripheral anchors; and
>
> a flexible valve element attached to the central portion of the frame and adjacent the band, said valve element being substantially free of connections to the frame except at the central portion of the frame and adjacent the band, said valve element having an upstream side facing said upstream region when the frame is anchored in the position between the upstream region and the downstream region and a downstream side opposite the upstream side facing said downstream region when the frame is anchored in the position between the upstream region and the

> downstream region, said valve element moving in response to a difference between fluid pressure in said upstream region and fluid pressure in said downstream region between an open position in which the element permits downstream flow between said upstream region and said downstream region and a closed position in which the element blocks flow reversal from said downstream region to said upstream region, wherein the valve element moves to the open position when fluid pressure in said upstream region is greater than fluid pressure in said downstream region to permit downstream flow from said upstream region to said downstream region and the valve element moves to the closed position when fluid pressure in said downstream region is greater than fluid pressure in said upstream region to prevent flow reversal from said downstream region to said upstream region.

Ex. 1001, 10:22–60.

D. The Prior Art

Petitioner's asserted grounds of unpatentability for the challenged claims rely on the following references:

Andersen	US 5,411,552	May 2, 1995	Ex. 1006
Leonhardt	US 5,957,949	Sept. 28, 1999	Ex. 1017
Imachi	US 5,413,599	May 9, 1995	Ex. 1020
Johnson	US 4,339,831	July 20, 1982	Ex. 1021

E. Grounds of Unpatentability at Issue

The Petition challenges claims 1, 2, 4–8, 10–13, 17–19, 21, 22, and 25–30 of the '782 patent on the following three grounds of unpatentability. Pet. 3. We instituted trial on all three grounds, and for all claims subject to each asserted ground. Dec. 2, 26.

Reference(s)	Basis	Claims Challenged
Leonhardt	§ 102	1, 2, 4–8, 10–13, 17–19, 21, 22, and 25–30
Leonhardt and Andersen	§ 103	1, 2, 4–8, 10–13, 17–19, 21, 22, and 25–30
Leonhardt, Johnson, and Imachi	§ 103	1, 2, 4–8, 10–13, 17–19, 21, 22, and 25–30

III. ANALYSIS

A. Relevant Legal Principles

To prevail in challenging Patent Owner's claims, Petitioner must demonstrate by a preponderance of the evidence that the claims are unpatentable. 35 U.S.C. § 316(e); 37 C.F.R. § 42.1(d). "In an [*inter partes* review], the petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable." *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016) (citing 35 U.S.C. § 312(a)(3) (requiring *inter partes* review petitions to identify "with particularity . . . the evidence that supports the grounds for the challenge to each claim")). The burden of persuasion rests with Petitioner. *See Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015) (citing *Tech. Licensing Corp. v. Videotek, Inc.*, 545 F.3d 1316, 1326–27 (Fed. Cir. 2008)) (discussing the burden of proof in *inter partes* review). Furthermore, Petitioner cannot satisfy its burden of proving obviousness by employing "mere conclusory statements." *In re Magnum Oil Tools Int'l, Ltd.*, 829 F.3d 1364, 1380 (Fed. Cir. 2016).

"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.*, 814 F.2d 628, 631 (Fed. Cir. 1987). 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). Whether a reference anticipates is assessed from the perspective of an ordinarily skilled artisan. *See Dayco Prods., Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1368 (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.").

A 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) where in evidence, so-called secondary considerations, including commercial success, long-felt but unsolved needs, failure of others, and unexpected results. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

For an obviousness analysis, prior art references must be "considered together with the knowledge of one of ordinary skill in the pertinent art." *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994) (quoting *In re Samour*, 571 F.2d 559, 562 (CCPA 1978)). Moreover, "it is proper to take into account not only specific teachings of the reference but also the inferences which one skilled in the art would reasonably be expected to draw therefrom." *In re Preda*, 401 F.2d 825, 826 (CCPA 1968). That is because an obviousness analysis "need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." *KSR*, 550 U.S. at 418.

B. Level of Ordinary Skill in the Art

Petitioner contends that a person having ordinary skill in the art to which the '782 patent pertains "is a medical doctor or has an advanced degree (at least a master's degree) in a relevant engineering discipline with several years of experience or someone who holds a lesser degree with more experience in the field of artificial heart valves." Pet. 13–14 (citing Ex. 1001; Ex. 1006; Ex. 1008; Ex. 1009; Ex. 1010; Ex. 1020; Ex. 1003, ¶¶ 15–17). Patent Owner does not dispute this contention in its Preliminary Response, Response, or Sur-Reply, nor does Patent Owner offer its own definition of the level of ordinary skill in the art.

Factual indicators of the level of ordinary skill in the art include "the various prior art approaches employed, the types of problems encountered in the art, the rapidity with which innovations are made, the sophistication of the technology involved, and the educational background of those actively working in the field." *Jacobson Bros., Inc. v. U.S.*, 512 F.2d 1065, 1071 (Ct.

Cl. 1975); *see also Orthopedic Equip. Co. v. U.S.*, 702 F.2d 1005, 1011 (Fed. Cir. 1983) (quoting with approval *Jacobson Bros*.). We find, based on our review of the record before us, that Petitioner's stated level of ordinary skill in the art is reasonable because it is consistent with the evidence at this stage of the proceeding, including the asserted prior art and, for the purposes of this Final Written Decision, we adopt Petitioner's definition.

C. Claim Construction

In an *inter partes* review, claim terms in an unexpired patent are given their broadest reasonable construction in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b); *see also Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2142–46 (2016) (concluding that 37 C.F.R. § 42.100(b) "represents a reasonable exercise of the rulemaking authority that Congress delegated to the Patent Office"). Under the broadest reasonable construction standard, claim terms are given their ordinary and customary meaning, as would be understood by one of ordinary skill in the art in the context of the entire disclosure. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). Also, we are careful not to read a particular embodiment appearing in the written description into the claim if the claim language is broader than the embodiment. *See In re Van Geuns*, 988 F.2d 1181, 1184 (Fed. Cir. 1993) ("[L]imitations are not to be read into the claims from the specification.").

Petitioner indicates that the parties filed a Joint Memorandum on Claim Construction (Ex. 1041) in the related district court action identified above. Pet. 14. Petitioner also indicates that Patent Owner, in the related district court action, served infringement contentions (Ex. 1039) including an exhibit (Ex. 1040) indicating how Patent Owner "defines and/or

construes" the challenged claims. Pet. 15. Based on these alleged constructions from the district court action, Petitioner proposes constructions for "frame," "peripheral anchor(s)," "central portion located between the plurality of peripheral anchors," "band," "first band," "second band," "flexible valve element," "U-shaped elements/U-shaped frame elements," "flexibly resilient," "junction," "convex upstream side," and "concave downstream side." Pet. 15–17 (citing Ex. 1040; Ex. 1041).

Patent Owner proposes constructions for "central portion," "each of said frame elements has a distance between its respective ends," "plurality of U-shaped frame elements sized and shaped for insertion," "attached to," and "joined together generally midway between respective ends." PO Resp. 4–16.

In this Final Written Decision, we construe only those claim terms in controversy, and we do so only to the extent necessary to resolve the controversy. *See Wellman, Inc. v. Eastman Chem. Co.*, 642 F.3d 1355, 1361 (Fed. Cir. 2011) ("claim terms need only be construed 'to the extent necessary to resolve the controversy'") (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999)). Furthermore, we expressly interpret below only those claim terms that require analysis to resolve arguments related to the patentability of the challenged claims. In view of our analysis discussed below, construing these terms is not necessary for us to assess the asserted grounds of unpatentability. Therefore, we determine that only the claim terms addressed below require express construction.

1. Band

Each of independent claims 1, 10, 18, 28 recites a "band." Independent claims 17 and 30 both recite a "first band" and a "second band." Petitioner asserts that "band" should be construed as "[a] structure generally in the shape of a circular strip or ring; a band can be integrated with the frame." Pet. 16. Patent Owner does not propose a construction for the term "band," but presents arguments that seemingly cast doubt on Petitioner's construction. *See* Po Resp. 24 (arguing Leonhardt's graft material 24 is not a "band" but more like a "sleeve").

In the related district court action, the U.S. District Court for the Eastern District of Texas issued a Claim Construction Memorandum Opinion and Order. Ex. 2002. A district court's interpretation of claim terms may be useful in our claim construction and must be considered in our analysis. *See Knowles Elecs. LLC v. Iancu*, 886 F.3d 1369, 1376 (Fed. Cir. 2018) ("While 'the [PTAB] is not generally bound by a previous judicial interpretation of a disputed claim term[, this] does not mean . . . that it has no obligation to acknowledge that interpretation or to assess whether it is consistent with the [broadest reasonable interpretation] of the term.'" (quoting *Power Integrations, Inc. v. Lee*, 797 F.3d 1318, 1327 (Fed. Cir. 2015))).

With respect to claim 1 of the '782 patent, the District Court found that the claim language "expressly recites 'a band *attached* to the frame,' which implies that the band is not part of the frame." Ex. 2002, 37. The District Court also found "the specification [of the '782 patent] does not teach that the 'band' could be both integral with the frame *and* attached to

the frame," and expressly rejected the interpretation that a band can be integral with the frame. *Id.* at 38–39. The District Court then construed "band" to have its plain meaning. *Id.* at 40.

We agree with the District Court's reasoning that a band should not be interpreted as being integral with the frame. In addition, we find the remainder of Petitioner's proposed construction—a structure generally in the shape of a circular strip or ring—to be a good reflection of the plain meaning, although we disagree that a band is necessarily circular because a band in the '782 patent could assume another closed shape such as an oval. Therefore, we construe "band" as "a structure generally in the shape of a closed strip or ring."

2. Convex Upstream Side/Concave Downstream Side

Each of independent claims 10, 17, 18, and 29 recites that a flexible valve element having a "convex upstream side" and a "concave downstream side." The District Court declined to adopt an express construction for these terms and construed them to have their plain meaning. Ex. 2002, 63–64.

Petitioner asserts that "convex upstream side" should be construed as "[a] valve element having an upstream side that bulges out in the upstream direction," and "concave downstream side" should be construed as "[a] valve element having a downstream side that bulges away from the downstream direction." Pet. 17. Petitioner neither analyzes nor cites evidence from the Specification or prosecution history of the '782 patent in support of its position. *Id*. (citing Ex. 1040, 26–28, 40–41, 48–49, 81–82; Ex. 1041, 4).

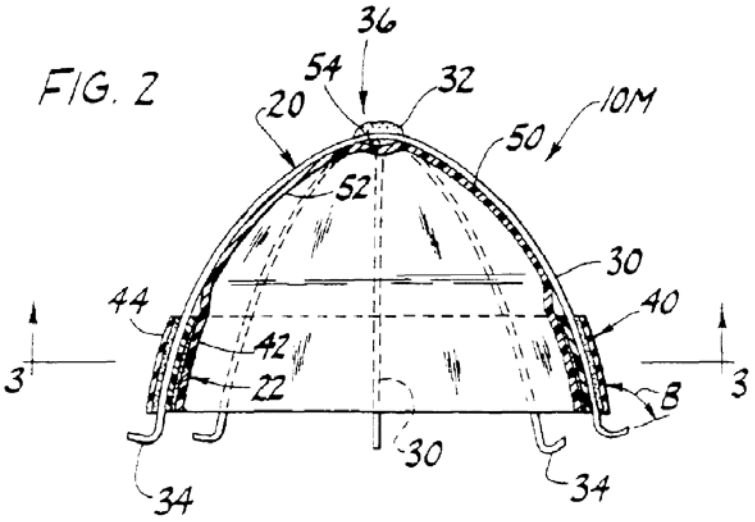
Patent Owner argues that Leonhardt fails to describe the convex and concave sides of the flexible valve element without providing its own interpretation of these phrases. PO Resp. 26–27. To resolve that dispute, we address the meaning of the phrases below.

The phrase "convex upstream side" plainly limits the "side" of the flexible valve element to a side that both faces "upstream" and exhibits a "convex" shape. Similarly, "concave downstream side" refers to a "side" that faces "downstream" and exhibits a "concave" shape. A plain reading of the phrases also indicates that the entire sides, not just a portion, are "convex" or "concave."

The Specification supports a plain reading of "convex upstream side" and "concave downstream side" as referring to characteristics of the sides as a whole rather than only a portion of each side. Claims should be interpreted in a manner that "corresponds with what and how the inventor describes his invention in the specification." *In re Smith Int'l, Inc.*, 871 F.3d 1375, 1383 (Fed. Cir. 2017). The Specification only describes flexible valve elements in which the entire side of the valve element is either convex or concave as follows.

> The valve element 22 has a *convex upstream side 50 facing an upstream region (e.g., the left atrium LA)* when the frame 20 is anchored between the cusps C of the damaged heart valve (e.g., mitral valve M) in a position between the upstream region and a downstream region; and *a concave downstream side 52 opposite the upstream side facing the downstream region (e.g., the left ventricle LV)* when the frame 20 is anchored between the cusps of the damaged heart valve in a position between the upstream region and the downstream region.

Ex. 1001, 6:25–35 (emphases added). Figure 2 and the pertinent portion of Figure 1, which are reproduced below left and right respectively, illustrate convex upstream side 50 and concave downstream side 52.



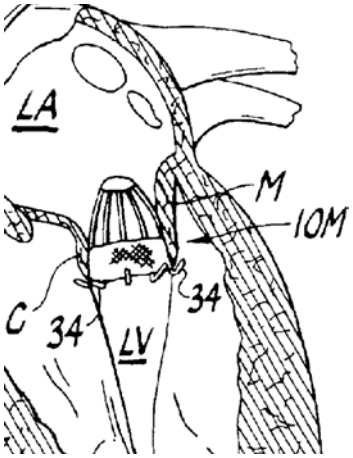
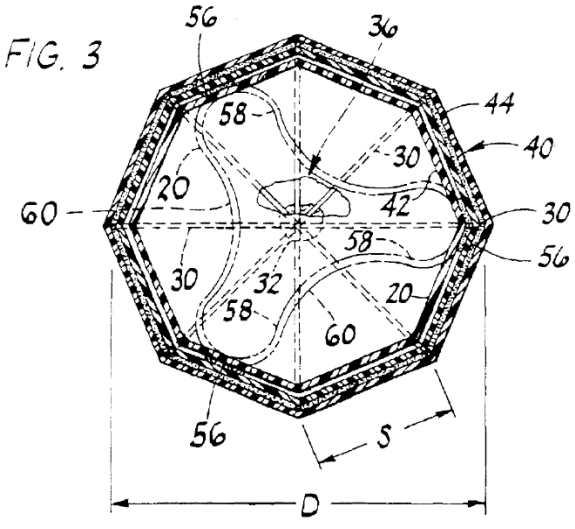


Figure 2, reproduced above left, is a cross-sectional view of valve 10M illustrating convex upstream side 50 and concave downstream side 52 of flexible valve element 22. *Id*. at 4:8. The portion of Figure 1 that is reproduced above right illustrates valve 10M placed with its concave side facing the left ventricle LV (i.e., the downstream region) and the convex side facing the left atrium LA (i.e., the upstream region). *Id*. at 4:6–7, 6:25–35.

The entirety of upstream side 50 is convex and the entirety of downstream side 52 is concave when valve element 22 is in the "closed position" as shown in the solid-line depiction of valve element 22 in Figures 2 (above) and 3 (reproduced at right). *Id*. at 6:35–51. Figure 3 illustrates an open valve element 22 in phantom lines



such that valve element 22 defines openings 60 to permit blood flow that are defined by flaps 58 between adjacent attachment points 56. *Id*. at 7:10–17. The Specification, therefore, describes only a valve having a "convex upstream side" and a "concave downstream side" in which the "convex" or "concave" shape of the "side" refers to the overall shape of the entire respective side when the valve is closed.

During the hearing, Patent Owner was asked to identify any evidence of record from the Specification or prosecution history that weighed against interpreting "convex" and "concave" as referring to the overall shapes of the opposing sides of the claimed flexible valve element in their entirety, and Patent Owner identified none. Tr. 72:16–79:11.

Based on the plain meaning of "convex upstream side" and "concave downstream side" and the description of the invention in the Specification, we conclude that the overall shape of the entire "upstream side" of the flexible valve element is convex, and the overall shape of the entire "downstream side" of the flexible valve element is concave.

D. Asserted Anticipation by Leonhardt

Petitioner contends claims 1, 2, 4–8, 10–13, 17–19, 21, 22, and 25–30 are anticipated under 35 U.S.C. § 102(a), (e) by Leonhardt. Pet. 3, 18–42. Petitioner relies upon the testimony of Dr. Dasi (Ex. 1003) in support of its contentions. *Id.* Patent Owner disputes Petitioner's contentions. PO Resp. 20–39. Patent Owner cites the testimony of Dr. Chronos (Ex. 2026) in support.

1. Overview of Leonhardt

Leonhardt "relates to artificial valves, specifically those placed percutaneously by a catheter" to replace existing valves, such as valves in the heart. Ex. 1017, 1:4–7. Figure 4 of Leonhardt is reproduced below.

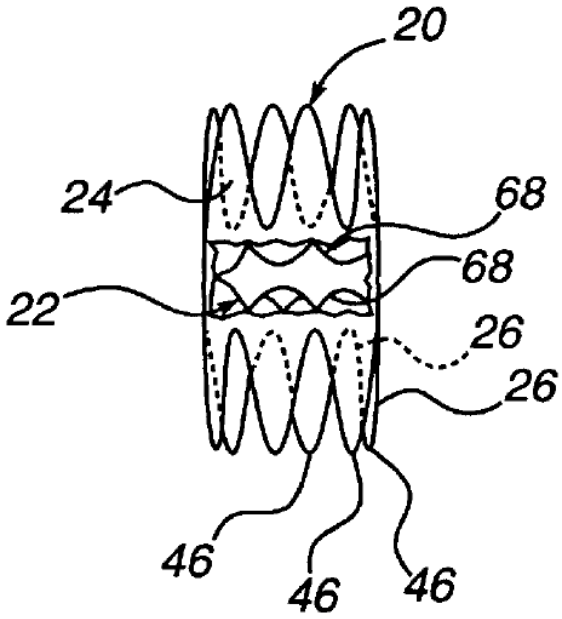


FIG. 4

Figure 4 depicts valve stent 20 comprising stent 26, biological valve 22, and graft material 24. *Id.* at 4:14–16. Stent 26, which is shown in more detail in Figures 1A–1C, is a single piece of super elastic wire formed into top and bottom portions that are substantially symmetrical to each other and have a wavy form or zig-zags 40. *Id.* at 4:27–38, Fig. 1A. Each end 58 of stent 26 is connected to another portion of the stent by crimping tubes 50 to define imaginary cylinder 48. *Id.* at 4:41–56, Figs. 1B, 1C. In other words, once crimped, stent 26 comprises a pair of cylinders at opposing ends of the stent. *Id.* at 5:27–30. Connecting bar 29, which is a central part of the

continuous wire from which the stent is formed, holds these cylinders at a predetermined distance apart. *Id.* at 5:31–33; Figs. 1A, 1B.

Graft material 24 "is a thin-walled biocompatible, flexible and expandable, low-porosity woven fabric" that encloses, and is sutured to, stent 26. *Id.* at 5:46–48, 53–63. Graft material 24 "is heat pressed to conform to the distal and proximal cylindrical ends of stent." *Id.* at 5:63–65. In addition, when valve stent 20 must flare at one or both ends, "graft material 24 may be cut out between the plurality of distensible fingers 46 formed by zig-zags 40 of stent 26." *Id.* at 6:9–13.

Biological valve 22 fits within the internal diameter of the imaginary cylinder defined by stent 26 and is attached to stent 26, graft material 24, or both. *Id.* at 6:25–30. Although "preferably a porcine valve treated and prepared for use in a human," biological valve 22 could also be "a mechanical valve or a synthetic leaflet valve." *Id.* at 6:23–24, 31–33.

Leonhardt also discloses deployment catheter 100 for the percutaneous delivery of valve stent 20 to the placement site. *Id.* at 6:34–37, Figs. 5, 6. Deployment catheter 100 includes outer sheath 106 having axially extending sheath passage 108, which receives push rod 112. *Id.* at 6:42–45. In use, valve stent 20 is loaded into outer sheath 106, and push rod 112 causes valve stent 20 to be deployed. *Id.* at 7:17–18, 10:53–58.

2. Claims 1, 2, and 4–8

Independent claim 1 recites, in pertinent part, an artificial valve for repairing a damaged heart valve comprising a flexibly resilient frame having a plurality of peripheral anchors and "a band attached to the frame limiting

spacing between adjacent anchors of said plurality of peripheral anchors." Ex. 1001, 10:22–33.

Petitioner argues that Leonhardt's stent 26 is the flexibly resilient frame. Pet. 19 (citing Ex. 1003 ¶ 55). Petitioner also argues that stent 26 includes two cylindrical portions disposed at each end thereof, and these cylindrical portions are made of frame elements that are the peripheral anchors. *Id.* at 20 (citing Ex. 1003 ¶ 58; Ex. 1040, 4–5). Presumably, these "frame elements" refer to Leonhardt's zig-zags 40 or distensible fingers 46. *See id.* at 21–22 (arguing "the zig-zag or 'wavy form' at respective points 40" define the U-shaped frame elements of claims 18 and 29). Petitioner then asserts that two different structures of Leonhardt can correspond to the recited band. First, Petitioner argues that the cylindrical portions at the ends of stent 26 are "circumferential rings of frame elements" that define a band. *Id.* at 24 (citing Ex. 1017, 4:52–65, 5:23–35, 5:45–48, Fig. 1B). Second, Petitioner argues graft material 24, which surrounds stent 26, is also a band. *Id.* As for the requirement that the band limit spacing between adjacent anchors, Petitioner asserts that "[t]he graft material of Leonhardt restricts the expansion of the self-expanding frame [(i.e., stent 26)], as confirmed by Leonhardt's instruction to 'cut out' the graft material to allow further outward expansion to form 'distensible fingers,'" such that "[t]he uncut graft material limits spacing as claimed." *Id.* at 24–25 (citing Ex. 1017, 6:9–22; Ex. 1003 ¶ 70).

Regarding the assertion that the cylindrical portion at either end of stent 26 is a "band," these cylindrical portions define a substantial part of stent 26, which Petitioner asserts corresponds to the recited frame. It is not

clear, however, how the cylindrical portions could be both a part of the frame and a band that is *attached to the frame* as required by claim 1. As the District Court noted in the related action, the claim language "a band *attached* to the frame" implies the band is not part of the frame. Ex. 2002, 37. In fact, the District Court expressly rejected the interpretation that "a band can be integrated with the frame." *Id.* at 39. Accordingly, we are not persuaded that the cylindrical portions of stent 26 are "bands."

Moreover, even assuming for the sake of argument that the cylindrical portions could be considered to be "bands," Patent Owner argues that the Petition never asserts these elements limit spacing as required by claim 1. PO Resp. 25 (citing Ex. 2026 § 2.1.1.2). We agree Petitioner does not provide adequate explanation for how the cylindrical portions, acting alone, would limit spacing between the anchors (i.e., distensible fingers 46).

Regarding the assertion that the recited "band" is met by graft material 24, Patent Owner argues that graft material 24 is not a "band" because it not shaped like a band; it extends the entire length of stent 26 and, thus, is more like a sleeve. *Id.* at 24 (citing Ex. 1017, 5:53–6:7, Fig. 3; Ex. 2026 § 2.1.1.2). In its Reply, Petitioner argues that Leonhardt describes a band because Patent Owner does not cite dimensions of a band that differentiate a band from a sleeve. Reply 4. As noted above, we construe the term "band" as "a structure generally in the shape of a closed strip or ring." *See supra* § III.C.1. Applying this construction, we agree with Patent Owner that graft material 24 is a sleeve-like structure and not a band. Leonhardt discloses that graft material 24 encloses and surrounds stent 26. Ex. 1017, 5:45–46, 5:63–64. With this configuration, graft material 24

cannot be considered a strip or ring. The absence of cited dimensions that would differentiate a band from a sleeve does not detract from the fact that graft material 24 encloses stent 26 in such a manner that precludes its classification as a band.

For the above reasons, we determine that neither Leonhardt's cylindrical portions nor graft material 24 are a band, let alone a band that limits spacing between adjacent peripheral anchors. Leonhardt thus fails to disclose all limitations of claim 1. Accordingly, for at least the foregoing reasons, Petitioner has not shown, by a preponderance of the evidence, that independent claim 1, or claims 2 and 4–8 depending therefrom, are anticipated by Leonhardt.

3. Claims 10–13

Independent claim 10 requires an artificial valve for repairing a damaged heart valve comprising a flexibly resilient frame having a plurality of peripheral anchors and "a band comprising an internal strip positioned inside and attached to the frame limiting spacing between adjacent anchors of said plurality of peripheral anchors." Ex. 1001, 11:26–37.

Just as with claim 1, Petitioner argues that Leonhardt's stent 26 is the flexibly resilient frame and the stent's frame elements that are the peripheral anchors. Pet. 19, 20 (citing Ex. 1003 ¶¶ 55, 58; Ex. 1040, 4–5). Regarding the band of claim 10, Petitioner argues that Leonhardt discloses using a native porcine valve. *Id.* at 24 (citing Ex. 1017, 6:23–34). Then, relying on the testimony of Dr. Dasi, Petitioner argues one of ordinary skill in the art would realize "a surgically harvested porcine valve that has been treated for human use and includes commissural points as described would necessarily

require 'root' tissue from the original annulus." *Id.* (citing Ex. 1003 ¶¶ 68–69). According to Petitioner, this root tissue is a band attached to the interior of the frame. *Id.* (citing Ex. 1003 ¶¶ 68–69). As for the requirement that the band limit spacing between adjacent anchors, Petitioner again asserts that "[t]he graft material of Leonhardt restricts the expansion of the self-expanding frame [(i.e., stent 26)], as confirmed by Leonhardt's instruction to 'cut out' the graft material to allow further outward expansion to form 'distensible fingers,'" such that "[t]he uncut graft material limits spacing as claimed." *Id.* at 24–25 (citing Ex. 1017, 6:9–22; Ex. 1003 ¶ 70).

Patent Owner argues that graft material 24 is not a "band." PO Resp. 24 (citing Ex. 1017, 5:53–6:7, Fig. 3; Ex. 2026 § 2.1.1.2). We agree with Patent Owner for the reasons discussed above. *See supra* § III.D.2. Regarding Petitioner's assertion that a band comprising and internal strip would be meet by the root tissue of a surgically harvested porcine valve, Patent Owner argues that there is no indication the root tissue would be harvested when using a native porcine valve in Leonhardt's device. PO Resp. 28 (citing Ex. 2026 § 2.8.1.4). Patent Owner also argues that

> [E]ven if such an internal band *were* expressly included in Leonhardt, the Petition never explains how that specific "band" (root tissue) would "limit[] spacing between adjacent anchors" as also required by claim 10. Instead, Petitioner explains why a *different element*, one that the Petition identifies as an *external* "band" in other claims (Leonhardt's graft 24), might limit spacing. Petitioner thus has not even contended that Leonhardt discloses a band that is both "an internal strip" and "limits spacing" as required by Claim 10.

Id. (internal citations omitted).

We agree with this argument. As pointed out by Patent Owner, Petitioner argues that the root tissue corresponds to the band comprising an internal strip (Pet. 24), and graft material 24 is a band that limits spacing between adjacent anchors (*id.* at 24–25). Petitioner does not direct us, however, to any statement in the Petition asserting that the root tissue limits spacing. Instead, replying to Patent Owner's argument, Petitioner contends that "neither PO nor Dr. Chronos directly addresses Dr. Dasi's explanation that a POSA would recognize the term 'base' used for attachment of the valve (not just its leaflets) is describing root tissue forming a ring sewn to the inside of the stent *that would limit spacing*." Reply 6 (citing Ex. 1003 ¶¶ 68–69) (emphasis added). Dr. Dasi merely testifies, however, that one of ordinary skill in the art "would recognize the term 'base' used in connection with the concept ofattachment of the valve (not just its leaflets) is describing root tissue that forms a ring sewn to the inside of the stent." Ex. 1003 ¶ 69. Dr. Dasi does not testify explicitly that the root tissue would limit spacing.

Furthermore, this testimony is a conclusory statement that is not supported sufficiently by objective evidence or analysis. We, thus, give little weight to this testimony. *See* 37 C.F.R. § 42.65(a) ("Expert testimony that does not disclose the underlying facts or data on which the opinion is based is entitled to little or no weight."). For the above reasons, the Petition does not establish adequately that Leonhardt discloses a band that comprises an internal strip and limits the spacing of peripheral anchors.

Claim 10 also recites a flexible valve element attached to the frame and having a convex upstream side and a concave downstream side. Ex. 1001, 11:38–44. Petitioner argues that Leonhardt's biological valve 22,

which is preferably an intact tricuspid porcine valve, is the flexible valve element. Pet. 25–26 (citing Ex. 1003 ¶¶ 75–76; Ex. 1017, 6:23–34). Petitioner also argues that the convex upstream side and concave downstream side limitations are met by a flexible valve element having the general structure of a native tricuspid heart valve. *Id.* at 26. According to Petitioner, to the extent the flexible valve element identified in Patent Owner's infringement contentions from the related district court action has convex upstream and concave downstream sides, biological valve 22 of Leonhardt does as well. *Id.* at 26–27 (citing Ex. 1003 ¶ 79; Ex. 1017, 6:23–34).

In response, Patent Owner argues that, in relying on the infringement contentions, Petitioner fails to cite proper evidence showing how Leonhardt meets these limitations and, thus, fails to provide the "detailed explanation" required to meet its burden. PO Resp. 26. Patent Owner also contends that it did not state in its infringement contentions that all valves having a structure similar to a native heart valve necessarily have a convex upstream side and a concave downstream side. *Id.* Petitioner replies that Patent Owner is ignoring the Board's conclusion in the Institution Decision that Leonhardt discloses a flexible valve element having a convex upstream side and a convex downstream side. Reply 5 (citing Dec. 21–22).

We agree with Patent Owner. Petitioner's reliance on Patent Owner's infringement contentions is not persuasive because there is no basis in the record to conclude that the product accused of infringement in the related district court action has the same elements as Leonhardt's device. For example, while Leonhardt discloses that valve 22 "is preferably a porcine

valve" (Ex. 1017, 6:23–24), the accused product is described as using a "flexible bovine pericardium" (Ex. 1040, 25) or "[b]ovine pericardium leaflets with [a] porcine pericardium sealing cuff" (*id.* at 26). Petitioner is not asserting that estoppel based on litigation positions applies. Tr. 14:3–17. We also agree that Petitioner does not provide and evidence or reasoning, independent of its reliance on the infringement contentions, that the valve 22 of Leonhardt would have a convex upstream side and a concave downstream side.

In addition, we determine that a tricuspid porcine valve does not anticipate either the convex upstream side or the concave downstream side as we have construed these terms. *See supra* § III.C.2. Although it seems reasonable to conclude that each one of the three cusps of a tricuspid valve individually has a convex upstream side and a concave downstream side,[2] this means only that the upstream *side* of the valve has three separate convex surfaces—not that the upstream side of the valve as a whole is convex. Similarly, the downstream side of the valve has three separate concave surfaces such that the downstream side as a whole is not concave. Petitioner asserts that the entire biological valve of Leonhardt—not one of the cusps—corresponds to the claimed flexible valve element. Pet. 25–26.

Last, Petitioner's argument based on our conclusion in the Institution Decision that Leonhardt discloses a flexible valve element having a convex upstream side and a convex downstream side (*see* Reply 5) is not persuasive because the Board is not bound by any findings made in its Institution

[2] The tricuspid valve depicted in Figure A on page 5 of the Petition suggests such a configuration.

Decision. *See TriVascular, Inc. v. Samuels*, 812 F.3d 1056, 1068 (Fed. Cir. 2016). Rather, when deciding whether to institute, "the Board is considering the matter preliminarily without the benefit of a full record. The Board is free to change its view of the merits after further development of the record, and *should do so* if convinced its initial inclinations were wrong," and "there is a significant difference between a petitioner's burden to establish a 'reasonable likelihood of success' at institution, and actually proving invalidity by a preponderance of the evidence at trial. *Id.*

For the above reasons, we determine that Leonhardt fails to disclose all limitations of claim 10. Accordingly, for at least the foregoing reasons, Petitioner has not shown, by a preponderance of the evidence, that independent claim 10, or claims 11–13 depending therefrom, are anticipated by Leonhardt.

4. Claim 17

Like claim 10, independent claim 17 requires an artificial valve for repairing a damaged heart valve comprising, in pertinent part, a flexible valve element attached to the frame and having a convex upstream side and a concave downstream side. Ex. 1001, 12:19–35. Petitioner argues that Leonhardt's biological valve 22, which is preferably an intact tricuspid porcine valve, is the flexible valve element having a convex upstream side and a concave downstream side. Pet. 25–26 (citing Ex. 1003 ¶¶ 75–76; Ex. 1017, 6:23–34). For the reasons discussed above in connection with claim 10, we determine that the Petition does not establish adequately that Leonhardt anticipates a flexible valve element having a convex upstream side and a concave downstream side. *See supra* § III.D.3.

Claim 17 also recites a first band surrounding and attached to the frame and a second band surrounding and attached to the frame downstream of the first band. Ex. 1001, 12:26–30. As with the band of claim 1, Petitioner asserts that two different structures of Leonhardt can correspond to the first band. First, Petitioner argues that the cylindrical portions at the ends of stent 26 are "circumferential rings of frame elements" that define a band. Pet. 24 (citing Ex. 1017, 4:52–65, 5:23–35, 5:45–48, Fig. 1B). Second, Petitioner argues graft material 24, which surrounds stent 26, is also a band. *Id.*

Regarding the second band of claim 17, Petitioner argues that "Leonhardt's stent arrangement includes two spaced-apart cylindrical portions of frame elements," and these two cylindrical portions are the first and second bands. Pet. 25 (citing Ex. 1003 ¶¶ 71–74; Ex. 1017, 4:26–65, 5:23–37, Fig. 1B). Also, although not asserted in the Petition, Dr. Dasi testifies that one of ordinary skill in the art "would interpret the downstream portion of graft material 24 of Leonhardt which extends beyond the mounting of the [flexible valve element] in the central portion, as meeting the second band recitation." Ex. 1003 ¶ 72. Dr. Dasi further testifies that "identifying different portions of a unitary structure as satisfying different claim elements is appropriate here." *Id.* ¶ 73.

For the reasons discussed above, however, we determine that neither Leonhardt's cylindrical portions nor graft material 24 are a band. *See supra* § III.D.2. Furthermore, we do not credit Dr. Dasi's testimony that different portions of graft material 24 could satisfy the recited first and second bands. This testimony comprises mere conclusory statements not supported by

objective evidence or analysis; Dr. Dasi does not explain why one of ordinary skill in the art would consider different portions of the unitary graft material to be distinct first and second bands.

For the above reasons, we determine that Petitioner does not establish adequately that Leonhardt discloses first and second bands as recited in claim 17. Accordingly, for at least the foregoing reasons, Petitioner has not shown, by a preponderance of the evidence, that independent claim 17 is anticipated by Leonhardt.

5. Claims 18, 19, 21, 22, and 25–27

Independent claim 18 recites an artificial valve for repairing a damaged heart valve comprising a plurality of U-shaped frame elements and "a band surrounding the frame and extending between adjacent elements of said plurality of frame elements to limit spacing between said adjacent elements."[3] Ex. 1001, 12:55–67. Claim 18 also recites a flexible valve element attached to the junction of the frame elements and having a convex upstream side and a concave downstream side. *Id.* at 13:1–6.

As with the previously discussed claims, Petitioner asserts that the claimed band can be satisfied by either the cylindrical portions of Leonhardt's stent 26 or Leonhardt's graft material 24. Pet. 24 (citing Ex. 1017, 4:52–65, 5:23–35, 5:45–48, Fig. 1B). Petitioner argues that Leonhardt's biological valve 22, which is preferably an intact tricuspid porcine valve, is the flexible valve element having a convex upstream side

[3] Claim 18 does not recite a frame as antecedent for "the frame." For purposes of this Decision, we consider "the frame" to refer to the U-shaped frame elements collectively.

and a concave downstream side. *Id.* at 25–26 (citing Ex. 1003 ¶¶ 75–76; Ex. 1017, 6:23–34).

For the reasons discussed above in connection with claim 1, however, we determine that neither Leonhardt's cylindrical portions nor graft material 24 are a band. *See supra* § III.D.2. Also, for the reasons discussed above in connection with claim 10, we determine that the Petition does not establish adequately that Leonhardt anticipates a flexible valve element having a convex upstream side and a concave downstream side. *See supra* § III.D.3.

We thus determine that Leonhardt fails to disclose all limitations of claim 18. Accordingly, for at least the foregoing reasons, Petitioner has not shown, by a preponderance of the evidence, that independent claim 18, or claims 19, 21, 22, and 25–27depending therefrom, are anticipated by Leonhardt.

6. Claim 28

Independent claim 28 recites, in part, an artificial valve for repairing a damaged heart valve comprising a flexibly resilient frame having a plurality of peripheral anchors and "a band attached to the frame limiting spacing between adjacent anchors of said plurality of peripheral anchors." Ex. 1001, 13:66–14:17. As with the band of claim 1, Petitioner asserts that two different structures of Leonhardt can correspond to the recited band. First, Petitioner argues that the cylindrical portions at the ends of stent 26 are "circumferential rings of frame elements" that define a band. Pet. 24 (citing Ex. 1017, 4:52–65, 5:23–35, 5:45–48, Fig. 1B). Second, Petitioner argues graft material 24, which surrounds stent 26, is also a band. *Id.*

For the reasons discussed above in connection with claim 1, however, we determine that neither Leonhardt's cylindrical portions nor graft material 24 are a band. *See supra* § III.D.2. We thus determine that Leonhardt fails to disclose all limitations of claim 28. Accordingly, for at least the foregoing reasons, Petitioner has not shown, by a preponderance of the evidence, that independent claim 28 is anticipated by Leonhardt.

7. Claim 29

Independent claim 29 recites, in part, an artificial valve for repairing a damaged heart valve comprising a flexible valve element attached to a frame and having a convex upstream side and a concave downstream side. Ex. 1001, 14:57–15:12. Petitioner argues that Leonhardt's biological valve 22, which is preferably an intact tricuspid porcine valve, is the flexible valve element having a convex upstream side and a concave downstream side. Pet. 25–26 (citing Ex. 1003 ¶¶ 75–76; Ex. 1017, 6:23–34).

For the reasons discussed above in connection with claim 10, we determine that the Petition does not establish adequately that Leonhardt anticipates a flexible valve element having a convex upstream side and a concave downstream side. *See supra* § III.D.3. We thus determine that Leonhardt fails to disclose all limitations of claim 29. Accordingly, for at least the foregoing reasons, Petitioner has not shown, by a preponderance of the evidence, that independent claim 29 is anticipated by Leonhardt.

8. Claim 30

Like claim 17, independent claim 30 requires an artificial valve for repairing a damaged heart valve comprising, in pertinent part, a first band surrounding and attached to a frame and a second band surrounding and

attached to the frame downstream of the first band. Ex. 1001, 16:3–13. Petitioner asserts that two different structures of Leonhardt can correspond to the first band. First, Petitioner argues that the cylindrical portions at the ends of stent 26 are "circumferential rings of frame elements" that define a band. Pet. 24 (citing Ex. 1017, 4:52–65, 5:23–35, 5:45–48, Fig. 1B). Second, Petitioner argues graft material 24, which surrounds stent 26, is also a band. *Id.*

Regarding the second band of claim 17, Petitioner argues that "Leonhardt's stent arrangement includes two spaced-apart cylindrical portions of frame elements," and these two cylindrical portions are the first and second bands. Pet. 25 (citing Ex. 1003 ¶¶ 71–74; Ex. 1017, 4:26–65, 5:23–37, Fig. 1B). Also, although not asserted in the Petition, Dr. Dasi testifies that one of ordinary skill in the art "would interpret the downstream portion of graft material 24 of Leonhardt which extends beyond the mounting of the [flexible valve element] in the central portion, as meeting the second band recitation." Ex. 1003 ¶ 72. Dr. Dasi further testifies that "identifying different portions of a unitary structure as satisfying different claim elements is appropriate here." *Id.* ¶ 73.

For the reasons discussed above in connection with claim 17, we determine that the Petition does not establish adequately that Leonhardt anticipates first and second bands. *See supra* § III.D.4. We thus determine that Leonhardt fails to disclose all limitations of claim 30. Accordingly, for at least the foregoing reasons, Petitioner has not shown, by a preponderance of the evidence, that independent claim 30 is anticipated by Leonhardt.

E. Asserted Obviousness over Leonhardt and Andersen

Petitioner contends claims 1, 2, 4–8, 10–13, 17–19, 21, 22, and 25–30 would have been obvious over Leonhardt and Andersen. Pet. 44–49. Patent Owner disputes Patent Owner's contentions. PO Resp. 39–48.

In asserting this ground, Petitioner states that its discussion of Leonhardt made in connection with the ground asserting the claims are anticipated by Leonhardt is equally applicable here. Pet. 44. Petitioner argues that Andersen, like Leonhardt, discloses a valve comprising "a stent and a biological cardiac valve and band mounted inside, which can be placed transluminally into a patient to define upstream and downstream regions." *Id.* (citing Ex. 1006, 2:34–68, 3:1–4, 3:37–42, 5:9–39, 6:3–44, Figs. 1, 2, 8–10; Ex. 1003 ¶¶ 92–100). According to Petitioner, Andersen's stent is a flexibly resilient frame including two or more rings having U-shaped members joined together midway between the respective ends. *Id.* at 45 (citing Ex. 1006, 2:39–42, 2:45–52, 2:60–64, 3:16–17, 5:9–28, 6:66–7:12, 7:17–23, Figs. 1, 2; Ex. 1003 ¶ 93). Petitioner further argues that the extremities of the rings can be peripheral anchors and the region between these peripheral anchors is a central portion. *Id.* at 46 (citing Ex. 1006, 5:33–35, 6:54–63, Figs. 1, 2, 8, 9; Ex. 1003 ¶ 94). Last, Petitioner asserts that Andersen, like Leonhardt, uses a biological valve obtained from a slaughtered pig and including a band of root tissue. *Id.* (citing Ex. 1006, 2:34–36, 5:11–17, 5:29–39, 7:12–16; Ex. 1003 ¶¶ 95–96).

Next, Petitioner asserts that "[i]t would have been obvious to interchange *elements* of Andersen for those of Leonhardt" because both references relate to replacement valves having a collapsible and expandable stent, a band, and a porcine valve for transcatheter implantation. *Id.* at 47

(citing Ex. 1003 ¶¶ 92–102) (emphasis added). Petitioner also asserts that one of ordinary skill in the art "would have reason to consider using the Andersen stent, *or aspects of it*, in place of the Leonhardt stent. *Id.* at 47–48 (emphasis added).

Patent Owner argues that one of ordinary skill in the art would not have been to combine Leonhardt and Andersen because Leonhardt teaches away from using features of Andersen. PO Resp. 40 (citing Ex. 2026 § 2.1.2.1). In particular, Patent Owner points to a portion of Leonhardt's specification that discusses perceived drawbacks of the valve disclosed in Andersen. *Id.* at 40–41 (citing Ex. 1017, 2:53–3:14).

> Leonhardt states that the Andersen valve
>
> > requires a special trisection balloon with three or more projecting beads to secure the valve within the deployment catheter during placement, and the stent does not exert sufficient force against the tissue to remain in place without a balloon expanding the stent tightly into the tissue wall. The stiffness of stainless steel does not comply with the natural movement of the cardiovascular system which may lead to stenosis at the implantation point. Furthermore, the suture points connecting the multiple rings are subject to movement and wear against each other and therefore the sutures or the rings may break at the connecting points.

Ex. 1017, 2:59–3:3. Leonhardt also states that the Andersen valve may not be removed or repositioned after placement, leading to potential problems in the event of misplacement or failure of the valve. *Id.* at 3:4–11. Also, the Andersen valve is alleged to not seal to the living tissue at the outside wall, likely leading to leaks and emboli. *Id.* at 3:11–14.

In reply, Petitioner asserts that

> Leonhardt suggests that Andersen's stent formed from stainless steel *may* result in a stent that is too stiff. (Ex. 1017, at 2:64–66.) But Leonhardt proposes using nickel-titanium alloys. (*Id.* at 5:11–22.) Andersen's valve was not repositionable. (*Id.* at 3:4–6.) Leonhardt, however, allows for repositioning. (*Id.* at 11:37–58.) Andersen is also allegedly only balloon-expandable. (*Id.* at 2:59–64.) But this is actually wrong. (Ex. 1006, at 7:21–23.) Moreover, Leonhardt itself teaches a self-expanding stent. (Ex. 1017, at 5:11–22.) So all of these "issues" are addressed.

Reply 15. With the exception of asserting that Leonhardt is wrong regarding the Andersen valve being only balloon-expandable, Petitioner's explanations with respect to the drawbacks of Andersen rely on asserting that Leonhardt does not have the same drawback. This approach, however, does not address Patent Owner's assertion that Leonhardt teaches away from combing with Andersen.

Nevertheless, a reference does not teach away "if it merely expresses a general preference for an alternative invention but does not 'criticize, discredit, or otherwise discourage' investigation into the invention claimed." *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314, 1327 (Fed. Cir. 2009) (quoting *In re Fulton*, 391 F.3d 1195, 1201 (Fed. Cir. 2004)). On the record before us, we are not persuaded that Leonhardt disparages the Andersen valve to the extent that it would discourage one of ordinary skill in the art from investigating the Andersen valve.

Patent Owner also argues that Petitioner has failed to put forth a proper obviousness analysis regarding Leonhardt and Andersen because it fails to explain how or why one of ordinary skill in the art would interchange elements of Andersen for elements of Leonhardt. PO Resp. 42.

We agree with Patent Owner. Petitioner states that it would have been obvious to interchange elements of Andersen for elements of Leonhardt (Pet. 47), but never identifies which specific elements are interchanged. The most specific statement from Petitioner regarding combining Leonhardt and Andersen is to use "the Andersen stent, *or aspects of it*, in place of the Leonhardt stent" (*id.* at 47–48 (emphasis added)), but even this statement does not describe the proposed modification with sufficient particularity. Also, the Petition does not identify any differences between the claimed subject matter and Leonhardt that the teachings of Andersen would satisfy.[4] *See Graham*, 383 U.S. at 17–18.

Dr. Dasi's testimony similarly lacks particularity. For example, Dr. Dasi opines that "the stents, flexible valve elements and bands taught *in the various references discussed herein* are all interchangeable, as are their various components," and "[s]ubstituting *the various elements* of Andersen for those of Leonhardt would be a very natural exercise for a POSA given this near identity of structure and function." Ex. 1003 ¶ 102 (emphases added). Thus, like the Petition, Dr. Dasi does not identify the specific elements that are to be substituted. Dr. Dasi also testifies that "a POSA would freely interchange the elements of Andersen for those of Leonhardt,

[4] We note that Dr. Dasi testifies that "I believe that a POSA would conclude that the valve of Andersen has each of the elements claimed in the independent claims of the '782 Patent based on the Patent Owner's Definitions and to the same extent as the device recited in Patent Owner's Contentions" (Ex. 1003 ¶ 100), but Petitioner does not assert that Andersen anticipates any of the challenged claims.

and that doing so would be a matter of design choice and optimization," but again does not identify which elements are interchanged. *See id.* ¶ 107.

Therefore, neither the Petition nor Dr. Dasi indicates with sufficient particularity, as required by 35 U.S.C. § 312(a)(3), what elements of Andersen are interchanged with elements of Leonhardt and, thus, in what manner Leonhardt and Andersen are combined. *See Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1369 (Fed. Cir. 2016) ("It is of the utmost importance that petitioners in the IPR proceedings adhere to the requirement that the initial petition identify 'with particularity' the 'evidence that supports the grounds for the challenge to each claim.'"). For this reason, Petitioner has not shown, by a preponderance of the evidence, that the challenged claims are unpatentable in view of the combination Leonhardt and Andersen.

We also agree with Patent Owner's argument that Andersen does not cure certain deficiencies of Leonhardt. *See* PO Resp. 43–47. Although the exact combination of Leonhardt and Andersen is not clear for the reasons discussed above, we note that Petitioner asserts that Andersen, like Leonhardt, uses a biological valve obtained from a pig as the flexible valve element. Pet. 46 (citing Ex. 1006, 5:29–39). For the reasons discussed above, however, we determine that the Petition does not establish adequately that porcine tricuspid valve includes a flexible valve element having a convex upstream side and a concave downstream side. *See supra* § III.D.3. Petitioner also asserts that because Andersen uses a porcine valve, Andersen discloses a band of root tissue. Pet. 46 (citing Ex. 1003 ¶¶ 95–96). For the reasons discussed above, however, we determine that the Petition does not

establish adequately that any root tissue harvested with a porcine valve would be a band that limits spacing. *See supra* § III.D.3. Petitioner's reply arguments do not address persuasively how Andersen overcomes these deficiencies. *See* Reply 16–19.

F. Asserted Obviousness over Leonhardt, Johnson, and Imachi

Petitioner contends claims 1, 2, 4–8, 10–13, 17–19, 21, 22, and 25–30 would have been obvious over Leonhardt, Johnson, and Imachi. Pet. 49–70. Patent Owner disputes Patent Owner's contentions. PO Resp. 48–55.

1. Overview of Johnson

Johnson "relates to a synthetic leaflet aortic or mitral heart valve prosthesis." Ex. 1021, 1:7–8. Figures 1 and 2 of Johnson are reproduced below.

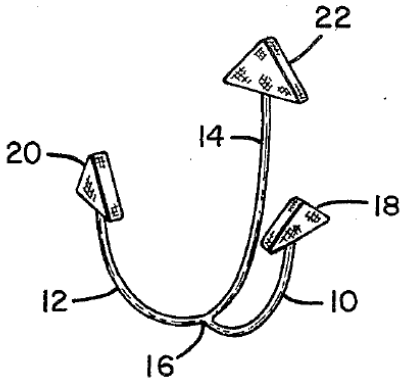


Fig. 1

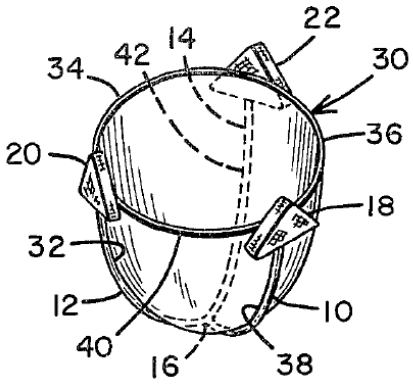


Fig. 2

Figure 1 shows the flexible central framework of a dynamic annulus heart valve, and Figure 2 shows the complete dynamic annulus heart valve. *Id.* at 3:54–58. The framework depicted in Figure 1 comprises three arcuate shaped struts 10, 12, and 14 joined together at point 16. *Id.* at 4:10–12. Alternatively, the framework could comprise four struts, in which case the

struts would extend radially at 90 degrees from one another. *Id.* at 5:22–27. Suture pads 18, 20, and 22 are attached to the extremities of the struts. *Id.* at 4:15–17. The struts may comprise a resilient or a springy material that is nonthrombogenic. *Id.* at 4:22–25.

Figure 2 shows flexible membrane 30 attached to the framework. *Id.* at 4:49–51. Membrane 30 has a hemispheric or paraboloid shape that fits within the framework and is attached to struts 10, 12, and 14 at all points extending from point 16 to suture pads 18, 20, and 22. *Id.* at 4:57–63. Thus,

> the dynamic annulus heart valve depicted in FIG. 2 constitutes a flexible central frame to which the flexible membrane is attached to form at least three valve leaflets which expand outwardly in the reverse direction of flow of blood to block passage of blood through a valve annulus and which contract inwardly against one another to allow forward flow of blood.

Id. at 5:12–19.

Figure 7 of Johnson is reproduced below.

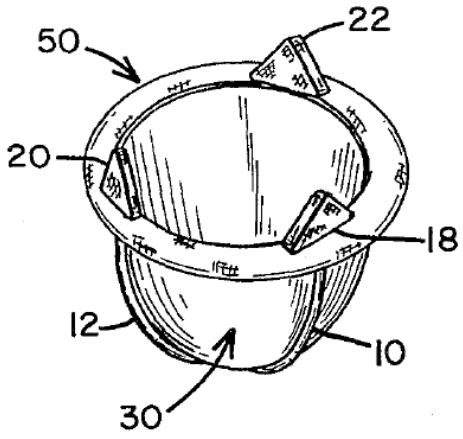


Fig. 7

Figure 7 shows the dynamic annulus heart valve with reconstruction ring 50. *Id.* at 6:8–10. Reconstruction ring 50 comprises inner doughnut

shaped body 52 made of a relaxed and pliant silicone rubber and fabric sleeve 54 surrounding body 52. *Id.* at 5:57–61, Fig. 6. Reconstruction ring 50 is sutured in place to the remaining heart tissue, whereby tissue ingrowth into fabric sleeve 54 will take place over time. *Id.* at 5:62–68.

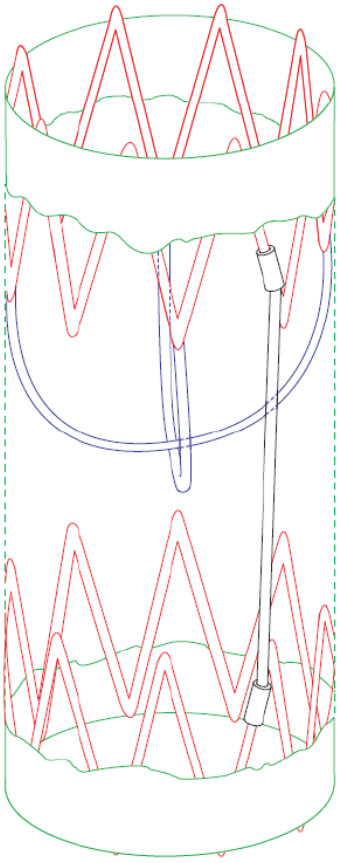
2. Overview of Imachi

Imachi "relates to a medical valve apparatus comprising a valve seat and a movable valve membrane, which is valuable, for example, as an artificial valve apparatus of a pulsatile artificial heart or a pulsatile artificial heart-lung machine." Ex. 1020, 1:9–13. In one embodiment, Imachi discloses a medical valve apparatus having funnel-shaped valve seat 8 with holes 9 and movable valve membrane 7 having a funnel-like shape conforming to valve seat 8. *Id.* at 3:49–60; Figs. 3A–3C.

3. The Proposed Combination

Petitioner argues that a person having ordinary skill in the art would have been motivated to substitute a funnel valve and cage structure taught in Johnson in place of Leonhardt's biological valve. Pet. 50. Petitioner provides a drawing, labelled "Fig. H" and reproduced below, purporting to schematically depict the structure resulting from the proposed combination.

FIG.H



Id. at 51. Figure H depicts the "birdcage-like frame" of Johnson the stent of Leonhardt. Petitioner relies on Imachi as an alternative teaching to omit the intermediate attachments between Johnson's flexible membrane 30 and struts 10, 12, and 14. *Id.* at 63–64.

4. Reasons for Combining

As one reason for combining Leonhardt and Johnson, Petitioner asserts that "no motivation should be required to substitute equivalent known elements in this way from among the known technology." *Id.* at 67; *see also id.* at 50 (making similar argument regarding substituting known equivalents). Patent Owner disputes this assertion, arguing that "Petitioner's

proposed combination is not replacing one valve for another valve or one frame for another frame. Rather, Petitioner proposes to place the entire non-collapsible frame and valve of one reference (Johnson) *inside* the collapsible frame of another reference (Leonhardt)." PO Resp. 49.

We find Patent Owner's argument persuasive. Petitioner's proposed modification is not the mere substitution of one element for another known in the field. Petitioner does not propose to simply replace the biological valve element of Leonhardt with the valve element of Johnson. Instead, as Patent Owner correctly notes, Petitioner proposes replacing the biological valve element of Leonhardt with the *entire* valve device of Johnson. Johnson's dynamic annulus heart valve and the biological valve element of Leonhardt, however, are distinct and different structures. Thus, contrary to Petitioner's assertion, Johnson's heart valve is not equivalent to the biological valve element of Leonhardt.

Petitioner also argues that "Leonhardt provides an express teaching to substitute mechanical and synthetic valves for its biological valve (Ex.1017 col.6:31–34) and Johnson provides motive for Leonhardt to make this substitution." Pet. 50. Petitioner adds that because one of ordinary skill in the art would know that patients most in need of transcatheter procedures are the frailest, the skilled artisan would be very interested in durable solutions and Johnson teaches a durable transcatheter valve. *Id.* (citing Ex. 1003 ¶¶ 39, 117, 156–158; Ex. 1021, 2:39–42, 3:37–47). More specifically, Petitioner argues "Johnson discloses that tissue valves, such as those preferred in Leonhardt, have had durability problems resulting from, *inter alia,* the fact that the leaflets are attached to a rigid or semirigid [sic] fixation

ring around the perimeter." *Id.* at 67. According to Petitioner, one of ordinary skill in the art would have been motivated to try the construction of Johnson's valve to replace a native tissue valve of Leonhardt to obtain a more durable valve. *Id.*

We are not persuaded by these arguments. Johnson describes several prior art prosthetic heart valves that "employ rigid or semi-rigid valve ring structures which do not enjoy the ability to flex or move with the movement of the tissue annulus as the heart expands and contracts." Ex. 1021, 2:26–30. Johnson indicates these ring structures are bulky in that they occupy up to 50 percent of the available annular area for blood flow. *Id.* at 2:33–34. According to Johnson, the absence of such a bulky fixation ring increases the durability of its valve design, while tissue or synthetic valve designs have durability problems because the leaflets are attached to a rigid or semi-rigid outer fixation ring. *Id.* at 3:36–41.

Contrary to Petitioner's assertion, the tissue valve of Leonhardt does not include a rigid or semi-rigid outer fixation ring that would present the durability problems described in Johnson. Instead, Leonhardt employs stent 26, which is a flexible frame made of super elastic material that allows it to deform under exerted forces and conform to structures occurring within vessel walls. Ex. 1017, 4:60–65. Thus, based on the record before us, there is no indication that Leonhardt would suffer the durability problems with which Johnson is concerned. As such, one of ordinary skill in the art would not expect the proposed modification to improve the durability of Leonhardt's valve and, thus, would not be motivated to make the proposed combination. Moreover, Leonhardt's disclosure of using a mechanical or

synthetic valve instead of a preferred biological valve (Ex. 1017, 6:31–33), by itself, does not provide sufficient reasoning for combining Leonhardt and Johnson in the manner proposed.

5. Conclusion

For the above reasons, we determine that Petitioner has not established an adequate rationale for combining Leonhardt and Johnson in the manner proposed. Therefore, Petitioner has not shown, by a preponderance of the evidence, that the challenged claims are unpatentable in view of the combination Leonhardt, Johnson, and Imachi.

G. Secondary Considerations

Patent Owner argues that numerous objective indications of the non-obviousness, such as peer recognition, long-felt but unresolved need, commercial success, and acceptance and adoption by industry, exist and weigh heavily against deeming the invention of the '782 patent obvious. PO Resp. 56–61. Because we are not persuaded Petitioner has demonstrated sufficiently that the combinations of Leonhardt and Andersen and Leonhardt, Johnson, and Imachi render the challenged claims obvious, we need not reach Patent Owner's assertions regarding secondary considerations.

H. Constitutional Issue

Patent Owner objects to *inter partes* review "because it is carried out by a final order issued by Administrative Patent Judges who have not been nominated by the President and confirmed by the Senate." PO Resp. 61–62. According to Patent Owner, Administrative Patent Judges are "principal Officers" under the Constitution's Appointments Clause (U.S. Const. Art. II,

§ 2, Cl. 2), meaning they must be nominated by the President and confirmed by the Senate in order to exercise their authority constitutionally with respect to *inter partes* reviews. *Id.*

Patent Owner, however, does not direct us to any authority holding that Administrative Patent Judges are principal Officers under the Appointments Clause. Furthermore, in 2008, Congress changed the law to provide that Administrative Patent Judges be appointed by the Secretary of Commerce in consultation with the Director. Pub. L. 110–313, 122 Stat 3014 (Aug.12, 2008). Accordingly, we are not persuaded that Administrative Patent Judges conducting *inter partes* reviews is unconstitutional.

I. Motion to Exclude Evidence and Motion to Strike

Petitioner's Motion to Exclude Evidence seeks to exclude from Patent Owner's Sur-Reply the sentence at lines 13–15 on page 5 and the sentence at lines 2–4 on page 6, as well as the corresponding figure provided after this sentence. Mot. to Exclude 1. Petitioner argues these sentences and the figure should be excluded under Federal Rules of Evidence (FRE) 802 as impermissible hearsay, under FRE 402 as irrelevant, and under FRE 702 because there is no showing the author has the requisite scientific, technical, or other specialized knowledge. *Id.* at 2–6. Petitioner also argues the second sentence and its corresponding figure should be excluded under 37 C.F.R. § 42.63(a). *Id.* at 7. Patent Owner disputes these arguments. Opp. Mot. to Exclude 3–11.

We do not rely, however, on either of these sentences or the corresponding figure in rendering our decision. Therefore, we *dismiss* Petitioner's Motion to Exclude Evidence as moot.

Petitioner's Motion to Strike requests the Board to strike the same material from Patent Owner's Sur-Reply. Mot. To Strike 1. Because we do not rely on any of this material in rendering our decision, we *dismiss* Petitioner's Motion to Strike as moot.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that claims 1, 2, 4–8, 10–13, 17–19, 21, 22, and 25–30 of the '782 patent have not been shown to be *unpatentable*;

FURTHER ORDERED that Petitioner's Motion to Exclude Evidence (Paper 45) is *dismissed* as moot;

FURTHER ORDERED that Petitioner's Motion to Strike (Paper 46) is *dismissed* as moot;

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

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