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Paper 55
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 IPR2018-00107
Patent 6,821,297 B2

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

WEATHERLY, *Administrative Patent Judge*.

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

I. INTRODUCTION

A. BACKGROUND

St. Jude Medical, LLC ("Petitioner") filed a petition (Paper 3, "Pet.") to institute an *inter partes* review of claims 1–3, 8, 9, 22, 23, 31–35, 37–39, and 45 (the "challenged claims") of U.S. Patent No. 6,821,297 B2 (Ex. 1001,

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

"the '297 patent"). 35 U.S.C. § 311. Petitioner supported the Petition with a Declaration from Lakshmi Prasad Dasi, Ph.D. (Ex. 1003). Snyders Heart Valve LLC ("Patent Owner") timely filed a Preliminary Response. Paper 10 ("Prelim. Resp."). On May 3, 2018, based on the record before us at the time, we instituted an *inter partes* review of all challenged claims. Paper 16 ("Institution Decision" or "Dec."). The challenges to the claims are:

References	Basis	Claims challenged
U.S. Patent No. 5,855,601 (Ex. 1008, "Bessler")	§ 102	1–3, 8, 9, 22, 23, 31–35, 37–39, and 45
U.S. Patent No. 5,957,949 (Ex. 1017, "Leonhardt")	§ 102	1–3, 8, 9, 22, 23, 31–35, 37–39, and 45
Bessler	§ 103	1–3, 8, 9, 22, 23, 31–35, 37–39, and 45
Leonhardt	§ 103	1–3, 8, 9, 22, 23, 31–35, 37–39, and 45
Bessler and U.S. Patent No. 6,623,518 B2 (Ex. 1053, "Thompson")	§ 103	3, 23, and 29
Bessler and International Patent Pub. No. WO 1997/016133 A1 (Ex. 1054, "Taylor")	§ 103	3, 23, and 29
Bessler and U.S. Patent No. 4,339,831 (Ex. 1021, "Johnson")	§ 103	1–3, 8, 9, 22, 23, 31–35, 37–39, and 45
Bessler, Johnson, and Thompson	§ 103	3, 23, and 39
Bessler, Johnson, and Taylor	§ 103	3, 23, and 39

After we instituted this review, Patent Owner filed a Patent Owner Response in opposition to the Petition (Paper 30, "PO Resp.") that was supported by a Declaration from Dr. Nicholas Chronos (Ex. 2026).

Petitioner filed a Reply in response to the Patent Owner's Response (Paper 38, "Reply"). With our prior authorization, Patent Owner filed a Surreply in response to the Reply (Paper 40, "Surreply"). Patent Owner did not move to amend any claim of the '297 patent.

With our prior authorization, Petitioner filed a motion to strike portions of the Surreply (Paper 45 "Motion"), and Patent Owner filed an opposition to the Motion (Paper 47 "Opp." or "Opposition").

We heard oral argument on January 30, 2019. A transcript of the argument has been entered in the record (Paper 54, "Tr.").

We have jurisdiction under 35 U.S.C. § 6. The evidentiary standard is a preponderance of the evidence. *See* 35 U.S.C. § 316(e); 37 C.F.R. § 42.1(d). This Final Written Decision is issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73.

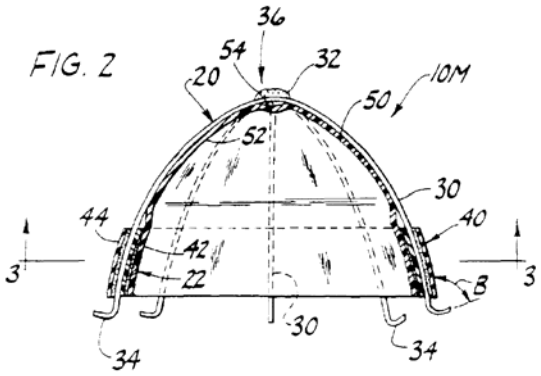
For the reasons expressed below, we conclude that Petitioner has demonstrated by a preponderance of evidence that all challenged claims are unpatentable, but not for every challenge. We provide our analysis of every challenge to claims below.

B. RELATED PROCEEDINGS

The parties identified as a related proceeding the co-pending district court proceeding of *Snyders Heart Valve LLC v. St. Jude Medical SC, Inc., et al*, Case Number 4:16-cv-00812 (E.D. Tex.). Pet. 1; Paper 5, 2. Patent Owner also identified *Snyders Heart Valve LLC v. Medtronic, Inc. et al*, 4:16-cv-00813 (E.D. Tex.). Paper 5, 2. Petitioner identified three petitions for *inter partes* review filed in IPR2018-00105, -00106, and -00109 as being related. *See* Pet. 1 (identifying these proceedings using Petitioner's docket numbers).

C. THE '297 PATENT

The '297 patent, titled "Artificial Heart Valve, Implantation Instrument and Method Therefor," issued November 23, 2004, with claims 1–46. Ex. 1001, (54), (45), 19:11–24:65. The '297 patent is directed to "artificial heart valves for repairing damaged heart valves." *Id.* at 1:15–16. Figures 2 and 3 of the '297 patent are reproduced below.



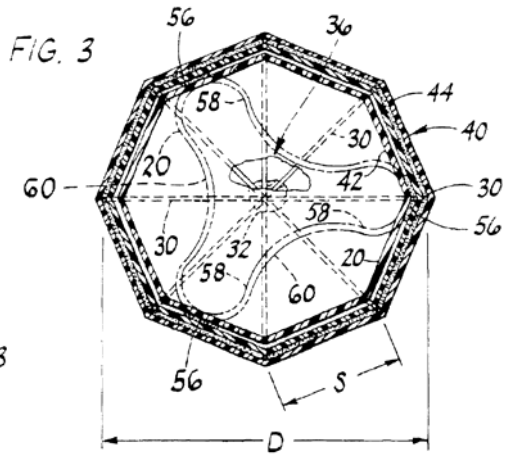


Figure 2 depicts "a vertical cross section of an artificial valve," and Figure 3 depicts "a cross section of the valve taken in the plane of line 3–3 of FIG. 2." *Id.* at 4:11–13. Artificial valve 10M shown in Figures 2 and 3 "is specifically configured for repairing a damaged mitral valve," although the '297 patent also discloses an artificial valve configured to repair a damaged pulmonary heart valve. *Id.* at 4:33–5:5.

Artificial valve 10M comprises flexibly resilient external frame 20 and flexible valve element 22. *Id.* at 5:17–19. Frame 20 includes U-shaped stenting elements 30 that are joined together generally midway between their respective ends at junction 32. *Id.* at 5:25–30. 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 5:30–38. 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 5:58–62. Frame 20 further includes central portion 36 located between peripheral anchors 34. *Id.* at 6:4–7.

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 6:8–17. Band 40 preferably includes internal strip 42 and external strip 44 joined in face-to-face relation. *Id.* at 6:52–56.

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 7:7–18. 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 7:17–22. 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 7:22–27.

More specifically, apex 54 of upstream side 50 is attached to junction 32 of frame 20. *Id.* at 7:55–57. 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 56. *Id.* at 7:57–8:1. Flaps 58 and corresponding portions

of band 40 define openings 60 when valve element 22 moves to its open position. *Id.* at 8:1–5.

Figure 4 of the '297 patent is reproduced below.

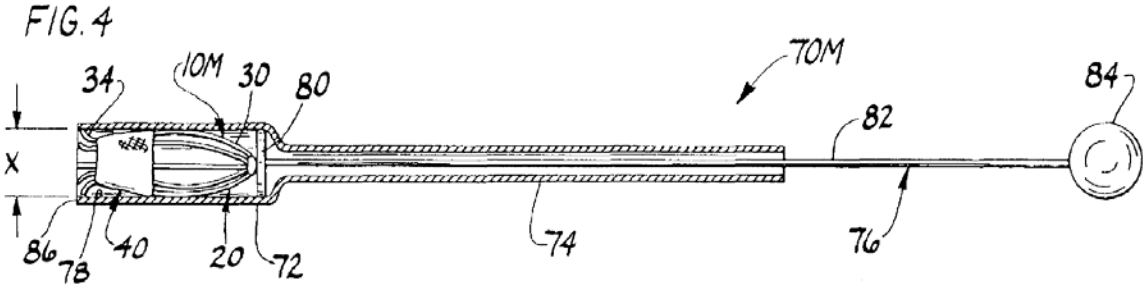


Figure 4 depicts "a vertical cross section of an instrument for implanting a valve using an endothoracoscopic procedure." *Id.* at 4:14–16. The instrument of Figure 4 includes tubular holder 72 and elongate tubular manipulator 74 attached to the holder for manipulating the holder into position. *Id.* at 8:28–31. 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 8:31–34.

Claims 1, 22, 31, and 38 are the independent claims among the challenged claims. *Id.* at 19:11–52 (claim 1), 21:54–22:25 (claim 22), 22:57–23:33 (claim 31), 23:56–24:45 (claim 38). Claim 1, which is representative, recites:

> 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 along a centerline extending between the plurality of peripheral anchors and between the upstream region and the downstream region when said frame is inserted in the position between the upstream region and the downstream region;

a flexible valve element attached to the central portion of the frame 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 flexible 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 flexible valve element permits downstream flow between said upstream region and said downstream region and

a closed position in which the flexible valve element blocks flow reversal from said downstream region to said upstream region,

wherein the flexible 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 flexible 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; and

an opening extending through at least one of said frame and said flexible valve element for receiving an implement.

Id. at 19:11–52 (with line breaks added for clarity).

II. ANALYSIS

A. LEGAL STANDARDS

Petitioner challenges the patentability of claims 1–3, 8, 9, 22, 23, 31–35, 37–39, and 45 on the grounds that the claims are either anticipated or obvious in light of various references including: Bessler, Leonhardt, Thompson, Taylor, and Johnson. To prevail in its challenges to the patentability of the claims, Petitioner must establish facts supporting its challenges by a preponderance of the evidence. 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")). This burden remains with Petitioner during the trial. *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).

"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). The Supreme Court in *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398 (2007), reaffirmed the framework for determining obviousness as set forth in *Graham v. John Deere Co.*, 383

U.S. 1 (1966). The *KSR* Court summarized the four factual inquiries set forth in *Graham* that we apply in determining whether a claim is unpatentable as obvious under 35 U.S.C. § 103(a) as follows:
(1) determining the scope and content of the prior art, (2) ascertaining the differences between the prior art and the claims at issue, (3) resolving the level of ordinary skill in the pertinent art, and (4) considering objective evidence indicating obviousness or nonobviousness. *KSR*, 550 U.S. at 406 (citing *Graham*, 383 U.S. at 17–18). In an *inter partes* review, 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). Thus, to prevail Petitioner must explain how the proposed combinations of prior art would have rendered the challenged claims unpatentable. With these standards in mind, we address each challenge below.

B. LEVEL OF ORDINARY SKILL

Petitioner contends that a person having ordinary skill in the art to which the '297 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. 15 (citing Ex. 1001; Ex. 1006; Ex. 1008; Ex. 1009; Ex. 1010; Ex. 1020; Ex. 1003, ¶¶ 15–17). Patent Owner neither disputes this contention in its Response, or Surreply, nor proffer 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 record, including the asserted prior art and, for the purposes of this Final Written Decision, we adopt Petitioner's definition.

C. THE PARTIES' POST-INSTITUTION ARGUMENTS

In our Institution Decision, we concluded that the argument and evidence adduced by Petitioner demonstrated a reasonable likelihood that at least one claim was unpatentable as anticipated by Leonhardt, and we instituted trial on all challenges identified in the table in Part I.A above. Dec. 15. We must now determine whether Petitioner has established by a preponderance of the evidence that the specified claims are unpatentable over the cited prior art. 35 U.S.C. § 316(e). We previously instructed Patent Owner that "any arguments for patentability not raised in the [Patent Owner Response] will be deemed waived." Paper 17, 7; *see also In re Nuvasive, Inc.*, 842 F.3d 1376, 1381 (Fed. Cir. 2016) (holding that patent owner's failure to proffer argument at trial as instructed in scheduling order constitutes waiver). Additionally, the Board's Trial Practice Guide states that the Patent Owner Response "should identify all the involved claims that are believed to be patentable and state the basis for that belief." Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,766 (Aug. 14, 2012).

D. CLAIM INTERPRETATION

"A claim in an unexpired patent that will not expire before a final written decision is issued shall be given its broadest reasonable construction in light of the specification of the patent in which it appears." 37 C.F.R. § 42.100(b) (2018); *see also Cuozzo Speed Techs., LLC v. Lee*, 136 S.Ct. 2131, 2144–46 (2016) (affirming that USPTO has statutory authority to construe claims according to Rule 42.100(b)). When applying that standard, we interpret the claim language as it would be understood by one of ordinary skill in the art in light of the specification, and absent any special definition, we give claim terms their ordinary and customary meaning. *See In re Suitco Surface, Inc.*, 603 F.3d 1255, 1260 (Fed. Cir. 2010); *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007) ("The ordinary and customary meaning is the meaning that the term would have to a person of ordinary skill in the art in question." (internal quotation marks omitted)). Only terms that are in controversy need to be construed, and then only to the extent necessary to resolve the controversy. *See Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999).

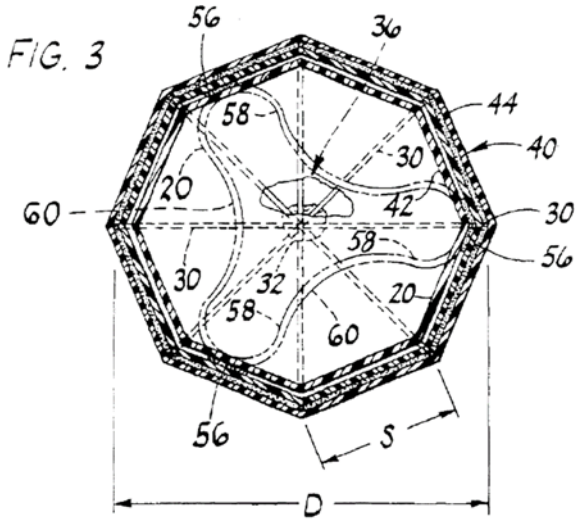
We consider it necessary to construe the terms below to resolve issues presented by the parties during the trial.

1. Claims 1, 22, 31, and 38: "attached to"

Independent claims 1, 22, 31, and 38 require that the "flexible valve element" is "attached to" a frame in various ways. Ex. 1001, 19:25 (claim 1), 21:64 (claim 22), 23:3–4 (claim 31), 24:3 (claim 38). Patent Owner argues that "attached to" as recited in each claim means "directly attached to" and excludes securing the valve element to a frame indirectly through an intervening structure. PO Resp. 7. We disagree.

Patent Owner correctly notes that the Specification "contemplates direct attachment" of the flexible valve element to the frame. *Id*. at 8. However, the portion of the Specification on which Patent Owner relies also describes indirectly attaching the flexible valve element to a frame by securing it to a band that is directly attached to the frame. Ex. 1001, 7:55–66. This type of indirect attachment is illustrated in Figure 3, reproduced below right. The Specification describes Figure 3 as follows:

> As illustrated in FIG. 3, the flexible valve element 22 is attached to the central portion 36 of the frame 20 at a position substantially centered between the anchors 34. Although the valve element 22 may be attached to the frame 20 by other means without departing from the scope of the present invention, the valve element of the preferred embodiment is attached to the frame by adhesive bonding. *Further, the flexible valve element 22 is attached to the frame 20, and more particularly to the band 40, at several attachment points 56 around the frame*.



Id. at 7:57–66 (emphasis added). This passage indicates that the flexible valve element is attached to the frame in two ways: (1) directly by being bonded to the central portion 36 of frame 20 and (2) indirectly by being attached to band 40 at attachment points 56. The Specification later expresses a preference for bonding valve element 22 to band 40 with adhesive. *Id*. at 8:11–14. Interpreting "attached to" to mean "directly attached to" as suggested by Patent Owner would be inconsistent with the Specification's broader description of how valve element 22 is attached to frame 20.

We interpret claim language "in light of the specification of the patent in which it appears." 37 C.F.R. § 42.100(b) (2018). Doing so requires us to interpret claim language 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 inventor describes both direct and indirect methods of attaching the flexible valve element to the frame. Accordingly, we interpret "attached to" as encompassing both direct and indirect ways of attaching the flexible valve element to the frame.

2. Claims 1, 31, and 38: "central portion of the frame"

Each of claims 1, 31, and 38 recites a relationship between the flexible valve element and the "central portion of the frame." Patent Owner argues that "central portion of the frame" means "central structural frame portion," which cannot refer solely to an "empty space." PO Resp. 3–7. Patent Owner explains that, during the related litigation, Petitioner agreed that the central portion of the frame must "actually be part of the structure of the frame." *Id*. at 6 (quoting Ex. 2001, 119–20). Accordingly, we discern no dispute on the issue of whether "central portion of the frame" refers to a structural portion of the frame; it does.

3. Claim 22: "flexible valve element . . . having a convex upstream side . . . and a concave downstream side"

Claim 22 recites a "flexible valve element . . . having a convex upstream side . . . and a concave downstream side." Ex. 1001, 21:64–22:3. 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 argues that "convex upstream side" means "an upstream side that bulges out in the upstream direction," and "concave downstream side" means "a downstream side that bulges away from the downstream

side." Pet. 19. Petitioner neither analyzes nor cites evidence from the Specification or prosecution history of the '297 patent in support of its position. *Id*. (citing Ex. 1040, 4; Ex. 1041, 36–37).

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. 26–28. To resolve that dispute and compare the claims to other prior art including Bessler and Johnson, 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." Claim 22 recites "a flexible valve element fixedly attached to the frame so that *at least a portion of the element* is substantially immobile with respect to *at least a portion of the frame*." Ex. 1001, 21:64–66 (emphasis added). Thus, when only a portion of the flexible valve element must exhibit a characteristic, the claim expressly refers to a "portion" of the valve element.

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*, 871 F.3d at 1383. 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, 7:8–18 (emphasis 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.

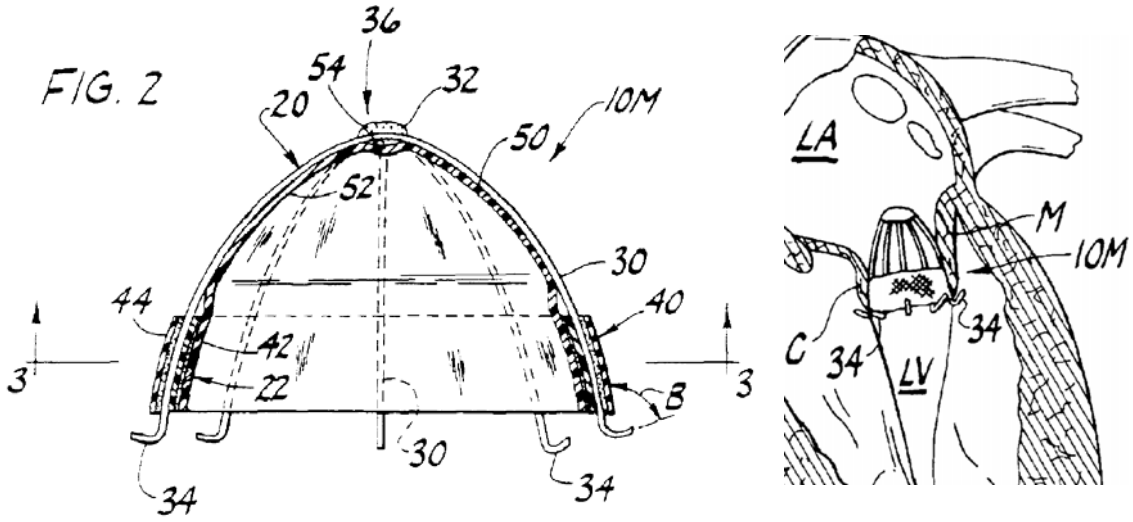
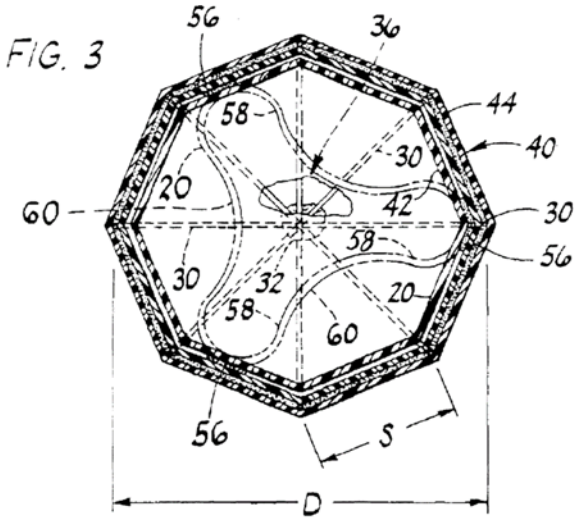


Figure 2, reproduced above left, is a cross-sectional view of valve 10M illustrating convex upstream side 50 and concave downstream side 52 of flexible valve element 22. *Id*. at 4:11. The portion of Figure 1 that is reproduced above right illustrates valve 10M placed with its concave side facing the left ventricle LV (i.e., the downstream region) and the convex side facing the left atrium LA (i.e., the upstream region). *Id*. at 4:9–10, 7:8–18.



The entirety of upstream side 50 is convex and the entirety of downstream side 52 is concave when valve element 22 is "extended outward" 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 7:18–36. Figure 3 illustrates an open valve element 22 in phantom lines such that valve element 22 is "collapsed inward" with openings 60 to permit blood flow that are defined by flaps 58 between adjacent attachment points 56. *Id*. at 7:64–8:5.[2] 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,

[2] The Specification describes another embodiment of the flexible valve element 222 having convex upstream side 250 and concave downstream side 252 that is configured materially the same way as flexible valve element 22. *Id*. at 10:13–29, Figures 8, 9.

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.

E. CLAIMS 1–3, 8, 9, 22, 23, 31–35, 37–39, AND 45: ANTICIPATION BY BESSLER

Petitioner contends that Bessler anticipates claims 1–3, 8, 9, 22, 23, 31–35, 37–39, and 45. Pet. 19–36. For the reasons expressed below, we conclude that Petitioner has proven by a preponderance of evidence that Bessler anticipates claims 38, 39, and 45, but has failed to do so for claims 1–3, 8, 9, 22, 23, 31–35, and 37.

1. Overview of Bessler

Bessler "relates to novel heart valves that are especially adapted for placement using minimally invasive surgical techniques and to the method and device useful for such placement." Ex. 1008, 1:8–11. Bessler's Figure 4, reproduced at right, depicts artificial heart valve 30 having a generally cylindrical shape defined by stent member 32. *Id.* at 5:28–31. Stent member 32 is a wire formed into a closed zig-zag configuration having straight sections 33 joined by bends 34. *Id.* at 5:31–34. Flexible valve member 35 extends across the cylindrical stent and includes a plurality of leaflets 36. *Id.* at 5:34–37. Leaflets 36 "are the actual valve and allow for one-way flow of blood." *Id.* at 5:37–38. Cuff portion 37 extends from the periphery of the leaflet portion and along walls 31 of stent member 32 and is attached to the stent member by sutures 38. *Id.*

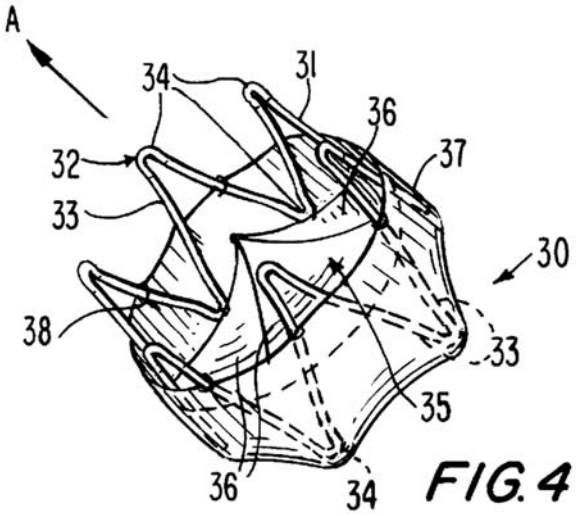


FIG. 4

at 5:38–42. In another embodiment, the stent member includes a plurality of barbs 64 for holding the valve in place. *Id.* at 5:67–6:2, Fig. 7.

The configuration and flexible, resilient material of construction of stent member 32 allows the valve to collapse into relatively small cylinder 40. *Id.* at 5:43–45, Fig. 5. Bessler also discloses device 90 including flexible catheter 91 for percutaneous and transluminal delivery of a heart valve to the desired site. *Id.* at 7:26–30, Figs. 12, 13. Device 90 includes hollow pusher member 93 disposed within catheter 91 and guidewire 94 disposed within pusher member 93 to guide the distal end of the catheter to the desired site. *Id.* at 7:33–38. Means 96 disposed with pusher member 93 holds a collapsed valve in the distal end of catheter 91 and allows the valve to be released when desired. *Id.* at 7:38–40.

2. Petitioner's Argument and Evidence

Petitioner contends that Bessler anticipates each of claims 1–3, 8, 9, 22, 23, 31–35, 37–39, and 45 and identifies specific portions of Bessler that describe each element of the artificial valve of those claims. Pet. 30–37 (citing Ex. 1008, 2:57–63, 3:46–4:21, 4:60–5:14, 5:19–6:31, 7:26–67, 9:59–61, FIGS. 1–7, 12–15). Petitioner also relies on Dr. Dasi's testimony to support its contentions. *Id*. (citing Ex. 1003 ¶¶ 59–88).

3. Analysis of Patent Owner's Counterarguments

Each of independent claims 1, 22, 31, and 38 recite materially differing versions of an artificial valve. Patent Owner argues that Bessler fails to anticipate each independent claim and proffers distinct arguments for patentability of dependent claims 3, 9, 23, and 39. For the reasons expressed below, we find that Patent Owner's arguments are persuasive for claims 1, 22, and 31, and thus also for their respective dependent claims 2, 3, 8, 9, 22,

23, 31–35, 37. However, we also determine that Petitioner has demonstrated by a preponderance of evidence that Bessler anticipates claims 38, 39, and 45.

a) Claims 1–3, 8, 9, 31–35, and 37

Patent Owner argues that Bessler does not anticipate independent claims 1 and 31 because Bessler's flexible valve member is not directly attached to a central portion of its frame. PO Resp. 14; Surreply 1–2. For claims 1 and 31, the central portion of the frame is "located *along a centerline* extending between the plurality of peripheral anchors." Ex. 1001, 19:19–20 (claim 1), 22:67–23:2 (claim 31) (emphasis added).

Petitioner contends that Bessler describes various embodiments in which the valve is attached to a central portion of the frame. Pet. 29–30 (citing Ex. 1008, 3:54–4:3, 5:20–28, 5:35–43, 5:60–6:2, 6:19–31, FIGS. 1–4, 7) For example, Bessler's valve 35 includes cuff portion 37 that wraps around periphery of walls 31, extends in direction A, and is attached to stent 32 via sutures 38. Ex. 1008, 5:28–43. This arrangement is illustrated in Figure 4, which we reproduce at right. Leaflets 36, when closed as shown in Figure 4, form a valve that prevents flow opposing direction A. *Id*. at 5:37–38. Petitioner identifies the "central portion" of stent 32 as the "straight sections 33." Pet. 21.

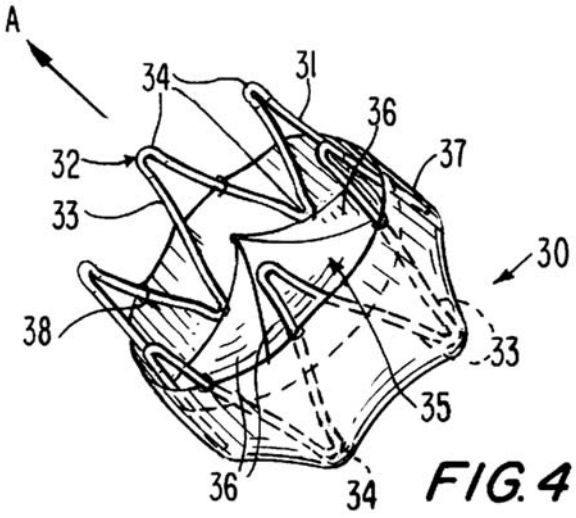


FIG. 4

Petitioner's argument that Bessler's valve is attached to the central part of the frame of claims 1 and 31 fails. Bessler's valve is undeniably

attached to its frame because the cuff portion of the valve is sutured to its stent. Claims 1 and 31 require the valve element to be attached to a portion of the frame located along the radial centerline. Ex. 1001, 19:19–20 (claim 1), 22:67–23:2 (claim 31). Bessler's valves fail to meet this requirement. Bessler's stent 32 is a hollow cylinder devoid of structure located along its centerline,[3] and the "central portion of the frame" identified by Petitioner, straight sections 33, is part of walls 31 located on the radial periphery of stent 32. *Id*. at 5:28–43, Figure 4. Regardless of how Bessler's valve is attached to the wall of its stent, the valve is not attached to structure "located along a centerline" as recited in claims 1 and 31. Therefore, we determine that Petitioner fails to establish by a preponderance of evidence that Bessler anticipates claims 1 and 31 or their respective dependent claims 2, 3, 8, 9, 32–35, and 37.

b) Claims 22 and 23

Independent claim 22 requires the flexible valve to include a "convex upstream side" and a "concave downstream side." Ex. 1001, 21:64–22:3. As explained in Part II.D.3 above, 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.

Petitioner contends that Bessler's valve 35 includes a "convex upstream side" and a "concave downstream side" formed by the plurality of leaflets 36. Pet. 23–24, 42 (citing Ex. 1008, 3:54–64, 5:20–27, 5:36–42, 6:19–24; Ex. 1003 ¶ 72). Dr. Dasi testifies that Bessler's valve exhibits a

[3] Bessler's stents 21, 50, 60 are the same as stent 32 in this respect. Ex. 1008, Figures 1, 6, 7.

complex shape in which individual portions bulge in the upstream direction. *Id*. ¶ 72.

Bessler fails to describe a valve element having opposing convex and concave sides because Bessler's valve does include any side in which the entire side exhibits a convex or concave shape. Accordingly, we determine that Petitioner has failed to prove by a preponderance of evidence that Bessler anticipates claim 22 or its dependent claim 23.

c) Claims 38, 39, and 45

(1) Independent Claim 38

(a) Flexible Valve Element Attached to Central Portion of the Frame

Patent Owner groups claim 38 with claims 1 and 31 when arguing that Bessler fails to describe a valve element directly attached to the frame. PO Resp. 14. Patent Owner argues that, although Bessler's cuff is directly attached to its stent, Bessler's valve leaflets are not directly attached to the frame. *Id*. This argument is unpersuasive because, as explained in Part II.D.1 above, we do not interpret claim 38 to require "direct attachment" of the valve to the frame.

Independent claim 38 recites a frame having "a central portion located between the plurality of peripheral anchors" without further requiring the central portion being "located along a centerline" as recited in claims 1 and 31. Ex. 1001, 24:1–2. Accordingly, the "central portion" of the frame of claim 38 may refer to any portion of the frame that is "between the plurality of peripheral anchors," including a portion that is longitudinally centered.

Cuff portion 37 of Bessler's valve element 35 is attached to stent 32 by sutures 38. Ex. 1008, 5:28–43, Figure 4. Sutures 38 are located close to

the longitudinal center of straight portions 33. *Id*. at Figure 4. The cuff portion 25 of Bessler's valve 22 is similarly attached via sutures 26. *Id*. at Figure 1. A similar arrangement is illustrated in Bessler's valve 63 which is shown with its cuff attached to the walls of the stent near the tops of sections 61 near the longitudinal center of sections 62. *Id*. at Figure 7. Accordingly, Bessler describes attaching its valve to a "central portion" of the frame.

Bessler's longitudinally "central portion" is also located "between the plurality of peripheral anchors." Bessler's Figure 4 illustrates bends 34 in one embodiment and barbs 64 in another that anchor the stent in place once it has been appropriately positioned. *Id*. at 5:28–6:2, Figures 4, 7; Ex. 1003 ¶¶ 63–64. In this way, Bessler "anchors" its stent using a "plurality of peripheral anchors" as recited in claim 38. Bessler's longitudinally centered portion of its stents is located between these "peripheral anchors." For all these reasons, we determine that Bessler's valves are "attached to the central portion of the frame," which is "located between the plurality of peripheral anchors."

(b) Sized and Shaped for Insertion

Claim 38 recites that its "artificial valve" includes a "frame sized and shaped for insertion between the upstream region and the downstream region." Ex. 1001, 23:63–66. The preamble recites that the artificial valve of the claimed combination is "for repairing a damaged heart valve having a plurality of cusps separating an upstream region from a downstream region." *Id*. at 23:57–61.

Patent Owner argues that Bessler fails to describe a valve that is "sized and shaped for insertion between the upstream region and the

downstream region" because Bessler requires removal of the native heart valve prior to insertion of its replacement valve. PO Resp. 14–16. Patent Owner correctly notes that Bessler's valve is implanted after removal of "the diseased or defective heart valve." Ex. 1008, 2:63–65. Patent Owner further explains that when the native heart valve is removed, it is no longer a "damaged heart valve having a plurality of cusps" as recited in the preamble of claim 38. *Id*. at 16.

Patent Owner's argument is unpersuasive because the preamble does not limit the claim as implied. First, the preamble of claim 38 recites the "damaged heart valve" as a mechanism for defining the locations of the upstream and downstream regions. However, those regions remain in the same locations regardless of whether a surgeon has removed the cusps of the damaged heart valve. By reciting that the valve includes a "frame sized and shaped for insertion between the upstream region and the downstream region," the claim merely recites a frame that fits in a location between those two regions. That location remains the same regardless of whether the cusps of the native valve are present. Second, claim 38 is directed to a combination of an artificial valve and an instrument, not a method of implanting an artificial valve without removing the native valve. The claim refers to the cusps of the native valve only to identify the location separating the upstream and downstream regions without commenting upon whether the cusps remain in place when the claimed valve is implanted. Accordingly, the claim may encompass any valve sized and shaped to fit in this location including valves sized and shaped to fit the location after a native heart valve is removed.

Patent Owner also argues that Bessler's barbed embodiment would malfunction if implanted on top of damaged cusps of a native heart valve. Surreply 3 (citing Ex. 1024, 3:48–4:4). Patent Owner cites a patent of another inventor, Bailey, to support its argument. *Id*. Patent Owner's argument is unpersuasive. First, the cited portion of Bailey says nothing about whether Bessler's non-barbed embodiments, which Petitioner also contends to anticipate claim 38, would "malfunction" if implanted without removing an existing native heart valve. Ex. 1024, 3:48–4:4. Second, we have no evidence in the record on whether Bailey is an authoritative source of information for whether any embodiment of Bessler would "malfunction" under any circumstances. Third, the claim encompasses valves sized and shaped for insertion in a location where the native valve has been removed.

For all these reasons, we determine that Petitioner has proven by a preponderance of evidence that Bessler describes a valve with a frame that is "sized and shaped for insertion between the upstream region and the downstream region."

(c) Remaining Elements of Claim 38

We determine that Petitioner has proven by a preponderance of evidence that Bessler describes all remaining elements of claim 38. Our determination is based on Petitioner's argument and evidence, which we adopt as our own. Pet. 23–24, 42 (citing Ex. 1008, 3:54–64, 5:20–27, 5:36–42, 6:19–24; Ex. 1003 ¶ 72).

(d) Conclusion

For the foregoing reasons, we determine that Petitioner has proven by a preponderance of evidence that Bessler anticipates independent claim 38.

(2) Dependent Claim 39

Claim 39 depends from claim 38 and further recites that the: "frame includes a mount for selectively connecting the valve to the instrument." Ex. 1001, 24:46–48. Petitioner identifies the claimed "mount" as the peaks of Bessler's stent around which sutures loop to hold the stent in the instrument until the stent is deployed. Pet. 34–35 (citing Ex. 1008, 7:43–51, 7:53–61, Figures 14, 15; Ex. 1003 ¶¶ 82–83). Patent Owner argues that Bessler's sutures are not a releasable "fastener mounted on the frame" and that just "because you can wrap threads around the Bessler frame does not mean that the frame itself has a 'fastener' or 'mount.'" PO Resp. 16–17; *see also* Surreply 3–4 (reiterating same argument). We disagree.

Claim 39 does not recite a "fastener mounted on the frame" or a "fastener" of any type as implied by Patent Owner. Rather, claim 39 merely recites a "mount for selectively connecting the valve to the instrument." The peaks of Bessler's stent are such a "mount" as reflected by Bessler's use of this structure for "selectively connecting the valve to the instrument" with sutures 105. Accordingly, we determine that Petitioner has proven by a preponderance of evidence that Bessler anticipates claim 39.

(3) Dependent Claim 45

Patent Owner does not argue that Bessler fails to describe any limitation introduced in dependent claim 45, which depends from claim 38. Petitioner identifies the manner in which Bessler describes the limitations introduced in claim 45. Pet. 36–37 (citing Ex. 1008, 7:26–42, Figures 12–13; Ex. 1003 ¶ 87). We adopt as our own Petitioner's argument and evidence, and, on that basis and for the reasons expressed above

regarding base claim 38, we determine that Petitioner has proven that Bessler anticipates claim 45.

(4) Conclusion

For the reasons expressed above, we determine that Petitioner has proven by a preponderance of evidence that Bessler anticipates claims 38, 39, and 45.

4. Summary

For the reasons expressed above, we determine that Petitioner has proven by a preponderance of evidence that Bessler anticipates claims 38, 39, and 45, but has failed to do so for claims 1–3, 8, 9, 22, 23, 31–35, and 37.

F. CLAIMS 1–3, 8, 9, 22, 23, 31–35, 37–39, AND 45: OBVIOUSNESS BY BESSLER

Petitioner argues that even if Bessler fails to describe elements as claimed, an ordinarily skilled artisan would consider "variations" of Bessler to meet the claimed limitations would have been obvious "in view of the general knowledge in the art and the limited number of ways of using known elements to achieve expected results." Pet. 48–50. Petitioner addresses specific "variations" relating to meeting limitations introduced in claims 3 and 23 requiring "releasable fasteners" and limitations introduced in dependent claim 9 requiring a "band." *Id*. However, none of Petitioner's arguments persuasively addresses Bessler's failure to describe elements recited in independent claims 1, 22, and 31 as discussed in Part II.E above. Accordingly, we conclude that Petitioner has failed to prove by a preponderance of evidence that Bessler alone renders claims 1–3, 8, 9, 22, 23, 31–35, and 37 unpatentable as obvious.

Because we determine that Bessler anticipates claims 38, 39, and 45, we consider Petitioner's challenge that Bessler renders these claims unpatentable as obvious to be moot, and we offer no opinion on that aspect of Petitioner's challenge.

G. CLAIM 3, 23, AND 39:
OBVIOUSNESS IN VIEW OF BESSLER AND THOMPSON

1. Claims 3 and 23

Claims 3 and 23 depend ultimately from claims 1 and 22 respectively and recite that the artificial valve further comprises: "a releasable fastener mounted on the frame for selectively connecting the valve to an instrument." Ex. 1001, 19:56–58 (claim 3), 23:26–28 (claim 23). Petitioner relies upon Thompson as describing the "releasable fastener" and Bessler as describing the elements recited in base claims 1 and 22. Pet. 51–53.

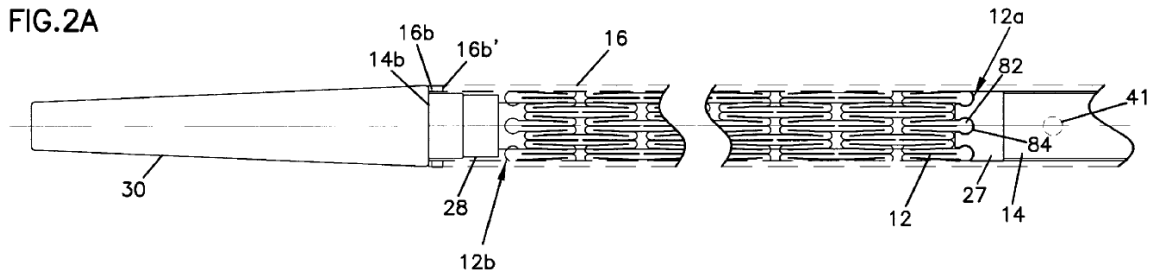
We have already determined that Bessler fails to describe at least one element of each of base claims 1 and 22. *See* Part II.E.3.a) (claim 1), Part II.E.3.b) (claim 22). Petitioner's reliance upon Thompson does not cure the deficiencies in its showing of anticipation for base claims 1 and 22. Therefore, we determine that Petitioner has failed to demonstrate by a preponderance of evidence that the combination of Bessler and Thompson renders claims 3 and 23 unpatentable as obvious.

2. Claim 39

Claim 39 depends from claim 38 and further recites that the: "frame includes a mount for selectively connecting the valve to the instrument." Ex. 1001, 24:46–48.

Petitioner relies upon Thompson as describing the "mount for selectively connecting the valve to the instrument" in the form of its male

interlock structures 82 on the end of its stent 12. Pet. 51 (citing Ex. 1053, 6:37–43, Figure 2A). Thompson's male structures 82 mate with complementary female structures 84 on Thompson's collar 27 within its delivery catheter. Ex. 1053, 6:42–56, Figure 2A. The interlocking of male structures 82 and female structures 84 are shown on the right portion of Thompson's Figure 2A, which we reproduce below.



Thompson's Figure 2A illustrates its stent 12 in a collapsed form. *Id*. at 3:50–51.

Petitioner argues that an ordinarily skilled artisan would have found it obvious to replace Bessler's sutures 105 with the interlocking arrangement of structures 82, 83 because both Thompson and Bessler recognized the need to mitigate premature deployment of a stent from a delivery catheter. Pet. 51 (citing Ex. 1053, 1:65–2:2). Petitioner also contends that the combined teachings of Bessler and Thompson would result in a simpler device with fewer moving parts and a more compact design. *Id*. at 52 (citing Ex. 1003 ¶ 154). Thompson expressly indicates that its stent delivery system is useful for delivering a percutaneous valve, which is the type of implant described by Bessler. Ex. 1053, 11:30–38; Ex. 1003 ¶ 149.

Relying solely upon testimony by Dr. Chronos, Patent Owner argues that Petitioner fails to explain how Thompson's interlocking structures 82, 84 are compatible with the frames for Bessler's valves. PO Resp. 28–29 (citing Ex. 2026 ¶ 4.3.3.1). Patent Owner argues that the alleged lack of

compatibility precludes a finding of obviousness in view of the combined teachings of Bessler and Thompson. *Id*. Patent Owner reiterates its argument in its Surreply without citing any additional supporting evidence. Surreply 11–12. We find Petitioner's argument and evidence to be more persuasive than Patent Owner's evidence.

"[I]t is not necessary that the inventions of the references be physically combinable to render obvious the invention under review." *In re Sneed*, 710 F.2d 1544, 1550 (Fed. Cir. 1983). The relevant inquiry is whether the claimed subject matter would have been obvious to an ordinarily skilled artisan in light of the combined teachings of those references. *See In re Keller*, 642 F.2d 413, 425 (CCPA 1981). "Combining the teachings of references does not involve an ability to combine their specific structures." *In re Nievelt*, 482 F.2d 965, 968 (CCPA 1973). Petitioner persuades us that Thompson suggests using its interlocking features with percutaneous stent structures like those described by Bessler. Ex. 1053, 11:30–38; Ex. 1003 ¶ 149. Although we have determined that Bessler describes the mount introduced in claim 39, we also determine that the combined teachings of Bessler and Thompson render claim 39 unpatentable as obvious.

H. CLAIM 3, 23, AND 39:
OBVIOUSNESS IN VIEW OF BESSLER AND TAYLOR

1. Claims 3 and 23

Claims 3 and 23 depend ultimately from claims 1 and 22 respectively and recite that the artificial valve further comprises: "a releasable fastener mounted on the frame for selectively connecting the valve to an instrument." Ex. 1001, 19:56–58 (claim 3), 23:26–28 (claim 23). Petitioner relies upon Taylor as describing the "releasable fastener" and Bessler as describing the elements recited in base claims 1 and 22. Pet. 53–54.

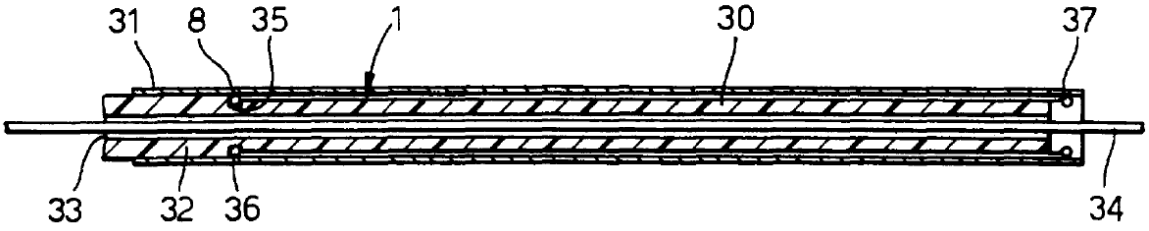
We have already determined that Bessler fails to describe at least one element of each of base claims 1 and 22. *See* Part II.E.3.a) (claim 1), Part II.E.3.b) (claim 22). Petitioner's reliance upon Taylor does not cure the deficiencies in its showing of anticipation for base claims 1 and 22. Therefore, we determine that Petitioner has failed to demonstrate by a preponderance of evidence that the combination of Bessler and Taylor renders claims 3 and 23 unpatentable as obvious.

2. Claim 39

Claim 39 depends from claim 38 and further recites that the: "frame includes a mount for selectively connecting the valve to the instrument." Ex. 1001, 24:46–48.

Petitioner relies upon Taylor as describing the "mount for selectively connecting the valve to the instrument" in the form of beads 8 of the stent at its proximal end 36. Pet. 53 (citing Ex. 1054, 25:16–20, Figure 8). Taylor's male structures 82 mate with complementary female structures 84 on Taylor's collar 27 within its delivery catheter. Ex. 1054, 25:16–20, Figure 8. Beads 8 on proximal end 36 of Taylor's stent mate with circumferential groove 35 in Taylor's pusher tube 32 as shown in Taylor's Figure 8, which we reproduce below.

Fig.8.



Taylor's Figure 8 illustrates its stent 1 in a collapsed form with beads 8 mated to groove 35 in pusher 32. *Id*. at 3:50–51.

Taylor incorporates beads 8 to ensure that the stent does not inadvertently fully release from the device.

Petitioner argues that an ordinarily skilled artisan would have found it obvious to replace Bessler's sutures 105 with the interlocking arrangement of beads 8 and circumferential groove 35 in a valve pusher because both Taylor and Bessler recognized the need to mitigate premature deployment of a stent from a delivery catheter. Pet. 53–54 (citing Ex. 1054, 25:13–20, 25:28–26:9, Figures 8–9; Ex. 1003 ¶¶ 150, 152). Petitioner also contends that the combined teachings of Bessler and Taylor would result in a simpler device with fewer moving parts and a more compact design. *Id*. at 54 (cross referencing motivations to combine teachings describing in connection with Bessler and Thompson). Taylor expressly indicates that its stent delivery system is useful for delivering stents in "peripheral and coronary blood vessels." Ex. 1054, 1:3–5.

Relying solely upon testimony by Dr. Chronos, Patent Owner argues that Petitioner fails to explain how Taylor's beads 8 are compatible with the frames for Bessler's valves. PO Resp. 28–29 (citing Ex. 2026 ¶ 4.3.4.1). Patent Owner argues that the alleged lack of compatibility precludes a finding of obviousness in view of the combined teachings of Bessler and Taylor. *Id*. Patent Owner reiterates its argument in its Surreply without citing any additional evidence. Surreply 11–12. We find Petitioner's argument and evidence to be more persuasive than Patent Owner's evidence.

"[I]t is not necessary that the inventions of the references be physically combinable to render obvious the invention under review." *In re Sneed*, 710 F.2d 1544, 1550 (Fed. Cir. 1983). The relevant inquiry is whether the claimed subject matter would have been obvious to an ordinarily

skilled artisan in light of the combined teachings of those references. *See In re Keller*, 642 F.2d 413, 425 (CCPA 1981). "Combining the teachings of references does not involve an ability to combine their specific structures." *In re Nievelt*, 482 F.2d 965, 968 (CCPA 1973). Petitioner persuades us that Taylor suggests using its interlocking bead structures with transluminally implanted stents like those described by Bessler. Ex. 1054, 25:13–20, 25:28–26:9, Figures 8–9; Ex. 1003 ¶¶ 150, 152. Although we have determined that Bessler describes the mount introduced in claim 39, we also determine that the combined teachings of Bessler and Taylor render claim 39 unpatentable as obvious.

I. CLAIMS 1–3, 8, 9, 22, 23, 31–35, 37–39, AND 45: OBVIOUSNESS IN VIEW OF BESSLER AND JOHNSON

Petitioner contends that the combination of Bessler and Johnson renders claims 1–3, 8, 9, 22, 23, 31–35, 37–39, and 45 unpatentable as obvious. Pet. 54–67. For the reasons expressed below, we conclude that Petitioner proves that all the challenged claims are unpatentable as obvious.

1. Overview of Johnson

Johnson is directed to a synthetic aortic or mitral heart valve prosthesis. Ex. 1021, 1:8–9. One embodiment of Johnson's valve is illustrated in Figure 2, reproduced at right. *Id*. at 3:57–58. Struts 10, 12, and 14 form an arcuate shape extending about 90° from point of joinder 16 to suture pads 18, 20, 22 are positioned at the free ends of the struts. *Id*. at 4:35–42. Flexible membrane 30 covers the frame formed the struts

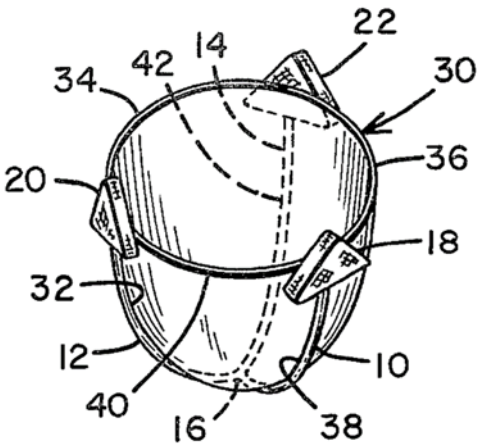


Fig. 2

to form a valve element having a hemispherical or paraboloid overall shape. *Id*. at 4:57–61.

Figures 4 and 5, reproduced below left and right, illustrate Johnson's valve in closed and open positions respectively. *Id*. at 5:37–50.

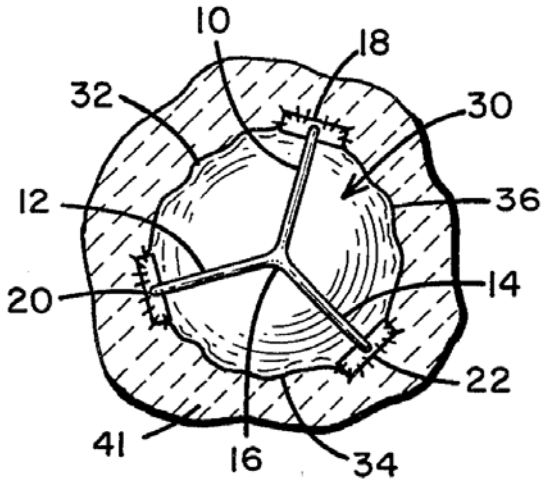


Fig. 4

Figure 4 is an axial view of Johnson's closed valve in the direction of blood flow.

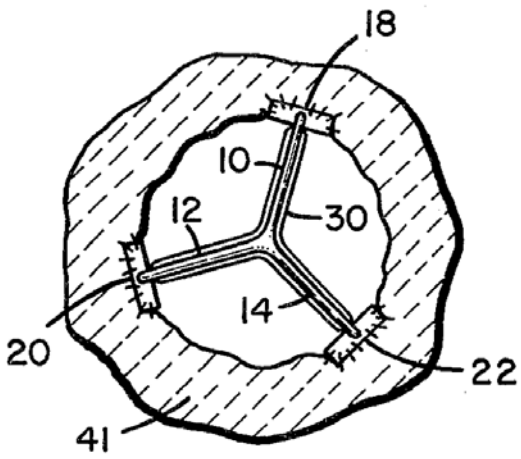


Fig. 5

Figure 5 is an axial view of Johnson's open valve in the direction of blood flow.

Membrane 30 includes free edges 32, 34, 36 that balloon out to contact tissue annulus 41 to which pads 18, 20, 22 are sutured when the valve is closed as shown in Figure 4. *Id*. at 5:37–45. Free edges 32, 34, 36 of membrane 30 collapse against one another in the open position shown in Figure 5 so that blood flows between annulus 41 and the collapsed membrane 30. *Id*. at 5:45–53. Although a three-strut frame is illustrated above, Johnson also describes an embodiment in which four struts are joined at joinder point 16 and radially distributed to form 90° angles between adjacent struts. *Id*. at 5:25–27.

2. Petitioner's Argument and Evidence

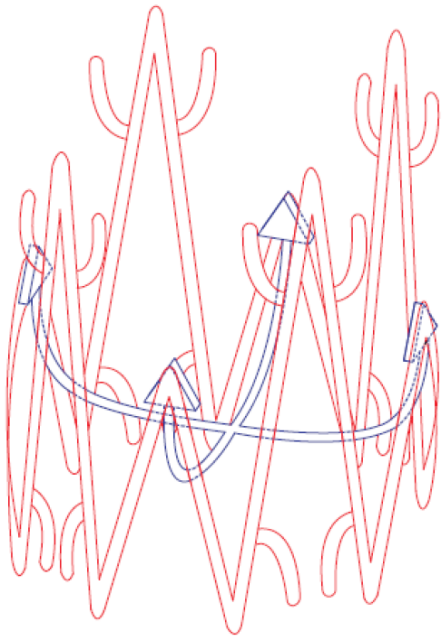
Petitioner supports its contentions that the proposed combination of Bessler and Johnson describes every element of all the challenged claims with citations to precise portions of Bessler and Johnson and testimony by Dr. Dasi. *Id*. at 57–66 (citing Ex. 1008, 2:25–28, 2:55–62, 3:46–64, 4:12–21, 4:53–58, 4:60–5:1, 5:3–27, 5:31–36, 5:40–6:18, 7:26–67, 8:46–49, Figures 1, 6, 7, 12–15; Ex. 1021, 2:39–61, 3:26–47, 4:10–68, 5:12–53, 6:2–7, 6:14–19, Figures 1, 2, 4, 5, 7, 8; Ex. 1003 ¶¶ 122–144).

Petitioner's proposed combination of Bessler and Johnson addresses the ways in which Bessler alone fails to describe each missing element of the independent claims 1, 22, and 31 that we noted in Parts II.E.3.a)–b) above. In connection with claims 1 and 31, Johnson's struts form a frame that includes structure, near joinder point 16, that is located along the centerline of the valve. Ex. 1021, 4:35–42. Johnson's membrane 30 is attached along the entire length of its struts 10, 12, 14, including the common joinder point 16 of those struts. *Id*. at 4:61–63. These aspects of Johnson meet the requirement of claims 1 and 31 that the flexible valve element be attached to a central portion of the structure of the frame that is located along a centerline of the artificial valve. In connection with claim 22, Johnson describes the required "convex upstream side" and "concave downstream side" because Johnson's membrane 30 drapes over its struts 10, 12, 14 to form a hemispheric shape. *Id*. at 4:57–66, Figures 2, 7, 8.

3. Motive to Combine Bessler and Johnson

Petitioner contends that an ordinarily skilled artisan would have been motivated to incorporate Johnson's "dynamic annulus heart valve" into Bessler's stent and cuff structure to obtain a more durable valve. *Id*. at 56 (citing Ex. 1003 ¶¶ 118–119). Petitioner provides the Figure at right to illustrate its proposed combination without the flexible valve element to ease vizualization. *Id*.

FIG.E



Petitioner contends that Bessler recognized the benefits of delivering prosthetic heart valves through a catheter to avoid the invasive nature of open heart surgery. *Id*. at 54 (citing Ex. 1008, 1:14–34). Petitioner further contends that Bessler and Johnson both recognized, however, that prosthetic heart valves delivered through a catheter may suffer from a lack of durability. *Id*. at 54–55 (citing Ex. 1008, 2:11–12; Ex. 1021, 3:37–47). Johnson suggested that its valve would exhibit "extreme durability" by attaching its membrane to the center of its frame and leaving the peripheral edges free to open and close against a tissue annulus. Ex. 1021, 3:36–47. Petitioner argues that Bessler's recognition of potential durability issues associated with prosthetic valves implanted via catheter would have motivated an ordinarily skilled artisan to look to incorporate Johnson's durable valve design into Bessler's stent, which was adapted for the safer, less invasive transcatheter delivery. Pet. 55–56 (citing Ex. 1003 ¶¶ 115–116, 118–119). Because Johnson's device drapes a flexible membrane over a framework of curved flexible struts joined at one end to a

common central point, Petitioner contends that an ordinarily skilled artisan would consider Johnson's valve for use in a collapsible device. *Id*. at 57 (citing Ex. 1021, 2:43–50; Ex. 1003 ¶ 121). Dr. Dasi testifies that an ordinarily skilled artisan would have reasonably expected to be able to succeed in making the proposed combination of Bessler and Johnson because Johnson's valve with enhanced durability in Bessler's frame would work in the same way as described in Johnson, and Bessler's stent and delivery instrument would have permitted Johnson's valve to be delivered percutaneously. *Id*. at 66–67 (citing Ex. 1003 ¶¶ 41, 145–147).

4. Analysis of Patent Owner's Counterarguments

Patent Owner argues that the combination of Bessler and Johnson fails to render any claims obvious for two reasons. PO Resp. 30–33. First, Patent Owner argues that an ordinarily skilled artisan would not have been motivated to combine teachings of Bessler and Johnson for any challenged claim and that the proposed combination is based upon impermissible hindsight. *Id*. at 30–33. Second, Patent Owner argues that Johnson does not cure deficiencies in Petitioner's showing that Bessler fails to disclose a frame that is sized and shaped for insertion between the upstream and downstream regions as recited in all claims. *Id*. at 33. Patent Owner also argues that the proposed combination of Bessler and Johnson fails to describe a frame with a "collapsible configuration" as recited in dependent claim 32. *Id*. at 33–34. We address each argument below and determine that none is persuasive.

a) Alleged Lack of Motivation to Combine

Patent Owner argues that Petitioner's proposed combination of Bessler and Johnson is improper because it contends that placing Johnson's

strut-based frame into Bessler's stent "would increase the collapsible diameter of the TAVR[4] valve, rendering it too large for transluminal delivery." PO Resp. 32 (citing Ex. 1009, 21:27–29; Ex. 2026 ¶ 4.1.5.1). Patent Owner's argument is unpersuasive for at least three reasons.

First, the claims are not limited to TAVR procedures. The '297 patent describes and its claims encompass valves suitable for more than TAVR procedures. The Specification describes valve 10A, which is a TAVR valve, Ex. 1001, 4:64–66, but it also describes valve 10M, which is a replacement for a mitral valve, *id*. at 4:66–67. Because of the surgical method of delivering a TAVR valve 10A and the typical diameter of the aorta, the Specification indicates that valve 10A must collapse within the delivery catheter to a diameter of 4–8 mm, preferably 6 mm. *Id*. at 6:24–29, *see also* Figure 5 (illustrating instrument 70A). By contrast, delivering a mitral valve replacement 10M uses an instrument that collapses valve 10M to a larger diameter of 12–18 mm. Therefore, the claimed artificial valve may be delivered in an instrument of up to 18 mm in diameter, larger than the smaller 8 mm maximum diameter indicated for a TAVR valve.

Second, Johnson's strut-based frame and membrane are both flexible and very thin. Johnson's flexible struts are 0.030 inches (0.76 mm) in diameter and its membrane 30 is no more than 0.003 inches (0.08 mm) thick. Ex. 1021, 4:37–53. Struts 10, 12, 14 are formed of "a resilient or a springy material which is nonthrombogenic such as titanium or polytetrafluoroethylene or Teflon® polymer." *Id*. at 4:22–25. Bessler's stent is made of wire of only about 0.012–0.035 inches (0.30–0.89 mm) in

[4] TAVR appears to refer to "transcatheter aortic valve replacement." Ex. 3001 ¶ 1; Ex. 2002, p. 56, n.7.

diameter. Ex. 1008, 6:11–12. Bessler's stent collapses into a very small cylinder such that little space remains within its wire frame. *Id*. at 5:44–46, Figure 5. Given the stated, sub-millimeter sizes of all the relevant components of Johnson and Bessler, we see no reason why Johnson's strut-based frame and membrane combined with Bessler's stent would not easily collapse into the 18 mm diameter instrument 70M of the '297 patent.

Third, the only objective evidence cited by Patent Owner, Ex. 1009, 21:27–29, fails to support the proposition that the Johnson's valve within Bessler's stent would be "too large for transluminal delivery." The cited passage reads: "The presence of the internal cover makes an additional layer of plastic material that occupies the inside of the frame and increases the final size of the IV [implantable valve][5]." Ex. 1009, 21:27–29. At most, this passage demonstrates that adding more material to an implantable valve increases its collapsed diameter. The multilayer implantable valve being discussed in the Exhibit replaces an aortic valve, includes a stent structure made from bars 0.1–0.6 mm in diameter, and compresses to a diameter of 4–5 mm. Ex. 1009, 14:23–16.

For all these reasons, Dr. Chronos's assertion that incorporating Johnson's strut-based frame and membrane into Bessler's stent would render the combined structure too large is not supported by the objective evidence of record. Patent Owner's argument rests upon Dr. Chronos's testimony. Accordingly, we find Patent Owner's argument unpersuasive. Instead, we determine that Petitioner has proven that an ordinarily skilled artisan would

[5] Ex. 1009, 1:12–13.

have been motivated to combine the teachings of Bessler and Johnson as alleged.

b) Sized and Shaped for Insertion as Recited in Independent Claims 1, 22, 31, and 38

Patent Owner argues that Bessler fails to describe a frame that is sized and shaped for insertion between the upstream and downstream regions recited in the claims and that combining Johnson with Bessler does not cure the deficiency in Bessler's disclosure. PO Resp. 33. We disagree.

As explained in Part II.E.3.c)(1)(b) above, we find that Bessler meets these limitations of independent claim 38. Independent claims 1, 22, and 31 recite the same limitations as claim 38. *Compare* Ex. 1001, 23:57–66 (claim 38), *with id*. at 19:12–17 (claim 1), *and id*. at 21:55–60 (claim 22), *and id*. at 22:57–65 (claim 31). For the same reasons that we expressed above in connection with our analysis of this limitation in claim 38, we also determine that Bessler alone describes the limitation as recited in claims 1, 22, and 31.

c) Collapsible Valve as Recited in Dependent Claim 32

Claim 32 depends from claim 31 and further recites: "a holder having a hollow interior sized for holding the artificial valve when the frame is in the collapsed configuration." Ex. 1001, 23:34–37. Patent Owner argues that because Johnson's valve is "not a collapsible valve," placing it within Bessler's stent would also render the combination non-collapsible. PO Resp. 33–34 (citing Ex. 2026 ¶ 3.2.1.1 (addressing alleged non-collapsibility of Johnson valve)); Surreply 14. Dr. Chronos cites no objective evidence for his conclusion that Johnson cannot collapse to a width of less than 18 mm. Ex. 2026 ¶ 3.2.1.1. Based on our review of Johnson as described above, we find Dr. Chronos's testimony to be inconsistent with Johnson, which

describes a frame made of very thin (less than 1 mm) struts that are flexible and covered by a very thin (less than 0.1 mm) membrane. Ex. 1021, 4:22–57. Accordingly, Petitioner persuades us that the combination of Bessler and Johnson describes the collapsible valve of claim 32.

d) Remaining Elements of Claims 1–3, 8, 9, 22, 23, 31–35, 37–39, and 45

Patent Owner identifies no other deficiency in Petitioner's showing that the combination of Bessler and Johnson describes every other element of claims 1–3, 8, 9, 22, 23, 31–35, 37–39, and 45. *See* PO Resp. 30–34. We adopt as our own Petitioner's argument and evidence and find that Petitioner proves by a preponderance of evidence that the combination of Bessler and Johnson describes all elements of claims 1–3, 8, 9, 22, 23, 31–35, 37–39, and 45. Pet. 57–66 (citing Ex. 1008, 2:25–28, 2:55–62, 3:46–64, 4:12–21, 4:53–58, 4:60–5:1, 5:3–27, 5:31–36, 5:40–6:18, 7:26–67, 8:46–49, Figures 1, 6, 7, 12–15; Ex. 1021, 2:39–61, 3:26–47, 4:10–68, 5:12–53, 6:2–7, 6:14–19, Figures 1, 2, 4, 5, 7, 8; Ex. 1003 ¶¶ 122–144).

e) Conclusion

We also conclude that Petitioner has proven by a preponderance of evidence that an ordinarily skilled artisan would have been motivated to combine teachings of Bessler and Johnson to arrive at the artificial valves and instruments recited in claims 1–3, 8, 9, 22, 23, 31–35, 37–39, and 45. Petitioner also persuades us that the combination of Bessler and Johnson describes every element of these claims. Accordingly, we conclude that Petitioner has proven by a preponderance of evidence that the combination of Bessler and Johnson renders claims 1–3, 8, 9, 22, 23, 31–35, 37–39, and 45 unpatentable as obvious.

J. CLAIMS 3, 23, AND 39:
OBVIOUSNESS IN VIEW OF BESSLER, JOHNSON, AND THOMPSON

Claims 3 and 23 depend ultimately from claims 1 and 22 respectively and recite that the artificial valve further comprises: "a releasable fastener mounted on the frame for selectively connecting the valve to an instrument." Ex. 1001, 19:56–58 (claim 3), 23:26–28 (claim 23). Claim 39 depends from claim 38 and further recites that the: "frame includes a mount for selectively connecting the valve to the instrument." Ex. 1001, 24:46–48. Petitioner relies upon Thompson as describing the "releasable fastener" and the combination of Bessler and Johnson as describing the elements recited in base claims 1, 22, and 38. Pet. 67–68 (citing Ex. 1003 ¶¶ 149, 151, 153, 155).

When addressing this challenge, Patent Owner relies upon its argument that the combination of Bessler and Thompson fails to render claims 3, 23, and 39 unpatentable. PO Resp. 34–35. We have already determined that the combination of Bessler and Johnson renders claims 3, 23, and 39 obvious. *See* Part II.I above. We have also concluded that the combined teachings of Bessler and Thompson render claim 39 unpatentable as obvious. *See* Part II.G.2 above. For all the reasons expressed in those portions of this Decision, we also conclude that the combined teachings of Bessler, Johnson, and Thompson render claims 3, 23, and 39 unpatentable as obvious.

K. CLAIMS 3, 23, AND 39:
OBVIOUSNESS IN VIEW OF BESSLER, JOHNSON, AND TAYLOR

Claims 3 and 23 depend ultimately from claims 1 and 22 respectively and recite that the artificial valve further comprises: "a releasable fastener mounted on the frame for selectively connecting the valve to an instrument."

Ex. 1001, 19:56–58 (claim 3), 23:26–28 (claim 23). Claim 39 depends from claim 38 and further recites that the: "frame includes a mount for selectively connecting the valve to the instrument." Ex. 1001, 24:46–48. Petitioner relies upon Taylor as describing the "releasable fastener" and the combination of Bessler and Johnson as describing the elements recited in base claims 1 and 22. Pet. 68.

When addressing this challenge, Patent Owner relies upon its argument that the combination of Bessler and Taylor fails to render claims 3, 23, and 39 unpatentable. PO Resp. 34–35. We have already determined that the combination of Bessler and Johnson renders claims 3, 23, and 39 obvious. *See* Part II.I above. We have also concluded that the combined teachings of Bessler and Taylor render claim 39 unpatentable as obvious. *See* Part II.H.2 above. For all the reasons expressed in those portions of this Decision, we also conclude that the combined teachings of Bessler, Johnson, and Taylor render claims 3, 23, and 39 unpatentable as obvious.

L. CLAIMS 1–3, 8, 9, 22, 23, 31–35, 37–39, AND 45: ANTICIPATION BY LEONHARDT

Petitioner contends that Leonhardt anticipates claims 1–3, 8, 9, 22, 23, 31–35, 37–39, and 45 under 35 U.S.C. § 102(a), (e). Pet. 3, 27–34, 37–48. Petitioner supports its contentions with the testimony of Lakshmi Prasad Dasi, Ph.D. *Id.* Patent Owner argues that Leonhardt fails to describe various elements recited in independent claims 1, 22, 31, and 38, and other elements introduced in dependent claims 3, 9, 23, and 39. PO Resp. 18–28. For the reasons expressed below, we determine that Petitioner has failed to prove by a preponderance of evidence that Leonhardt anticipates any claim.

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. We reproduce Figure 4 of Leonhardt at right, which is a side view of Leonhardt's valve stent 20. Valve stent 20 comprises 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 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.

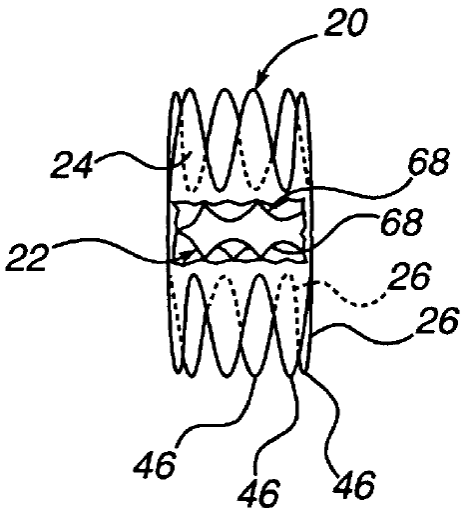


FIG. 4

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. Petitioner's Argument and Evidence

Petitioner contends that Leonhardt anticipates each of independent claims 1, 22, 31, and 38 and identifies specific portions of Leonhardt that describe each element of the artificial valve of those claims. Pet. 27–34, 37–48 (citing Ex. 1017, 1:5–21, 2:43–50, 3:15–49, 4:53–5:52, 6:9–34, 7:10–17, 8:42–9:5, 9:50–11:36, 11:59–12:5, FIGS. 1B, 1C, 2–4, 9A–9D). Petitioner also relies on Dr. Dasi's testimony to support its contentions. *Id.* (citing Ex. 1003 ¶¶ 90–105).

3. Analysis of Patent Owner's Counterarguments

Each of independent claims 1, 22, 31, and 38 recite materially differing versions of an artificial valve. Patent Owner argues that Leonhardt fails to anticipate each independent claim and proffers distinct arguments for patentability of dependent claims 3, 9, 23, and 39. For the reasons expressed below, we find that Patent Owner's arguments are persuasive for

independent claims 1, 22, 31, and 38 and thus also for their respective dependent claims 2, 3, 8, 9, 22, 23, 31–35, 37, 39, and 45.

a) Claims 1–3, 8, 9, 31–35, and 37

Patent Owner argues that Leonhardt does not anticipate independent claims 1 and 31 because Leonhardt's flexible valve member is not attached to a central portion of its frame. PO Resp. 18–19. For claims 1 and 31, the central portion of the frame is "located *along a centerline* extending between the plurality of peripheral anchors." Ex. 1001, 19:19–20 (claim 1), 22:67–23:2 (claim 31) (emphasis added).

Petitioner contends that Leonhardt describes a porcine valve element that is sutured or glued to stent 26, graft material 24, or both. Pet. 41 (citing Ex. 1017, 6:23–32, FIG. 4). Leonhardt's stent 26 includes two cylindrical sections that are joined by connecting bar 29, which is the "central part of the continuous wire from which stent 26 is formed." Ex. 1017, 5:31–33. The combination of stent 26 and connecting bar 29 constitutes Leonhardt's frame. Connecting bar 29 is also sutured, and thus attached, to graft material 24. *Id*. at 5:36–37.

Petitioner's argument that Leonhardt's valve is attached to the central part of the frame of claims 1 and 31 fails. Leonhardt's valve is undeniably attached to its frame because the valve is sutured or glued to stent 26. However, claims 1 and 31 require the valve element to be attached to a portion of the frame located along the radial centerline. Ex. 1001, 19:19–20 (claim 1), 22:67–23:2 (claim 31). Leonhardt's frame (stent 26 coupled via connecting bar 29) is a hollow cylinder devoid of structure located along its centerline. *Id*., Figure 1C. Thus, regardless of how Leonhardt's valve is attached to stent 26 and connecting bar 29, it is not attached to a structure

"located along a centerline" as recited in claims 1 and 31. Therefore, we determine that Petitioner fails to establish by a preponderance of evidence that Leonhardt anticipates claims 1 and 31 or their respective dependent claims 2, 3, 8, 9, 32–35, and 37.

b) Claims 22 and 23

Independent claim 22 requires the flexible valve to include a "convex upstream side" and a "concave downstream side." Ex. 1001, 21:64–22:3. As explained in Part II.D.3 above, 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.

Petitioner contends that Leonhardt's "biologic porcine" valve 22 includes a "convex upstream side" and a "concave downstream side." Pet. 31, 42 (citing Ex. 1017, 6:23–34; Ex. 1003 ¶ 97). However, the portion of Dr. Dasi's testimony relied on (e.g., Ex. 1003 ¶ 97) does not contain such an opinion. Dr. Dasi testifies that a porcine valve comprises portions that individually bulge in the upstream direction. *Id.* ¶ 97. Dr. Dasi testifies that a porcine valve has the same "architecture" as a human valve. Ex. 1003 ¶ 27 (citing Ex. 1001, 1:66–24). He also provides detailed illustrations of human valves and explains that porcine valves are shaped the same way as human valves. *Id.* ¶ 28, Figure B. However, Petitioner does not provide adequate support for its contention that Leonhardt's valve 22 contains a convex side or a concave side.

Patent Owner argues that Leonhardt fails to describe the convex and concave opposing sides of a flexible valve element because Leonhardt's depiction of valve 22 in its Figure 4 does not reflect opposing sides, one

convex and the other concave. PO Resp. 26–28. Patent Owner does not address Dr. Dasi's detailed testimony of what an ordinarily skilled artisan would understand the shape of a porcine valve to be. *Id*. We accept Dr. Dasi's uncontroverted testimony about the shape of the porcine valve to which Leonhardt refers.

Nevertheless, Leonhardt fails to describe a valve element having opposing convex and concave sides because Leonhardt's porcine valve does include any side in which the entire side exhibits a convex or concave shape. As above, we have construed "convex" side as referring to an entire side that is convex and "concave" side as referring to an entire side that is concave. Leonhardt does not meet these claim limitations. Accordingly, we determine that Petitioner has failed to prove by a preponderance of evidence that Leonhardt anticipates claim 22 or its dependent claim 23.

c) Claims 38, 39, and 45

(1) Flexible Valve Element Attached to Central Portion of the Frame

Initially, Patent Owner groups claim 38 with claims 1 and 31 when arguing that Leonhardt fails to describe a valve element directly attached to the central portion of the frame. PO Resp. 18–19. This argument is unpersuasive for two reasons. First, claim 38 recites "central portion" more broadly than claims 1 and 31, and Leonhardt includes a "central portion" as recited in claim 38. Second, as explained in Part II.D.1 above, we do not interpret claim 38 to require "direct attachment" of the valve to the frame.

Independent claim 38 recites a frame having "a central portion located between the plurality of peripheral anchors" without further requiring the central portion being "located along a centerline" as recited in claims 1 and 31. Ex. 1001, 24:1–2. Accordingly, the "central portion" of the frame

of claim 38 may refer to any portion of the frame that is "between the plurality of peripheral anchors," including a portion that is longitudinally centered.

Patent Owner argues that Petitioner fails to identify a "central structural frame portion" to which Leonhardt's valve is "directly attached." PO Resp. 20.

Petitioner correctly notes that Leonhardt's valve element 22 is sutured or glued to stent 26, graft material 24, or both. Pet. 41 (citing Ex. 1017, 6:23–32, FIG. 4). Leonhardt's stent 26 includes two cylindrical sections that are joined by connecting bar 29, which is the "central part of the continuous wire from which stent 26 is formed." Ex. 1017, 5:31–33. The combination of stent 26 and connecting bar 29 constitutes Leonhardt's frame. Thus, Leonhardt describes securing valve 22 to stent 26 both directly and indirectly via attachment to graft material 24.

Additionally, Leonhardt's Figure 4 illustrates valve 22 as being positioned in the longitudinal central portion of the frame. *Id*., Figure 4. Accordingly, Leonhardt attaches its valve to a "central portion" of the frame as required in claim 38.

Leonhardt's longitudinally "central portion" is also located "between the plurality of peripheral anchors." Leonhardt's Figure 2 illustrates that both ends of valve stent 20 flare radially outward "to conform and seal to the tissue," *id*. at 6:21–22, Figure 2, by using "light activated bioadhesive material 56 on the outside of graft material 24," *id*. at 8:44–45. In this way, Leonhardt "anchors" valve stent 20, which includes graft 24, stent 26, and valve 22, around its periphery using a "plurality of peripheral anchors" as recited in claim 38. Leonhardt's longitudinally centered portion of stent 26

is located between these "peripheral anchors." For all these reasons, we determine that Leonhardt's valve 22 is "attached to the central portion of the frame," which is "located between the plurality of peripheral anchors."

(2) Substantially Immobile

Patent Owner also argues that Leonhardt fails to describe a valve element that is "substantially immobile" with respect to the "central portion of the frame" because Leonhardt fails to include a "central portion of the frame." PO Resp. 23. For the reasons expressed immediately above, we find that Leonhardt describes the claimed "central portion" of the frame and a valve that is "substantially immobile" with respect to that frame.

(3) Installer That Is Releasably Attachable to the Frame

Patent Owner also argues that Leonhardt fails to describe an "installer" that is "releasably attachable to the frame." *Id*. at 23–24. The limitation at issue from claim 38 reads in its entirety as follows:

> an instrument including
>
> a holder . . .
>
> * * *
>
> *an installer* received within the hollow interior of the holder and *releasably attachable to the frame* of the artificial heart valve for maneuvering the artificial heart valve from the hollow interior of the holder into position between the upstream region and the downstream region.

Ex. 1001, 24:32–45 (emphasis added). Although the "installer" is largely defined by its function of "maneuvering the artificial heart valve . . . into position," the installer must also be "releasably attachable to the frame."

Petitioner contends that Leonhardt's pushrod 112 is an installer that is releasable attachable to the frame. Pet. 44–45. Patent Owner contends that

pushrod 112 is not "releasably attachable to the frame" but simply contacts and pushes stent 26 during deployment. PO Resp. 23–24. Petitioner responds that Leonhardt's suture loops 174, which pass through pushrod 112 and loop around stent 26, are used to "releasably couple" pushrod 112 to stent 26. Reply 8–9. Patent Owner persuasively notes that, although suture loops 174 pass through pushrod 112, they do not "attach" pushrod 112 to stent 26. Surreply 7. We agree with Patent Owner.

The combination of Leonhardt's pushrod 112 and suture loops 174 does maneuver valve 20 into position. Ex. 1017, 8:23–27, 9:8–15. However, pushrod 112 alone cannot pull valve 20 back toward Leonhardt's deployment catheter 100; instead, suture loops 174 in "[s]pool apparatus 170 allows valve stent 20 to be retrieved into outer sheath 106 if repositioning or removal is necessary." *Id*. at 9:8–10. Suture loops 174 "extend through a central axial passage of push rod 112," which indicates that suture loops 174 are not attached to pushrod 112. *Id*. at 9:12–15. We determine that Leonhardt thus fails to attach its valve stent 20 to pushrod 112. Instead, pushrod 112 merely contacts valve stent 20 during deployment.

(4) Conclusion

Because Leonhardt fails to describe the installer that is "releasably attachable to the frame" as required in claim 38, we conclude that Petitioner has failed to demonstrate by a preponderance of evidence that Leonhardt anticipates claim 38 or its dependent claims 39 and 45.

4. Summary

For the reasons expressed above, we determine that Petitioner has failed to prove by a preponderance of evidence that Leonhardt anticipates claims 1–3, 8, 9, 22, 23, 31–35, 37–39, and 45.

M. CLAIMS 1–3, 8, 9, 22, 23, 31–35, 37–39, AND 45: OBVIOUSNESS BY LEONHARDT

Petitioner argues that even if Leonhardt fails to describe elements as claimed, an ordinarily skilled artisan would consider "variations" of Leonhardt to meet the claimed limitations would have been obvious "in view of the general knowledge in the art and the limited number of ways of using known elements to achieve expected results." Pet. 50. Petitioner addresses specific "variations" relating to meeting limitations introduced in claims 3 and 23 requiring "releasable fasteners." *Id*. However, none of Petitioner's arguments persuasively addresses Leonhardt's failure to describe elements recited in independent claims 1, 22, 31, and 38 as discussed in Part II.I above. Accordingly, we conclude that Petitioner has failed to prove by a preponderance of evidence that Leonhardt alone renders claims 1–3, 8, 9, 22, 23, 31–35, 37–39, and 45 unpatentable as obvious.

N. OBJECTIVE INDICIA OF NON-OBVIOUSNESS

Patent Owner argues that numerous objective indications "weigh heavily against deeming the invention of the '297 patent obvious" exist, including: peer recognition, long-felt but unresolved need, commercial success, and acceptance and adoption by industry. PO Resp. 35–40. Patent Owner's evidence relating to various heart valves is:

1. letters addressed to Dr. Snyders from industry executives discussing a "funnel valve" (Exs. 2007, 2008);
2. a draft article co-authored by Dr. Snyder entitled "Evaluation of a Transluminal Prosthetic Valve Implant in the Mitral Position" that discusses results of "funnel valve" implant procedures (Ex. 2009);

3. a press release describing the acquisition of "CoreValve, Inc., developer of a transcatheter, transfemoral aortic heart valve replacement" by Medtronic, Inc. (Ex. 2010);
4. a report in the Orange County Register of the settlement of a patent dispute between Medtronic Inc. and Edwards Lifesciences involving "minimally invasive heart valves" such as Medtronic's "CoreValve" product (Ex. 2011);
5. documents describing invitations to Dr. Snyder to present a paper at the 4th annual NewEra Cardiac Care: Innovation and Technology meeting, January 4–7, 2001 (Exs. 2012, 2013, 2014).

PO Resp. 35–40 (citing Exs. 2007, 2008, 2009, 2010, 2011, 2012, 2013, 2014).

Petitioner responds to this evidence by correctly noting that none of the evidence establishes a nexus between any praise, recognition, commercial success, or acceptance and adoption by industry with a product that is covered by any claim of the '297 patent. Reply 19–21.

When weighing allegations that objective indicia favor a conclusion of non-obviouseness, we must consider "whether 'the marketed product embodies the claimed features.'" *ClassCo, Inc. v. Apple, Inc.*, 838 F.3d 1214, 1222 (Fed. Cir. 2016) (quoting *Brown & Williamson Tobacco Corp. v. Philip Morris Inc.*, 229 F.3d 1120, 1130 (Fed. Cir. 2000)). Patent Owner submits no evidence to establish that Dr. Snyder's "funnel valve" (Exs. 2007, 2008, 2009) or acquisitions, licenses, and litigation settlements involving products made by Medtronic, Edwards Lifesciences, or CoreValve relate to any product covered by any claim. PO Resp. 35–40. In its Surreply, Patent Owner baldly asserts without citing any persuasive

evidence or analysis that the Medtronic CoreValve "is covered by Dr. Snyder's patents." Surreply 15. When questioned during the hearing on this very insufficiency of its evidence, Patent Owner failed to identify where it had established the required nexus to the claimed invention. Tr. 133:16–134:16. Based on our consideration of the record as whole, we determine that Patent Owner has failed to establish any nexus between its alleged objective indicia of non-obviousness and the claimed features. On that basis, we do not consider objective indicia to weigh against a conclusion of obviousness.

III. PETITIONER'S MOTION TO STRIKE

Petitioner's Motion to Strike seeks to exclude from Patent Owner's Surreply the sentence and citation at lines 2–4 on page 3. Mot. 1. That sentence and citation reads: "In fact, Bailey recognized the native annulus is more rigid than the native leaflets and that Bessler's barbs would malfunction if they were secured to native leaflets. (Ex. 1024 at 3:48-4:4)." *Id*. Petitioner argues that the offending sentence is "entirely new argument" regarding Bessler that should have been presented in the Patent Owner Response. *Id*. at 3.

We have considered the allegedly offending sentence in rendering our decision but do not consider Bailey to be persuasive evidence of whether Bessler's barbs would malfunction if they were secured to native leaflets. Bailey's statements are inadmissible hearsay when offered to prove the truth of the matter for which Patent Owner cites them. We also note that Patent Owner has not adduced any evidence that Mr. Bailey had any personal knowledge of the functionality of Bessler's barbed valves. Therefore, we *dismiss* Petitioner's Motion to Strike as moot.

IV. 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. 40–41. 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.

V. CONCLUSION

Based on the record before us, we conclude that Petitioner has demonstrated by a preponderance of the evidence that:

1. claims 38, 39, and 45 are unpatentable as anticipated by Bessler;
2. claim 39 is unpatentable as obvious in view of the combined teachings of Bessler and Thompson;
3. claim 39 is unpatentable as obvious in view of the combined teachings of Bessler and Taylor;

4. claims 1–3, 8, 9, 22, 23, 31–35, 37–39, and 45 are unpatentable as obvious in view of the combined teachings of Bessler and Johnson;
5. claims 3, 23, and 39 are unpatentable as obvious in view of the combined teachings of Bessler, Johnson, and Thompson; and
6. claims 3, 23, and 39 are unpatentable as obvious in view of the combined teachings of Bessler, Johnson, and Taylor.

We also conclude that Petitioner has not demonstrated by a preponderance of the evidence that:

1. claims 1–3, 8, 9, 22, 23, 31–35, 37 are unpatentable as anticipated by Bessler;
2. claims 1–3, 8, 9, 22, 23, 31–35, 37–39, and 45 are unpatentable as anticipated by Leonhardt;
3. claims 1–3, 8, 9, 22, 23, 31–35, 37 are unpatentable as obvious in view of Bessler;
4. claims 1–3, 8, 9, 22, 23, 31–35, 37–39, and 45 are unpatentable as obvious in view of Leonhardt;
5. claims 3 and 23 are unpatentable as obvious in view of the combined teachings of Bessler and Thompson; and
6. claims 3 and 23 are unpatentable as obvious in view of the combined teachings of Bessler and Taylor.

VI. ORDER

For the reasons given, it is:

ORDERED, based on a preponderance of evidence, that claims 1–3, 8, 9, 22, 23, 31–35, 37–39, and 45 of U.S. Patent 6,821,297 B2 are *unpatentable*; and

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

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