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Paper 47
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 IPR2018-00109
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 18 and 20 (the "challenged claims") of U.S. Patent No. 6,821,297 B2 (Ex. 1001, "the '297 patent").

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

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 7 ("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 12 ("Institution Decision" or "Dec."). The challenges to the claims are:

References	Basis	Claims challenged
U.S. Patent No. 5,957,949 (Ex. 1017, "Leonhardt")	§ 102	18 and 20
Leonhardt	§ 103	18 and 20
Leonhardt and U.S. Patent No. 4,339,831 (Ex. 1021, "Johnson")	§ 103	18 and 20

After we instituted this review, Patent Owner filed a Patent Owner Response in opposition to the Petition (Paper 26, "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 34, "Reply"). With our prior authorization, Patent Owner filed a Surreply in response to the Reply (Paper 36, "Surreply"). Patent Owner did not move to amend any claim of the '297 patent.

We heard oral argument on January 30, 2019. A transcript of the argument has been entered in the record (Paper 46, "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 failed to demonstrate by a preponderance of evidence that claims 18 and 20 are unpatentable. We provide our analysis of each challenge to claims 18 and 20 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.

FIG. 2

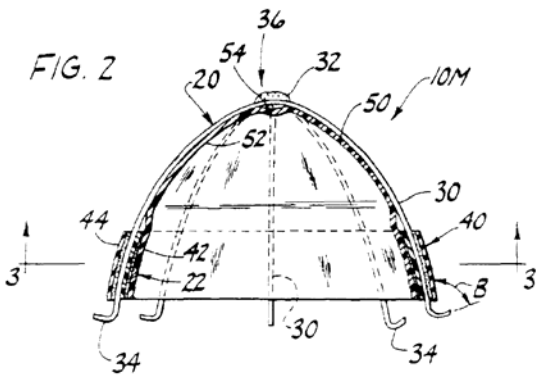


FIG. 3

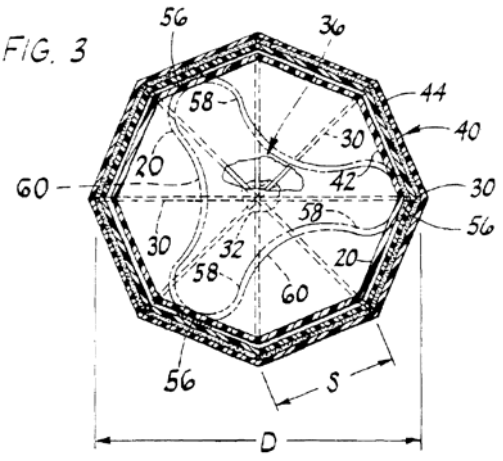


Figure 2 depicts "a vertical cross section of an artificial valve," and Figure 3 depicts "a cross section of the valve taken in the plane of line 3–3 of FIG. 2." *Id.* at 4:11–13. Artificial valve 10M shown in Figures 2 and 3 "is specifically configured for repairing a damaged mitral valve," although 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.

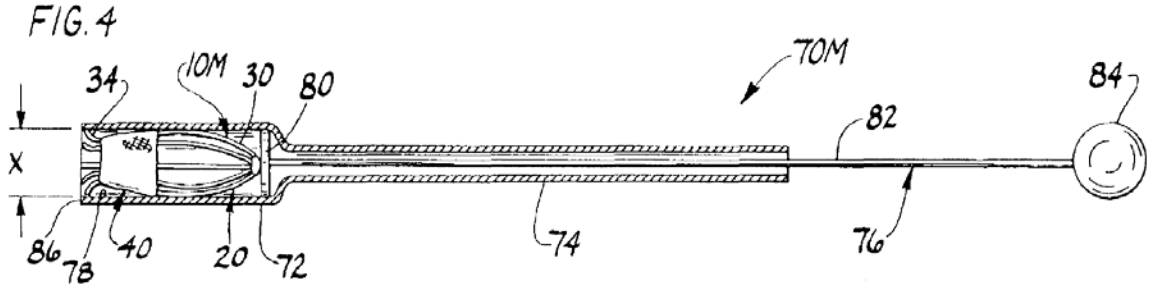


Figure 4 depicts "a vertical cross section of an instrument for implanting a valve using an endothoracoscopic procedure." *Id.* at 4:14–16. The instrument of Figure 4 includes tubular holder 72 and elongate tubular manipulator 74 attached to the holder for manipulating the holder into position. *Id.* 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 18 and 20 on the grounds that the claims are either anticipated or obvious in light of various references including: Leonhardt 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. *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, by way of testimony from Dr. Dasi, 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." Ex. 1003 ¶¶ 15–17 (citing Ex. 1001; Ex. 1008; Ex. 1009; Ex. 1010; Exs. 1033–1038; Ex. 1020; Ex. 1003, ¶¶ 15–17). Patent Owner neither disputes this contention in its Preliminary Response, 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).

Claim 1 recites that the flexible valve element is attached to 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.

E. CLAIMS 18 AND 20: ANTICIPATION BY LEONHARDT

Petitioner contends that Leonhardt anticipates claims 18 and 20 under 35 U.S.C. § 102(a), (e). Pet. 24–42. Petitioner supports its contentions with the testimony of Lakshmi Prasad Dasi, Ph.D. *Id.* Patent Owner argues that Leonhardt fails to describe a flexible valve element attached to the central portion of the frame as recited in independent claim 1. PO Resp. 11–14. For the reasons expressed below, we determine that Petitioner has failed to prove by a preponderance of evidence that Leonhardt anticipates claims 18 and 20, which depend from claim 1.

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.

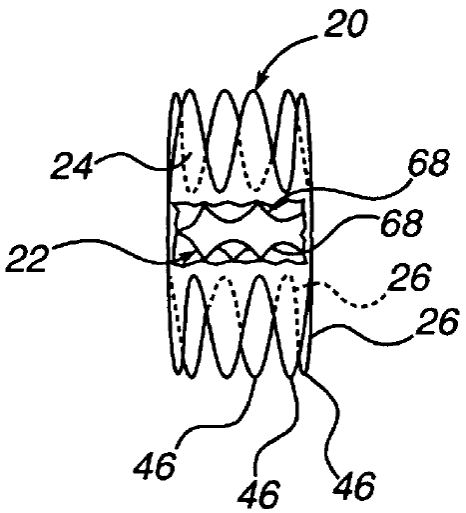


FIG. 4

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 claims 18 and 20 and identifies specific portions of Leonhardt that describe each element of the claimed methods of inserting an artificial valve. Pet. 24–42, 37–48 (citing Ex. 1017, 1:5–21, 2:43–50, 3:15–49, 4:8–11, 4:53–5:52, 6:9–34, 6:60–65, 7:10–17, 8:42–9:5, 9:49–12:5, FIGS. 1B, 1C, 2–7, 9A–9D). Petitioner also relies on Dr. Dasi's testimony to support its contentions. *Id*. (citing Ex. 1003 ¶¶ 71, 72, 74–88, 90–96, 111, 113–128).

3. Analysis of Patent Owner's Counterarguments

Patent Owner argues that Leonhardt does not anticipate claims 18 and 20 because Leonhardt's flexible valve member is not attached to a central portion of its frame as recited in base claim 1. PO Resp. 11–14. Claim 1 requires that the central portion of the frame is "located *along a centerline* extending between the plurality of peripheral anchors." Ex. 1001, 19:19–20 (emphasis added).

Petitioner contends that Leonhardt describes a porcine valve element that is attached to the central portion of the frame. Pet. 28 (citing Ex. 1017, 5:45–51, 6:23–31, 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 claim 1 fails. Leonhardt's valve is undeniably attached to its frame because the valve is sutured or glued to stent 26. Claim 1 requires the valve element to be attached to a portion of the frame located along the radial centerline. Ex. 1001, 19:19–20. However, Leonhardt's frame (stent 26 coupled via connecting bar 29) is a hollow cylinder devoid of structure located along its centerline. Ex. 1017, 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 claim 1 and thus claims 18 and 20. Therefore, we determine that Petitioner fails to establish by a preponderance of evidence that Leonhardt anticipates claims 18 and 20.

4. Summary

For the reasons expressed above, we determine that Petitioner has failed to prove by a preponderance of evidence that Leonhardt anticipates claims 18 and 20.

F. CLAIMS 18 AND 20: OBVIOUSNESS BY LEONHARDT

Petitioner argues that even if Leonhardt fails to describe elements as claimed, an ordinarily skilled artisan would consider that "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. 42. Petitioner also argues that "[a]s these are method claims, and not device claims, even if the valve device were somehow unobviously different, which it is not, that difference should be given minimal weight in evaluating the obviousness of the method." *Id*. at 44. Petitioner cites no authority for this proposition, and we are aware of none.

Claims 18 and 20 are directed to a "transluminal method of inserting an artificial valve as set forth in claim 1." *Id*. at 21:1–25 (claim 18), 21:31–50 (claim 20). Each time claims 18 and 20 refer to an "artificial valve" steps of the recited methods, they refer to the valve set forth in claim 1. None of Petitioner's arguments persuasively addresses Leonhardt's failure to describe a flexible valve element attached to a central portion of the frame located along a centerline. *See* Part II.E. Accordingly, we conclude that Petitioner has failed to prove by a preponderance of evidence that Leonhardt alone renders claims 18 and 20 unpatentable as obvious.

G. CLAIMS 18 AND 20: OBVIOUSNESS IN VIEW OF LEONHARDT AND JOHNSON

Petitioner contends that the combination of Leonhardt and Johnson renders claims 18 and 20 unpatentable as obvious. Pet. 45–60. For the reasons expressed below, we conclude that Petitioner has not proven by a preponderance of evidence that claims 18 and 20 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 to form a valve element having a hemispherical or paraboloid overall shape. *Id*. at 4:57–61.

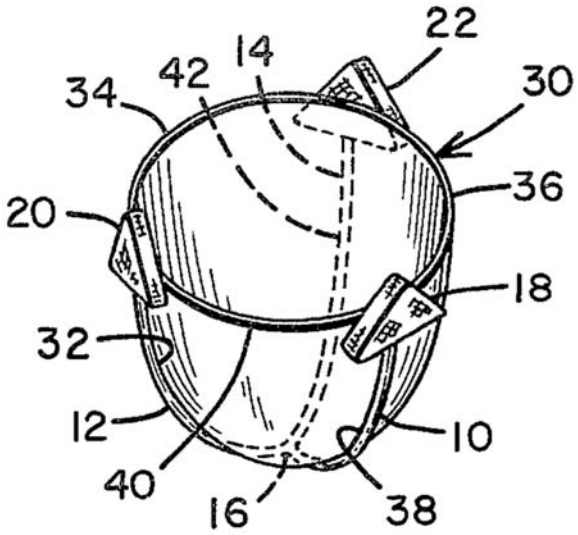


Fig. 2

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

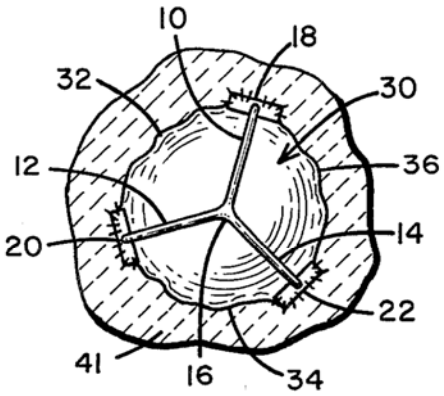


Fig. 4

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

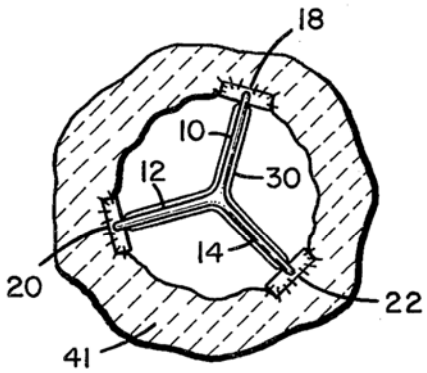


Fig. 5

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 Leonhardt and Johnson describes every element of claims 18 and 20 with citations to precise portions of Leonhardt and Johnson and testimony by Dr. Dasi. *Id*. at 45–59 (citing Ex. 1017, 3:33–44, 3:57–59, 4:14–15, 4:23–40, 4:53–5:52, 6:9–34, 7:11–16, 8:23–41, 9:49–11:68, Figures 1B, 1C, 2–8, 9A–9D; Ex. 1021, 2:39–3:19, 3:26–47, 4:10–68, 5:12–53, 6:2–8, 6:14–19, Figures 1, 2, 4, 5, 7, 8; Ex. 1003 ¶¶ 74–76, 101, 102, 105–133).

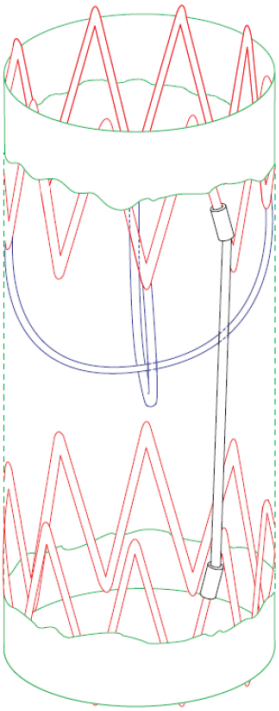
Petitioner's proposed combination of Leonhardt and Johnson addresses the ways in which Leonhardt alone fails to describe a flexible valve element attached to a central portion of the frame located along the centerline that we noted in Part II.E above. Johnson's struts form a frame that includes structure, joinder point 16, located along the centerline of the frame of the valve. Ex. 1021, 4:35–42. Johnson's membrane 30 is attached to 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 claim 1 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.

3. Motive to Combine Leonhardt and Johnson

Petitioner argues that a person having ordinary skill in the art would have been motivated to substitute a funnel valve and cage structure taught in Johnson in place of Leonhardt's biological valve. Pet. 46. Petitioner provides a drawing, labelled "Fig. H" and reproduced at right, purporting to schematically depict the structure resulting from the proposed combination. *Id.* at 47. Figure H depicts the "birdcage-like frame" of Johnson inserted within the stent of Leonhardt.

FIG.H



As one reason for combining Leonhardt and Johnson, Petitioner asserts that "no motivation should be required to substitute equivalent known elements from among the known technology." *Id.* at 59. Patent Owner disputes this assertion, arguing that "Petitioner's proposed combination is not replacing one valve for another valve or one frame for another frame. Rather, Petitioner proposes to place the entire non-collapsible frame and valve of one reference (*Johnson*) *inside* the collapsible frame of another reference (*Leonhardt*)." PO Resp. 15–16.

We find Patent Owner's argument persuasive. Petitioner's proposed modification is not the mere substitution of one element for another known in the field. Petitioner does not propose to simply replace the biological valve element of Leonhardt with the valve element of Johnson. Instead, as Patent Owner correctly notes, Petitioner proposes replacing the biological valve element of Leonhardt with the *entire* valve device of Johnson.

Johnson's dynamic annulus heart valve and the biological valve element of Leonhardt, however, are distinct and different structures. Thus, contrary to Petitioner's assertion, Johnson's heart valve is not equivalent to the biological valve element of Leonhardt.

Petitioner also argues that "Leonhardt provides motivation for the combination by teaching that mechanical and synthetic valves and the like could be used in place of the biological valve exemplified." Pet. 59 (citing Ex. 1017 col.6:31–34). Petitioner adds that because one of ordinary skill in the art would know that patients most in need of transcatheter procedures are the frailest, the skilled artisan would be very interested in durable solutions and Johnson teaches a durable transcatheter valve. *Id.* at 46 (citing Ex. 1003 ¶ 102; Ex. 1021, 2:39–42, 3:37–47). More specifically, Petitioner argues "Johnson discloses that tissue valves, such as those preferred in Leonhardt, have had durability problems resulting from, *inter alia,* the fact that the leaflets are attached to a rigid or semirigid fixation ring around the perimeter." *Id.* According to Petitioner, one of ordinary skill in the art would have been motivated to try the construction of Johnson's valve to replace a native tissue valve of Leonhardt to obtain a more durable valve. *Id.* at 60.

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

increases the durability of its valve design, while tissue or synthetic valve designs have durability problems because the leaflets are attached to a rigid or semi-rigid outer fixation ring. *Id.* at 3:36–41.

Contrary to Petitioner's assertion, the tissue valve of Leonhardt does not include a rigid or semi-rigid outer fixation ring that would present the durability problems described in Johnson. Instead, Leonhardt employs stent 26, which is a flexible frame made of super elastic material that allows it to deform under exerted forces and conform to structures occurring within vessel walls. Ex. 1017, 4:60–65. Thus, based on the record before us, there is no indication that Leonhardt would suffer the durability problems with which Johnson is concerned. As such, one of ordinary skill in the art would not expect the proposed modification to improve the durability of Leonhardt's valve and, thus, would not be motivated to make the proposed combination. Moreover, Leonhardt's disclosure of using a mechanical or synthetic valve instead of a preferred biological valve (Ex. 1017, 6:31–33), by itself, does not provide sufficient reasoning for combining Leonhardt and Johnson in the manner proposed.

4. Conclusion

For the above reasons, we determine that Petitioner has not established an adequate rationale for combining Leonhardt and Johnson in the manner proposed. Therefore, Petitioner has not shown, by a preponderance of the evidence, that the combination of Leonhardt and Johnson renders claims 18 and 20 unpatentable as obvious.

H. OBJECTIVE INDICIA OF NON-OBVIOUSNESS

Patent Owner argues that numerous objective indications of the non-obviousness, such as peer recognition, long-felt but unresolved need,

commercial success, and acceptance and adoption by industry, exist and "weigh heavily against deeming the invention of the '297 patent obvious." PO Resp. 18–23. Because we are not persuaded Petitioner has demonstrated sufficiently that Leonhardt alone or the combination of Leonhardt and Johnson render claims 18 and 20 obvious, we need not reach Patent Owner's assertions regarding objective indicia of non-obviousness.

III. 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. 24. 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.

IV. CONCLUSION

Based on the record before us, we conclude that Petitioner has not demonstrated by a preponderance of the evidence that claims 18 and 20 are unpatentable.

V. ORDER

For the reasons given, it is:

ORDERED, based on a preponderance of evidence, claims 18 and 20 of U.S. Patent 6,821,297 B2 are *not 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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