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Paper 32
Date: August 12, 2022

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MEDTRONIC COREVALVE LLC and MEDTRONIC, INC.,
Petitioner,

v.

SPEYSIDE MEDICAL, LLC,
Patent Owner.

IPR2021-00239
Patent 8,377,118 B2

Before PATRICK R. SCANLON, KEVIN W. CHERRY, and JAMES J. MAYBERRY, *Administrative Patent Judges.*

SCANLON, *Administrative Patent Judge*.

JUDGMENT
Final Written Decision
Determining No Challenged Claims Unpatentable
35 U.S.C. § 318(a)

I. INTRODUCTION

Medtronic CoreValve LLC and Medtronic, Inc. (collectively, "Petitioner") challenges claims 1, 2, 5, 7–11, 13, 14, and 18–23 of U.S. Patent No. 8,377,118 B2 (Ex. 1001, "the '118 patent"). We have jurisdiction under 35 U.S.C. § 6, and this Final Written Decision is issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73. For the reasons that follow, we determine that Petitioner has not shown by a preponderance of the evidence that claims 1, 2, 5, 7–11, 13, 14, and 18–23 of the '118 patent are unpatentable.

A. Procedural History

Petitioner filed a Petition (Paper 2, "Pet.") requesting an *inter partes* review of claims 1, 2, 5, 7–11, 13, 14, and 18–23 of the '118 patent. Speyside Medical, LLC ("Patent Owner") filed a Preliminary Response (Paper 6). With our authorization, Petitioner filed a Preliminary Reply (Paper 7) and Patent Owner filed a Preliminary Sur-reply (Paper 8).

We instituted a trial as to all challenged claims. Paper 9 ("Decision on Institution" or "Dec. Inst.").

After institution, Patent Owner filed a Patent Owner Response (Paper 16, "PO Resp."), Petitioner filed a Reply (Paper 20, "Pet. Reply"), and Patent Owner filed a Sur-reply (Paper 26, "PO Sur-reply").

Petitioner relies on the Declaration of Dr. William J. Drasler (Ex. 1002), the Reply Declaration of Dr. William J. Drasler (Ex. 1065), and the Declaration of Crena Pacheco (Ex. 1061) in support of its contentions. Patent Owner relies on the Declaration of Ivan Vesely, Ph.D. (Ex. 2004) in support of its contentions.

An oral hearing was held on May 16, 2022. A transcript of the hearing is included in the record. Paper 31 ("Tr.").

II. BACKGROUND

A. Real Parties in Interest

Petitioner identifies Medtronic CoreValve LLC and Medtronic, Inc. as the real parties in interest. Pet. 6. Petitioner adds that "[n]o other party had access to or control over the present Petition, and no other party funded or participated in preparation of the present Petition." *Id.*

Patent Owner identifies itself as the real party in interest. Paper 4, 2.

B. Related Matters

The '118 patent is the subject of litigation in the U.S. District Court for the District of Delaware, in a case styled *Speyside Medical, LLC v. Medtronic CoreValve LLC*, No. 20-cv-00361-LPS (filed March 13, 2020). Pet. 6; Paper 4, 2. Both parties identify the following *inter partes* review proceedings as related to the '118 patent: IPR2021-00240, IPR2021-00241, and IPR2021-00310 (each challenging U.S. Patent No. 9,510,941); IPR2021-00242 (challenging U.S. Patent No. 10,449,040); IPR2021-00243 (challenging U.S. Patent No. 9,445,897); and IPR2021-00244 (challenging U.S. Patent No. 9,603,708).[1] Pet. 6; Paper 4, 2.

C. The '118 Patent

The '118 patent, titled "Unstented Heart Valve with Formed in Place Support Structure," issued February 19, 2013, with claims 1–23. Ex. 1001, code (54), code (45), 79:24–82:22. The '118 patent is directed "to medical methods . . . for percutaneously implanting a stentless valve having a formed in place support structure." *Id.* at 1:28–31. We reproduce Figures 47A–E '118 patent below.

[1] The Board denied institution in IPR2021-00240, IPR2021-00241, IPR2021-00242, and IPR2021-00310.

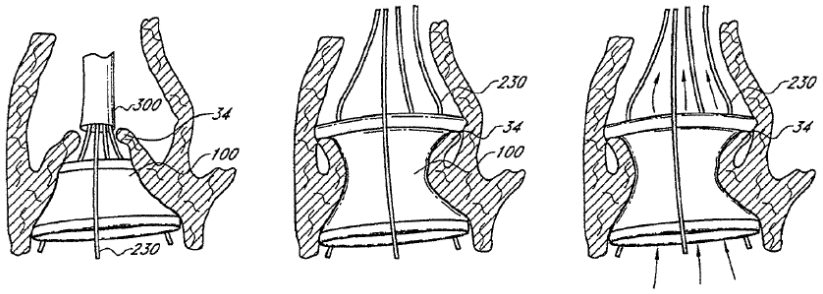


FIG. 47A FIG. 47B FIG. 47C

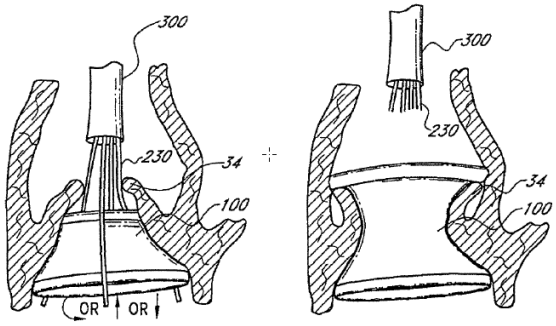


FIG. 47D FIG. 47E

Figures 47A–E depict "time sequence steps of deploying, testing and repositioning an artificial valve implant." Ex. 1001, 10:9–10. These figures depict deploying implant 100 at the aortic valve. *See, e.g.*, *id.* at 11:16–18 (identifying aortic valve 34). Implant 100 is delivered to the heart translumenally, such as through the femoral artery. *Id.* at 59:10–13; *see also* Figs. 57A, 57B (depicting accessing the heart through the femoral artery); 40:19–23 ("[D]elivery of the implant 100 via catheterization of the implantation site can include a mechanism to deploy or expel the implant 100 into the vessel. This mechanism may include a push or pull member to transmit forces to the distal portion of the catheter 300.").

As seen in Figure 47A, implant 100 is partially deployed into ventricle 32 (not identified in Figure 47A) from deployment catheter 300, with deployment control wires 230 attached. Ex. 1001, 50:8–10. Control wires

230 are used to seat implant 100 against aortic valve 34. Prior to this seating step, the distal end of implant 100 (that is, the end furthest from deployment catheter 300) is inflated. *See, e.g.*, *id.* at 73:42–48 ("The deployment catheter is advanced across the aortic valve. The prosthetic valve and inflatable cuff are unsheathed in the ventricle, but remain attached to the deployment control wires. The distal end of the inflatable cuff is inflated. The sheath is retracted far enough that the deployment control wires allow the prosthetic valve to function."). As seen in Figure 47A, the proximal end of implant 100 (that is, the end closest to deployment catheter 300) has not been inflated. *Id.* at 50:8–10.

Figure 47B shows implant 100 fully deployed. *Id.* at 50:10–11. That is, implant 100 "is . . . withdrawn across the native valve annulus . . . [and] then fully inflated." *Id.* at 73:48–49. The implant may be tested (Figure 47C) and, depending on the results, the proximal end of implant 100 may be deflated and the implant repositioned (Figure 47D). *Id.* at 50:12–14. Implant 100 is then fully deployed and the control wires are disconnected (Figure 47E). *Id.* at 50:14–16.

We reproduce the '118 patent's Figure 3B, below.

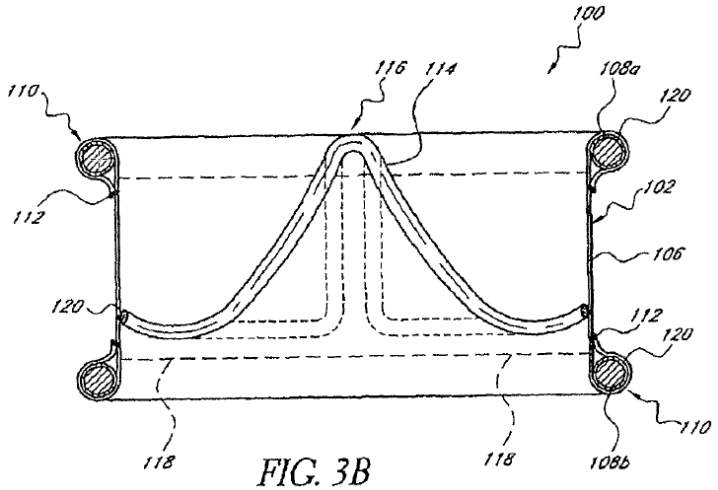


FIG. 3B

Figure 3B depicts a cross-sectional view of an exemplary implant. Ex. 1001, 8:5–6. Implant 100 includes inflatable cuff or body 102, which supports valve 104 (not depicted). *Id.* at 11:61–64. "[V]alve 104 is configured to move in response to the hemodynamic movement of the blood pumped by the heart 10 between an 'open' configuration where blood can [flow through] the implant 100 in a first direction . . . and a 'closed' configuration whereby blood is prevented from back flowing through the valve." *Id.* at 11:65–12:3. "[V]alve 104 can be located in the distal portion 128 of the implant 100." *Id.* at 15:16–17. "[V]alve 104 preferably is a tissue-type heart valve that includes a dimensionally stable, pre-aligned tissue leaflet subassembly." *Id.* at 27:29–31; *see also* Figure 5B (depicting a view of the valve's leaflets).

Cuff 102 includes thin flexible tubular material 106 such as a flexible fabric or thin membrane with little dimensional integrity. *Id.* at 12:5–7. Implant 100 includes inflation channels 120, such as rings 108a, 108b, positioned at the proximal and distal ends of cuff 102. *Id.* at 12:25–30. Implant 100 also includes inflatable struts 114. *Id.* at 12:37–38. When inflated, that is, expanded, rings 108 and struts 114 provide structural support to implant 100, allowing the implant to be formed in place. *Id.* at 12:50–52. "Uninflated, the implant 100 is a generally thin, flexible shapeless assembly that is preferably [i]ncapable of support and is advantageously able to take a small, reduced profile form in which it can be percutaneously inserted into the body." *Id.* at 12:53–57.

D. Challenged Claims

Petitioner challenges claims 1, 2, 5, 7–11, 13, 14, and 18–23 of the '118 patent, of which claim 1 is the sole independent claim. Claim 1 is reproduced below:

1. A method for replacing a patient's native aortic heart valve in a heart, the method comprising:

delivering an implantable expandable carrier element and an implantable replacement valve having leaflets endovascularly to a vicinity of the native aortic heart valve while the heart is beating, the carrier element having proximal and distal ends, the replacement valve configured to allow the flow of blood through the replacement valve in a first direction and prevents the flow of blood through the replacement valve in a second direction;

positioning the proximal and distal ends of the carrier element proximate opposing sides of the native aortic heart valve;

expanding the carrier element from a collapsed delivery configuration to a first expanded configuration;

using the carrier element to exclude the native aortic heart valve in the first expanded configuration,

forming a seal between the carrier element and one or more native anatomical features in the first expanded configuration;

using the leaflets of the replacement valve to replace leaflet actuation of the native aortic heart valve in the first expanded configuration;

evaluating the position of the carrier element;

at least partially collapsing the carrier element from the first expanded configuration to a moveable configuration, a length of the carrier element in the moveable configuration being substantially equal to or less than a length of the carrier element in the first expanded configuration;

repositioning the carrier element in the moveable configuration in the vicinity of the native aortic heart valve;

expanding the carrier element from the moveable configuration to a second expanded configuration to secure the carrier element in the vicinity of the native aortic heart valve, the proximal and distal ends of the carrier element being proximate

> opposing sides of the native aortic heart valve in the second expanded configuration;
>
> using the carrier element to exclude the native aortic heart valve in the second expanded configuration;
>
> forming a seal between the carrier element and one or more anatomical features in the second expanded configuration; and
>
> using the leaflets of the replacement valve to replace leaflet actuation of the native aortic heart valve in the second expanded configuration.

Ex. 1001, 79:24–67.

E. Instituted Grounds of Unpatentability

We instituted *inter partes* review of the challenged claims based on the following grounds of unpatentability asserted by Petitioner:[2]

Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
1, 2, 5, 7–11, 13, 14, 18–23	103(a)	Leonhardt,[3] Gabbay[4]
7	103(a)	Leonhardt, Gabbay, Bailey[5]
18	103(a)	Leonhardt, Gabbay, Moulopoulos[6]

Dec. Inst. 41; Pet. 9.

[2] The Leahy-Smith America Invents Act ("AIA") included revisions to 35 U.S.C. § 103 that became effective on March 16, 2013. Pub. L. No. 112-29, §§ 3(c), 3(n)(1), 125 Stat. 284, 287, 293 (2011). Because the application from which the '118 patent issued has an effective filing date prior to March 16, 2013, we apply the pre-AIA version of § 103.
[3] Leonhardt et al., US 5,957,949, issued Sept. 28, 1999 (Ex. 1004).
[4] Gabbay, US 2002/0032481 A1, published Mar. 14, 2002 (Ex. 1046).
[5] Bailey, et al., US 2003/0023300 A1, published Jan. 30, 2003 (Ex. 1005).
[6] Moulopoulos, US 3,671,979, issued June 27, 1972 (Ex. 1019).

III. ANALYSIS

A. Legal Standards

To prevail in its challenge, Petitioner must demonstrate by a preponderance of the evidence that the claims are unpatentable. 35 U.S.C. § 316(e); 37 C.F.R. § 42.1(d). "In an IPR, 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) (2012) (requiring *inter partes* review petitions to identify "with particularity . . . the evidence that supports the grounds for the challenge to each claim")). This burden of persuasion never shifts to the patent owner. *See Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015) (discussing the burden of proof in *inter partes* review).

A patent claim is unpatentable under 35 U.S.C. § 103(a) if the differences between the claimed subject matter and the prior art are such that the subject matter, as a whole, would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of ordinary skill in the art; and (4) when in evidence, objective indicia of non-obviousness (also called secondary considerations), such as commercial success, long-felt but unsolved needs, and failure of others. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966). We analyze grounds based on obviousness in accordance with the above-stated principles.

B. Level of Ordinary Skill in the Art

In determining whether an invention would have been obvious at the time it was made, 35 U.S.C. § 103 requires us to resolve the level of ordinary skill in the pertinent art at the time of the invention. *Graham*, 383 U.S. at 17. The person of ordinary skill in the art is a hypothetical person who is presumed to have known the relevant art at the time of the invention. *In re GPAC Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995). Factors that may be considered in determining the level of ordinary skill in the art include, but are not limited to, the types of problems encountered in the art, the sophistication of the technology, and educational level of active workers in the field. *Id.* In a given case, one or more factors may predominate. *Id.*

Petitioner submits that a person having ordinary skill in the art "would have had a minimum of either a medical degree and experience working as an interventional cardiologist or a Bachelor's degree in bioengineering or mechanical engineering (or a related field) and approximately two years of professional experience in the field of prosthetic cardiovascular implants," and "[a]dditional graduate education could substitute for professional experience, or significant experience in the field could substitute for formal education." Pet. 21–22 (citing Ex. 1002 ¶¶ 31–34).

We adopted Petitioner's proposed level of ordinary skill in the art in the Decision on Institution, stating it was "consistent with the evidence of record, including the asserted prior art." Dec. Inst. 9–10. In its Response, Patent Owner notes that it and its expert, Dr. Vesely, apply Petitioner's level of ordinary skill in the art for the purposes of this proceeding. PO Resp. 20.

Based on our review of the record before us, we continue to apply the level of ordinary skill in the art adopted in the Decision on Institution.

C. Claim Construction

"In an *inter partes* review proceeding, a claim of a patent . . . shall be construed using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. 282(b)." 37 C.F.R. § 42.100(b) (2020). Under that standard, we generally give claim terms their ordinary and customary meaning, as would be understood by a person of ordinary skill in the art at the time of the invention, in light of the language of the claims, the specification, and the prosecution history. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1313–14 (Fed. Cir. 2005) (en banc). Although extrinsic evidence, when available, may also be useful when construing claim terms under this standard, extrinsic evidence should be considered in the context of the intrinsic evidence. *Id.* at 1317–19.

Petitioner argues that "[a]ll claim terms should be construed according to their plain and ordinary meaning as would have been understood by a [person having ordinary skill in the art] in view of the specification." Pet. 22 (citing Ex. 1002 ¶ 64). Regarding the limitation "a length of the carrier element in the moveable configuration being substantially equal to or less than a length of the carrier element in the first expanded configuration" of claim 1, Petitioner adds that the prior art discloses this limitation regardless of the exact metes and bounds of the term "substantially." *Id.* at 23 (citing Pet. 46–48; Ex. 1002 ¶¶ 66–67); Pet. Reply 1 (arguing the Board need not construe this limitation).

In response, Patent Owner does not dispute Petitioner's assertion that all claim terms should be construed according to their plain and ordinary meaning, but argues that "[b]ased on the plain and ordinary meaning of the claims, the challenged claims are not obvious in view of the art relied on by Petitioner[]." PO Resp. 20–21. Patent Owner does argue that Petitioner

fails to apply the correct plain and ordinary meaning for the claim phrases "opposing sides of the native aortic heart valve" and "expanding the carrier element from the moveable configuration to a second expanded configuration," but asserts that it is not necessary for the Board to construe these phrases expressly. *Id.* at 21–22.

We note that a dispute regarding the meaning of the specific term "a length of the carrier element" in claim 1 arose during the hearing. In response to a question, Petitioner replied that "a length" would not necessarily mean the entire length of the carrier element. Tr. 13:6–19. Patent Owner, on the other hand, argued that "the way that it's been read by both parties in the papers is that 'a length' refers to the entire length" of the carrier element. Tr. 37:13–38:8.

We agree with Patent Owner that Petitioner's position is a new argument raised for the first time at the hearing. For instance, in arguing in the Petition that Leonhardt discloses the limitation "a length of the carrier element in the moveable configuration being substantially equal to or less than a length of the carrier element in the first expanded configuration," Petitioner states that Leonhardt's "*[v]alve/stent 20's length* in the repositioning configuration is substantially equal to *its length* in the fully deployed configuration." Pet. 47 (emphases added). Petitioner's expert, Dr. Drasler, similarly testifies that "*[t]he length of valve stent 20* in the repositioning configuration is substantially equal to *its length* in the fully deployed configuration." Ex. 1002 ¶ 137 (emphases added); *see also* Ex. 1065 ¶ 15 (Dr. Drasler testifying that claim 1 requires only substantially equal lengths), ¶ 17 (Dr. Drasler comparing "the maximum length of the '118 patent's hyperboloid prosthesis" to "the length in the [expanded] configuration"), ¶ 18 (Dr. Drasler testifying that claim 1 "concerns ***relative***

length in the moveable and expanded configurations"), ¶ 20 (Dr. Drasler testifying that claim 1 "requires only that the two configurations are 'substantially equal' in length"). Thus, Petitioner and Dr. Drasler clearly are referring to the entire length of the element. *See Dell Inc. v. Acceleron, LLC*, 884 F.3d 1364, 1369 (Fed. Cir. 2018) ("Unless it chose to exercise its waiver authority under 37 C.F.R. § 42.5(b), the Board was obligated to dismiss Dell's untimely argument given that the untimely argument in this case was raised for the first time during oral argument.").

Beyond addressing this new argument, we determine that we need not expressly construe any other claim term to resolve the parties' disputes because doing so would have no effect on the analysis below. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017); *see also Realtime Data, LLC v. Iancu*, 912 F.3d 1368, 1375 (Fed. Cir. 2019) ("The Board is required to construe 'only those terms that . . . are in controversy, and only to the extent necessary to resolve the controversy.'") (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999)).

D. Ground 1: Asserted Obviousness Based on Leonhardt and Gabbay

Petitioner asserts that claims 1, 2, 5, 8–11, 13, 14, and 18–23 are unpatentable under 35 U.S.C. § 103(a) based on Leonhardt and Gabbay.[7] Pet. 24–66. Patent Owner provides arguments addressing this asserted ground of unpatentability. PO. Resp. 22–53. We first summarize the references and then address the parties' contentions.

[7] Petitioner's assertion that claim 7 is unpatentable under 35 U.S.C. § 103(a) based on Leonhardt and Gabbay is discussed in connection with Petitioner's assertion that claim 7 is unpatentable under 35 U.S.C. § 103(a) based on Leonhardt, Gabbay, and Bailey. Pet. 24 n.4, 71–73.

1. Leonhardt

Leonhardt, titled "Percutaneous Placement Valve Stent," issued on September 28, 1999. Ex. 1004, codes (54), (45). Leonhardt is directed to "artificial valves . . . placed percutaneously by a catheter . . . [to] replace existing valves such as are in the heart." *See id.* at 1:4–7. We reproduce Leonhardt's Figures 1A-1C below.

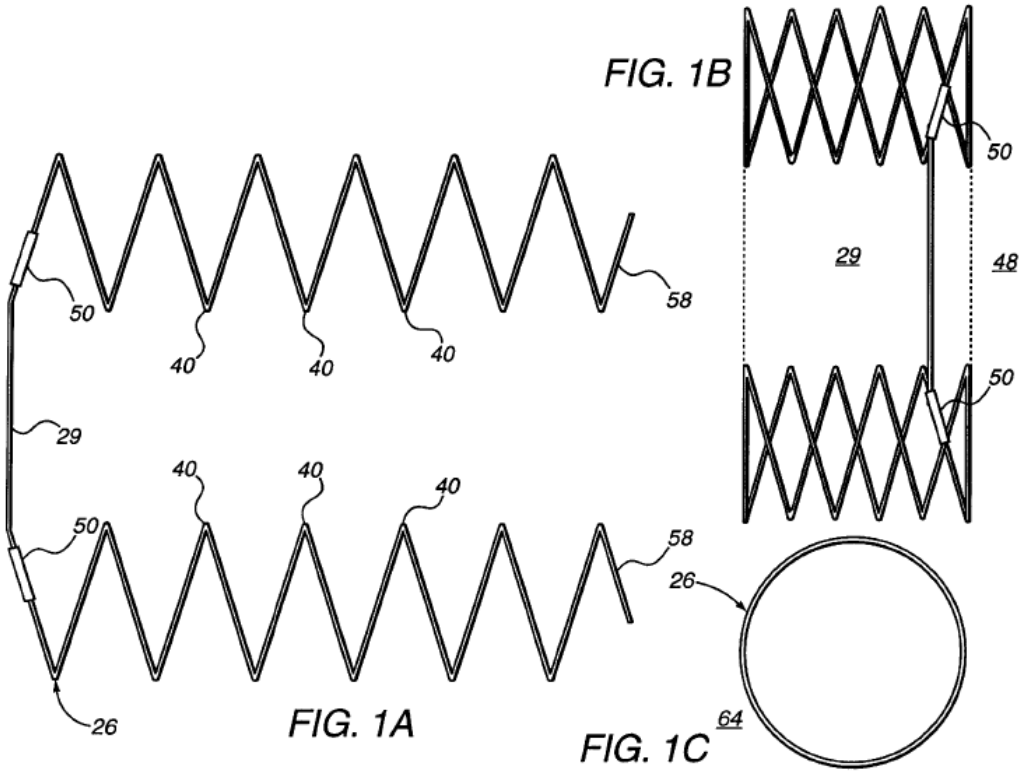


Figure 1A shows a spring stent prior to attaching the ends to form its cylindrical shape; Figure 1B shows the stent after attaching the ends to form its cylindrical shape; and Figure 1C is a top view of the stent after attaching the ends to form its cylindrical shape. Ex. 1004, 3:48–56.

Stent 26 is formed from a single piece of super elastic wire having two crimping tubes 50. *Id.* at 4:26–28. Stent 26 includes "top and bottom portions" that are substantially symmetrical and define a zig-zag or wavy form. *Id.* at 4:35–37. "At each end of stent 26 is a short extension 58

beginning another zig or wave. Short extension 58 is to close and attach the end to the first zig or wave closest to connecting bar 29" via crimping tubes 50. *Id.* at 4:40–46. Once crimped, stent 26 comprises two "cylinders," one at each end of the stent. *Id.* at 5:27–28. These cylindrical end portions of stent 26 are spaced a predetermined distance from each other by connecting bar 29. *Id.* at 5:31–33. As seen in Figures 1A–1B, the cylindrical end portions comprise a plurality of segments defining the zig-zag form, with each pair of adjoining segments connected at a vertex or tip in a V-shaped configuration.

We reproduce Leonhardt's Figure 4 below.

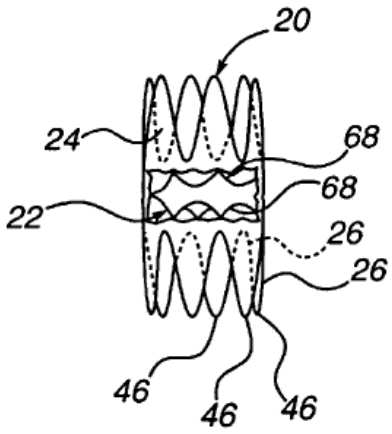
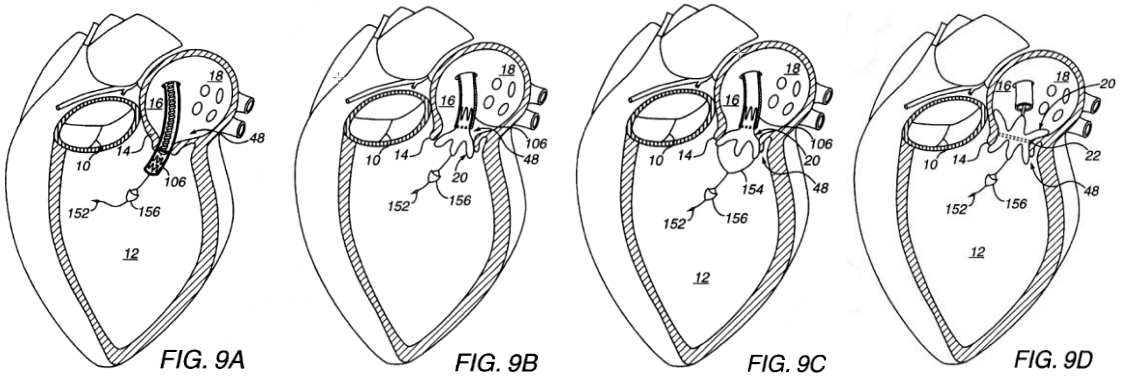


FIG. 4

Figure 4 depicts "a sectional view showing the biological valve within the stent." Ex. 1004, 3:61–62. "Valve stent 20 comprises a malleable graft material 24 enclosing deformable self-expanding stent 26 to which a biological valve 22 is attached. . . . The deployed valve stent 20 creates a patent one way fluid passageway." *Id.* at 5:45–51. Graft material 24 may be cut out between a plurality of distensible fingers 46, thereby allowing valve stent 20 to flare at one or both ends. *Id.* at 6:9–13.

We reproduce Leonhardt's Figures 9A–9D below.



Figures 9A–9D depict, as a series, "a method of deploying the valve stent in the mitral valve position." Ex. 1004, 4:8–10. Deployment catheter 100, with outer sheath 106, enters the body through a femoral artery (for replacing the aortic valve) and is moved to the heart. *Id.* at 9:50–10:11, Fig. 9A. Once in position, the distal end of valve stent 20 is deployed by withdrawing outer sheath 106 to allow distensible fingers 46 to self-expand. *Id.* at 10:53–58, Fig. 9B. "Expansion balloon 154 is then inflated to a pressure sufficient to hold the distal end of valve stent 20 secure against the living tissue . . . [which] allows valve stent 20 to mold itself quickly into the living tissue at the placement site and achieve a patent seal." *Id.* at 11:3–9, Fig. 9C. As seen in Figure 9C, expansion balloon 154 occludes blood flow. *See also* Ex. 1001, 72:24–35 (discussing Leonhardt and stating that, at this stage of deployment, "the devices effectively block all aortic output"). Outer sheath 106 is further withdrawn to release the proximal end of valve stent 20. Ex. 1004, 11:13–15. Expansion balloon 154 is deflated, moved to the proximal end of stent 20, and re-inflated to seat the proximal end of the sent. *Id.* at 11:15–22.

To reposition or remove valve stent 20, outer sheath 106 is advanced to the proximal end of valve stent 20, and distended fingers 46 at the proximal end of valve stent 20 are compressed to the diameter of outer

sheath 106. *Id.* at 11:37–49. Outer sheath 106 is then advanced over valve stent 20 such that it can be repositioned or removed. *Id.* at 11:49–53.

2. Gabbay

Gabbay relates to an implantable prosthetic heart valve device and a method of implanting the prosthesis. Ex. 1046 ¶ 2. Gabbay discloses valvular prosthesis 10 comprising valve portion 12 and stent portion 14. *Id.* ¶ 37, Fig. 2. Valve portion 12 includes inflow and outflow ends 16, 18 spaced apart by the length of cylindrical sidewall portion 20. *Id.* ¶ 38, Fig. 2.

Prosthesis 10 may be compressed to a reduced cross-sectional dimension while being implanted. *Id.* ¶ 50. Once implanted, "the prosthesis may be permitted to return toward its original cross-sectional dimension so as to engage a valve wall or other surrounding tissue at the desired position." *Id.* Figure 10 of Gabbay is reproduced below.

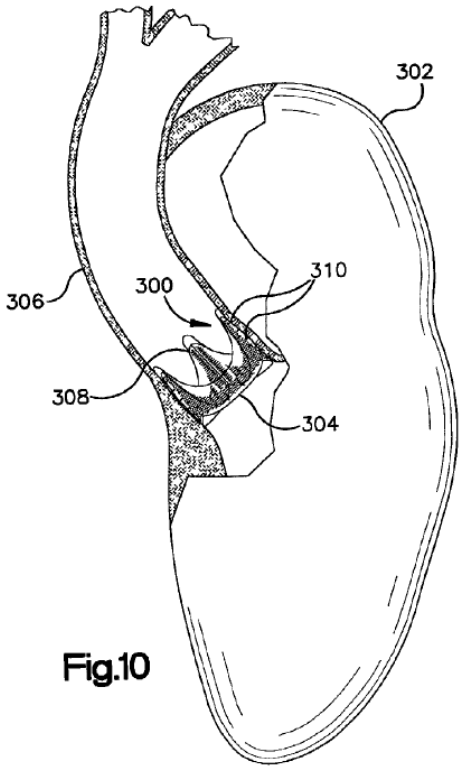


Fig.10

Figure 10 shows an example in which valvular prosthesis 300 is implanted in heart 302 in an aortic position. Ex. 1046 ¶ 68. Prior to valve implantation, the aortic valve, or at least calcified portions thereof, should be removed. *Id.* "An inflow end 304 of the prosthesis 300 is annularized with respect to the annulus of the aorta 306. An outflow portion 308 of the prosthesis 300 extends axially into the aorta 306, with the stent posts engaging the interior of the aortic wall." *Id.*

3. Independent Claim 1

Petitioner contends that the combination of Leonhardt and Gabbay discloses each limitation of independent claim 1. Pet. 34–51. To support its arguments, Petitioner identifies certain passages in the cited references and explains the significance of each passage with respect to the corresponding claim limitation. *Id.* Petitioner also articulates reasons to combine the relied-upon aspects of Leonhardt and Gabbay. *Id.* at 31–34.

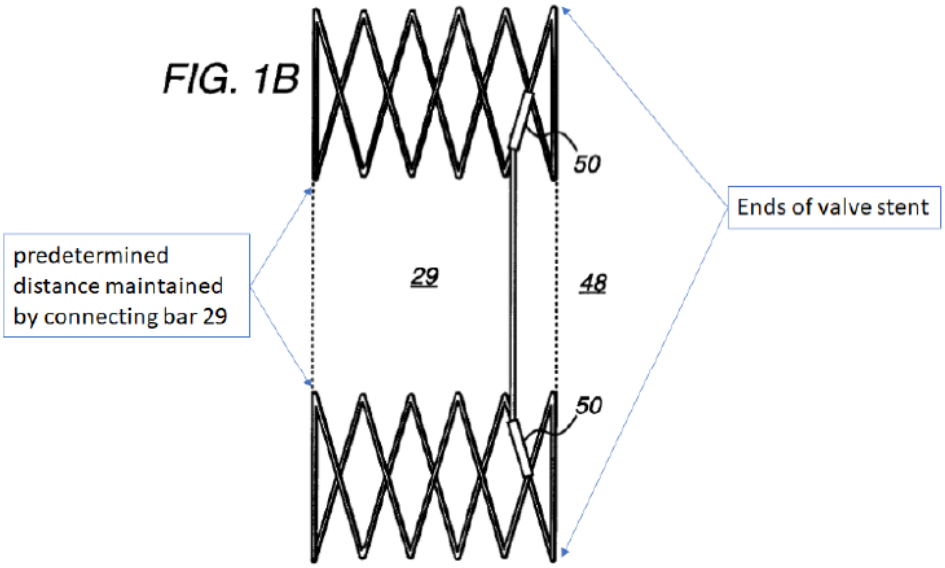
We focus our analysis on the claim 1 limitation "a length of the carrier element in the moveable configuration being substantially equal to or less than a length of the carrier element in the first expanded configuration." This issue is dispositive as to claim 1.

Petitioner argues that Leonhardt alone discloses this limitation; Petitioner does not rely on Gabbay for this limitation. Pet. 46–48 (citing Ex. 1002 ¶¶ 134–137). Specifically, Petitioner points to Leonhardt's disclosure that "'connecting bar 29' holds opposing 'cylinder' of 'valve stent 20' 'a predetermined distance from each other' in either configuration." *Id.* at 46–47. Petitioner also asserts that "[v]alve/stent 20's length in the repositioning configuration is substantially equal to its length in the fully deployed configuration because it comprises structures at each end 'spaced a

predetermined distance from each other by a connecting bar 29' in either configuration." *Id.* at 47 (citing Ex. 1004, 11:40–52, 5:28–34, 4:41–46).

In addition, Petitioner argues that Leonhardt's valve stent 20 holds its ends at a predetermined distance and can expand into a hyperboloid shape just as the '118 patent discloses that flexible fabric cuff 752 holds the ends of the prosthetic implant a maximum distance from each other and may be expanded into a hyperboloid shape. *Id.* (citing Ex. 1004, 13:51–58, 27:23–26, Fig. 25F; Ex. 1002 ¶ 137).

In its Response, Patent Owner argues that Petitioner fails to demonstrate sufficiently that the length of Leonhardt's carrier element in the moveable configuration is substantially equal to its length in the first expanded configuration because, by solely relying on connecting bar 29, Petitioner addresses only a portion of the length of Leonhardt's carrier element. PO Resp. 23–24 (citing Ex. 2004 ¶ 80; Pet. 47). In Patent Owner's view, connecting bar 29 "does not maintain a predetermined distance between the distal and proximal ***ends*** of the valve stent." *Id.* at 25. Patent Owner illustrates this assertion with an annotated version of Leonhardt's Figure 1B, which we reproduce below.



PO Resp. 25. For this annotated version of Figure 1B, Patent Owner added text with arrows identifying the distance between the axially inner tips of the two cylindrical, zig-zag end portions of stent 26 as the "predetermined distance maintained by connection bar 29" and text with arrows identifying the outer tips of the two cylindrical end portions of stent 26 as the "[e]nds of valve stent." *Id.* Patent Owner argues that the annotated figure shows that connection bar 29 maintains a predetermined distance between the inner tips of the two cylindrical end portions, but "[t]he Petition never addresses the impact of the expansion of the zig-zag portions at either end of the carrier on the length of the carrier." *Id.* (citing Ex. 2004 ¶ 81).

Patent Owner contends that this "failure to address the length of the carrier as a whole, as opposed to the length of the connecting bar 29, is significant because the shape of the particular valve stent described in Leonhardt changes substantially as it expands." *Id.* at 26 (citing Ex. 2004 ¶ 83; Ex. 1004, Fig. 9B). In particular, Patent Owner argues that Leonhardt discloses that the distensible fingers flare as they are released from the outer sheath, such that the tips of the fingers expand outward and pivot back

toward the center of the stent. *Id.* at 26–27 (citing Ex. 1004, 4:36–40, 6:11–13, 6:16–22, 10:56–57, Figs. 2, 4; Ex. 2004 ¶ 84). Patent Owner then argues that "[a]lthough the flaring of the stent as described in Leonhardt impacts the length of the carrier, neither the Petition nor Dr. Drasler addresses this because they focus solely on the length of the connecting bar 29." *Id.* at 28 (citing Ex. 2004 ¶ 85).

In addition, during the hearing, Patent Owner argued that the length of Leonhardt's stent becomes longer when it is collapsed as compared to when the stent is expanded. Tr. 38:22–24; *see also id.* at 40:21–41:2 (counsel for Patent Owner arguing that, when Leonhardt's stent is collapsed, the cylindrical end portions are going to become longer). Patent Owner attributed this change in length to not only the flaring or the pivoting back toward the center of the stent of Leonhardt's outer tips when the stent is expanded (Tr. 42:10–21), but also the zig-zag geometry of the cylindrical end portions (Tr. 45:12–20 ("And if you think about those triangles being compressed together, almost flat vertically, right, versus expanding outwards, it's just -- as a matter of geometry, it has to become shorter as it expands.")).

In the Reply, Petitioner asserts again that "Leonhardt's 'connecting bar 29' holds opposing 'cylinders' (structures at the prosthesis's ends) 'a predetermined distance from each other' at all times, including when expanded or when collapsed." Pet. Reply 2–3 (citing Ex. 1004, 11:40–52, 5:28–34, 4:41–46, Figs. 1A–1B; Pet. 25–26, 46–48; Ex. 1002 ¶¶ 73, 135). Petitioner also asserts that Patent Owner "concedes that the stent's moveable configuration length is 'substantially equal to' its first expanded configuration length: 'the ***stent*** in Leonhardt ***cannot become shorter in***

length when collapsed because ***the connecting bar is rigid***.'" *Id.* at 3 (quoting PO Resp. 29).

These assertions are not persuasive. Patent Owner does argue that "the stent in Leonhardt cannot become shorter in length when collapsed because the connecting bar is rigid." PO Resp. 29 (citing Ex. 2004 ¶ 86). But this assertion is made in the context of contrasting Leonhardt's device to the device depicted in Figure 25F of the '118 patent in response to Petitioner's argument that the two devices are similar. *See* PO Resp. 28–29. Patent Owner's primary argument rests on its assertion that connecting bar 29 is only *a portion* of the length of Leonhardt's carrier element. *Id.* at 24; *see also* PO Sur-reply 3 (arguing that Dr. Drasler explained that "[t]he length of the overall [Leonhardt] device is determined by the length of the connecting bar ***plus the stent components at each end***." (quoting Ex. 2027, 195:20–22)[8] (alterations in original)). For these reasons, we do not agree that Patent Owner has conceded the length of Leonhardt's stent in the moveable configuration is substantially equal to its length in the first expanded configuration.

Instead, we agree with Patent Owner that Leonhardt's cylindrical end portions change in shape and length, at least to some degree, when stent 26 is expanded or collapsed. *See* PO Resp. 26–28. We also credit Dr. Vesely's uncontroverted and well-reasoned testimony on this point. *See* Ex. 2004 ¶¶ 83–85. Furthermore, we agree that the Petition and Dr. Drasler rely

[8] Patent Owner actually cites to Exhibit 2013, but this is an apparent typographical error because the quoted language appears in lines 20–22 on page 195 of Exhibit 2027. We note that the quoted testimony reiterates Dr. Drasler's other testimony that "[t]he length of the Leonhardt device would be the length of the connecting bar plus the length of the stent components at each end of the connecting bar." Ex. 2027, 195:11–14.

solely on connecting bar 29 holding the cylindrical end portions a predetermined distance apart to support the assertion that the stent's length is substantially equal in each configuration. *See* Pet. 46–47; Ex. 1002 ¶¶ 134–137. As such, Petitioner has failed to explain the effect that the changes in Leonhardt's cylindrical end portions have on the overall length of stent 26. Accordingly, we are not persuaded that Petitioner has met its burden of showing, by a preponderance of the evidence, that Leonhardt discloses "a length of the carrier element in the moveable configuration being substantially equal to or less than a length of the carrier element in the first expanded configuration."

We also are unpersuaded by Petitioner's argument that Leonhardt's valve stent 20 meets this length limitation because it has a hyperboloid shape just like the '118 patent's embodiments of Figures 25F and 47A–47E. *See* Pet. 47; Pet. Reply 3–6. The problem with this argument is that it relies on an incorrect comparison. Petitioner compares Leonhardt's expanded valve stent 20 to the expanded devices of the '118 patent instead of comparing Leonhardt's valve stent 20 in its expanded and collapsed states.

Furthermore, this argument fails because, even though Leonhardt's valve stent 20 and the devices of the '118 patent may both assume a hyperboloid shape when expanded, the devices do not operate in the same manner. Leonhardt's valve stent achieves a hyperboloid-like shape when expanded because the cylindrical end portions flare outward while the middle section of the device is maintained at a constant length by rigid connecting bar 29. Ex. 1004, 6:9–22, Figs. 2, 9B–9D. To reposition or remove valve stent 20, distended fingers 46 of the proximal cylindrical end portion are compressed and inserted into outer sheath 106. *Id.* at 11:37–53.

In contrast, implant 100 of the '118 patent achieves a hyperboloid shape in the first expanded configuration when both the distal and proximal ends are inflated. Ex. 1001, 50:10–11, 73:42–50, Fig. 47B. For repositioning, the proximal end of implant 100 is deflated and assumes its moveable configuration. *Id.* at 50:12–14, 73:51–53, Fig. 47D. Although not described expressly in the Specification, implant 100 is depicted as being shorter in length in its moveable configuration than in its first expanded configuration. *Compare id.* at Fig. 47D, *with id.* at Fig. 47B. A shorter length in the partially deflated moveable configuration is consistent with the disclosure that, when uninflated, cuff 102 of implant 100 preferably is incapable of providing support. *See* Ex. 1001, 12:11–12. As for the embodiment of Figure 25F, Patent Owner argues that flexible fabric cuff 752 "permits the stent to become both shorter and narrower when in the collapsed delivery configuration, and longer and wider when the internal passages are filled with fluid and the entire carrier is expanded." PO Resp. 29. This assertion is supported by Dr. Vesely's uncontroverted testimony, which we find to be well-reasoned and credit. *See* Ex. 2004 ¶ 86.

Given these differences and the lack of explanation in the Petition, we determine that Petitioner has not sufficiently shown that Leonhardt's stent valve meets the length limitation by virtue of having a hyperboloid-like shape when expanded.

In view of the above, we are not persuaded on the complete record before us that Petitioner has met its burden of showing, by a preponderance of the evidence, that independent claim 1 is unpatentable over the combination of Leonhardt and Gabbay. Because we are not persuaded Petitioner has demonstrated sufficiently that the combination of Leonhardt

and Gabbay renders claim 1 obvious, we need not reach Patent Owner's assertions regarding objective indicia of nonobviousness.

4. Dependent Claims 2, 5, 8–11, 13, 14, and 18–23

Claims 2, 5, 8–11, 13, 14, and 18–23 depend from claim 1, and each of these dependent claims thus contains all the limitations of claim 1. Petitioner's challenges to dependent claims 2, 5, 8–11, 13, 14, and 18–23 do not overcome the deficiencies of Leonhardt and Gabbay with respect to claim 1. *See* Pet. 51–66, 73. Accordingly, for the same reasons discussed above in connection with claim 1, we also determine Petitioner has not demonstrated, by a preponderance of the evidence, that claims 2, 5, 8–11, 13, 14, and 18–23 are unpatentable over the combination of Leonhardt and Gabbay.

E. Grounds 2 and 3: Asserted Obviousness Based on Leonhardt, Gabbay, and Bailey and Leonhardt, Gabbay, and Moulopoulos

Petitioner contends that claim 7 would have been obvious over the combination of Leonhardt, Gabbay, and Bailey, and claim 18 would have been obvious over the combination of Leonhardt, Gabbay, and Moulopoulos. Pet. 67–78. Petitioner does not rely on either Bailey or Moulopoulos for disclosing the claim 1 limitation "a length of the carrier element in the moveable configuration being substantially equal to or less than a length of the carrier element in the first expanded configuration." *Id.* Thus, neither reference overcomes Leonhardt's failure to teach or suggest this limitation.

Accordingly, both of these grounds suffer from the same deficiency noted above with respect to the combination of Leonhardt and Gabbay. Therefore, for the same reasons discussed above, we are not persuaded on the complete record before us that Petitioner has demonstrated, by a

preponderance of the evidence, that claim 7 is unpatentable over the combination of Leonhardt, Gabbay, and Bailey or claim 18 is unpatentable over the combination of Leonhardt, Gabbay, and Moulopoulos.

IV. CONCLUSION

In summary:

Claim(s)	**35 U.S.C. §**	**Reference(s)/Basis**	**Claims Shown Unpatentable**	**Claims Not shown Unpatentable**
1, 2, 5, 7–11, 13, 14, 18–23	103	Leonhardt, Gabbay		1, 2, 5, 7–11, 13, 14, 18–23
7	103	Leonhardt, Gabbay, Bailey		7
18	103	Leonhardt, Gabbay, Moulopoulos		18
Overall Outcome				1, 2, 5, 7–11, 13, 14, 18–23

V. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that claims 1, 2, 5, 7–11, 13, 14, and 18–23 of U.S. Patent No. 8,377,118 B2 are not determined to be unpatentable; and

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

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