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Paper 11
Date: March 5, 2021

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MEDTRONIC COREVALVE LLC,
Petitioner,

v.

COLIBRI HEART VALVE LLC,

IPR2020-01453
Patent 8,900,294 B2

Before ERICA A. FRANKLIN, JAMES A. TARTAL, and ERIC C. JESCHKE

FRANKLIN, *Administrative Patent Judge*.

DECISION
Denying Institution of *Inter Partes* Review
35 U.S.C. § 314

I. INTRODUCTION

Medtronic CoreValve LLC ("Petitioner") filed a Petition requesting an *inter partes* review of claims 1–4 of U.S. Patent No. 8,900,294 B2 (Ex. 1001, "the '294 patent"). Paper 2 ("Petition" or "Pet."). Colibri Heart Valve LLC ("Patent Owner") filed a Preliminary Response to the Petition. Paper 6 ("Prelim. Resp."). We authorized the parties to file additional briefing to further address discretionary denial under 35 U.S.C. § 314(a). Ex. 3001. With that authorization, Petitioner filed a Reply to the Preliminary Response, Paper 8, and Patent Owner filed a Sur-reply to the Preliminary Response, Paper 9.

Under 35 U.S.C. § 314(a), an *inter partes* review may not be instituted unless the information presented in the petition "shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." Having considered the evidence and arguments of record, we determine that Petitioner has not shown a reasonable likelihood that it would prevail in showing the unpatentability of at least one challenged claim. Accordingly, we deny the Petition and decline to institute an *inter partes* review.

A. Real Parties-in-Interest

Petitioner identifies itself and Medtronic Inc. as the real parties-in-interest. Pet. 5. Patent Owner identifies itself as the real party-in-interest. Paper 4, 1.

B. Related Proceedings

Petitioner and Patent Owner provide notice of a district court litigation involving the '294 patent: *Colibri Heart Valve LLC v. Medtronic CoreValve LLC*, No. 8:20-cv-847 (C.D. Cal.). Pet. 5; Paper 4, 1.

C. The '294 Patent

The '294 patent is directed, in part, to a method of controlled release of a percutaneous replacement heart valve in a patient. Ex. 1001, 1:1–3. The replacement heart valve device comprises a stent member and a flexible valve means. *Id.* at 6:55–57. The stent member may be self-expanding or balloon-expandable. *Id.* at 6:57–59. The stent member is designed to have "a first polygonal shape in its compressed or collapsed configuration and a second, larger polygonal shape in its expanded configuration." *Id.* at 6:59–61. It may be made from various metal alloys, preferably nickel-titanium alloy, i.e., "nitinol." *Id.* at 7:27–28, 7:39–40. Such metal alloys are "resilient, flexible non-toxic, non-thrombogenic, physiologically acceptable and biocompatible materials." *Id.* at 7:41–43.

The valve means comprises a generally tubular portion and, preferably, a peripheral upstanding cusp or leaflet portion. *Id.* at 6:62–64. The valve means is "flexible, compressible, host-compatible, and non-thrombogenic." *Id.* at 8:27–28. It may be made from various materials, preferably mammal pericardium tissue. *Id.* at 8:33–34. The cusp or leaflet portion of the valve means is generally tubular in shape and comprises two to four leaflets. *Id.* at 7:5–8. The leaflet portion of the valve means is "formed by folding the pericardium material used to create the valve." *Id.* at 8:44–46. The leaflets function as the "actual" valve and allow blood to flow in one direction. *Id.* at 7:13–15.

A preferred embodiment of the replacement heart valve device is shown in Figure 5 of the '294 patent, set forth below:

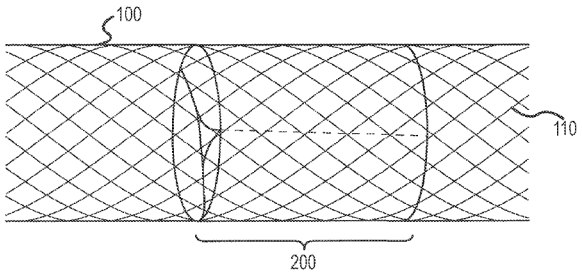


FIG.5

Figure 5 depicts "a side view of one embodiment of the replacement heart valve device of the present invention mounted within a self-expanding stent, with the stent in the expanded position." *Id.* at 6:31–34. As shown in Figure 5, the valve means 200 is disposed within the cylindrical stent member 100. *Id.* at 6:64–65. "The tubular portion of the valve means 200 is attached to the stent member 100 by a plurality of sutures . . . ." *Id.* at 7:9–10; *see also id.* at 10:27–29 ("The valve means 200 is then attached to the inner channel of the stent member 100 by suturing the outer surface of the valve means' pericardium material to the stent member."). "The attachment position of the valve is preferably closer to the proximal and wider part of the stent." *Id.* at 10:38–40.

The delivery and implantation system of the present invention includes a flexible catheter, set forth below in Figure 8 of the '294 patent:

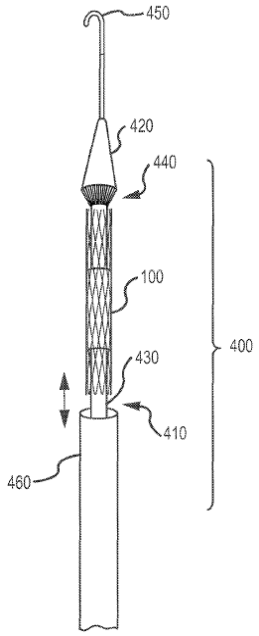


FIG.8

Figure 8 "depicts the implantation/delivery system used with the present invention in a preferred embodiment." *Id.* at 6:41–42.

The Specification explains,

> The distal end 410 of the catheter 400, which is hollow and carries the replacement heart valve device of the present invention in its collapsed configuration, is guided to a site where it is desired to implant the replacement heart valve. The catheter has a pusher member 420 disposed within the catheter lumen 430 and extending from the proximal end 440 of the catheter to the hollow section at the distal end 410 of the catheter. Once the distal end 410 of the catheter is positioned as desired, the pusher mechanism 420 is activated and the distal portion of the replacement heart valve device is pushed out of the catheter and the stent member 100 partially expands. In this position the stent member 100 is restrained so that it doesn't pop out and is held for controlled release, with the potential that the replacement heart valve device can be recovered if there is a problem with the positioning. The catheter 400 is then retracted slightly and the replacement heart valve device is completely pushed out of the catheter 400 and released from the catheter to allow the stent member 100 to fully expand.

Id. at 11:44–62. According to the Specification, "[t]his method of percutaneous endovascular heart-valve replacement, in contrast to open heart surgical procedures, requires only local anesthesia, partial or no cardiac bypass, one to two days hospitalization, and should result in reduced mortality rate as compared to open heart procedures." *Id.* at 13:23–27.

D. Illustrative Claim

Petitioner challenges independent claim 1 and dependent claims 2–4 of the '294 patent. Independent claim 1, set forth below, is illustrative.

> 1. A method of controlled release of a percutaneous replacement heart valve as a location of a native heart valve in a patient, the method comprising:
>
> obtaining a replacement heart valve device and a delivery and implantation system:
>
> the replacement heart valve device including:
>
> a stent member that is collapsible, expandable and configured for percutaneous delivery; and
>
> ***a valve residing entirely within an inner channel of the stent member and attached to a proximal portion of the stent member***, the valve including two to four individual leaflets made of fixed pericardial tissue;
>
> the delivery and implantation system including:
>
> a pusher member and a moveable sheath, wherein the pusher member includes a guide wire lumen and wherein the moveable sheath includes a lumen configured for receiving the pusher member;
>
> after the obtaining step, loading the replacement heart valve device into the lumen of the moveable sheath such that the replacement heart valve device is collapsed onto the pusher member to reside in a collapsed configuration on the pusher member and is restrained in the collapsed configuration by the moveable sheath;
>
> after the loading step, advancing the delivery and implantation system transluminally over a guide wire within the patient to position the replacement heart valve device for deployment within the patient at the location of the native heart valve;

after the advancing step, partially deploying a distal portion of the replacement heart valve device within the patient by pushing out the pusher member from the moveable sheath to expose the distal portion of the replacement heart valve device;

after the partially deploying step, restraining the replacement heart valve device so that it does not pop out and is held for controlled release, with a potential that the replacement heart valve device can be recovered if there is a problem with positioning; and

after the restraining step, recovering the distal portion of the replacement heart valve device within the moveable sheath that was exposed in order to address a problem with the position of the replacement heart valve device within the patient.

Ex. 1001, 13:38–14:35 (emphasis added).

E. Asserted Grounds of Unpatentability

Petitioner asserts that claims 1–4 would have been unpatentable on the following seven grounds.

Claims Challenged	35 U.S.C. §	Reference(s)
1–4	103(a)[1]	Garrison[2]
1–4	103(a)	Garrison, Leonhardt[3]
1–4	103(a)	Garrison, Cox[4]
1–4	103(a)	Garrison, Leonhardt, Cox

[1] The Leahy-Smith America Invents Act ("AIA"), Pub. L. No. 112-29, 125 Stat. 284, 287–88 (2011), amended 35 U.S.C. § 103, effective March 16, 2013. Because the application from which the '294 patent issued has an effective filing date prior to March 16, 2013, the pre-AIA version of § 103 applies.

[2] Garrison et al., US 6,425,916 B1, issued Jul. 30, 2002 ("Garrison," Ex. 1005).

[3] Leonhardt et al., US 5,957,949, issued Sep. 28, 1999 ("Leonhardt," Ex. 1006).

[4] Cox, US 5,713,950, issued Feb. 3, 1998 ("Cox," Ex. 1021).

Claims Challenged	35 U.S.C. §	Reference(s)
1–3	103(a)	DiMatteo, Limon[5]
4	103(a)	DiMatteo, Limon, Gabbay[6]
4	103(a)	DiMatteo, Limon, Phelps[7]

We refer to the first four grounds including Garrison as the "Garrison grounds," and the three grounds including DiMatteo as the "DiMatteo" grounds.

Petitioner also relies on the Declaration of William J. Drasler, Ph.D. (Ex. 1002) for its patentability challenges.

II. ANALYSIS

A. Person of Ordinary Skill in the Art

The level of skill in the art is a factual determination that provides a primary guarantee of objectivity in an obviousness analysis. *Al-Site Corp. v. VSI Int'l Inc.*, 174 F.3d 1308, 1324 (Fed. Cir. 1999) (citing *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966); *Ryko Mfg. Co. v. Nu-Star, Inc.*, 950 F.2d 714, 718 (Fed. Cir. 1991)).

Petitioner asserts that a person of ordinary skill in the art at the time of the invention 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 percutaneously, transluminally implantable cardiac prosthetic devices. Additional graduate education could substitute for professional experience, or significant experience in the field could substitute for formal education.

[5] Limon et al., US 6,077,295, issued Jun. 20, 2000 ("Limon," Ex. 1008).
[6] Gabbay, US 7,025,780 B2, issued Apr. 11, 2006 ("Gabbay," Ex. 1009).
[7] Phelps et al., WO 00/15147, published Mar. 23, 2000 ("Phelps," Ex. 1010).

Pet. 18 (citing Ex. 1002 ¶¶ 30–33.). Patent Owner does not dispute the Petitioner's definition of a person of ordinary skill in the art in its Preliminary Response. Prelim. Resp. 3.

At this stage of the proceeding, we adopt Petitioner's definition as we find it is consistent with the level of skill in the art at the time of the invention as reflected by the prior art and the '294 patent. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001) (explaining that specific findings regarding ordinary skill level are not required "where the prior art itself reflects an appropriate level and a need for testimony is not shown" (quoting *Litton Indus. Prods., Inc. v. Solid State Sys. Corp*., 755 F.2d 158, 163 (Fed. Cir. 1985))).

B. Claim Construction

The Board applies 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) (2019). Under that standard, claim terms "are generally given their ordinary and customary meaning" as understood by a person of ordinary skill in the art at the time of the invention. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–13 (Fed. Cir. 2005) (en banc). "In determining the meaning of the disputed claim limitation, we look principally to the intrinsic evidence of record, examining the claim language itself, the written description, and the prosecution history, if in evidence." *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 469 F.3d 1005, 1014 (Fed. Cir. 2006) (citing *Phillips*, 415 F.3d at 1312–17). Extrinsic evidence is "less significant than the intrinsic record in determining 'the legally operative meaning of claim language.'" *Phillips*, 415 F.3d at 1317.

Petitioner asserts that all claim terms in the challenged claims should receive their plain and ordinary meanings. Pet. 18. Petitioner highlights two

claim terms without proposing an express construction for either one. *Id.* at 19. For the phrase in claim 1 reciting "a potential that the replacement heart valve device can be recovered . . . to address a problem with the position of the replacement heart valve device within the patient," Petitioner asserts only that the prior art discloses the limitation, whether it is limiting or not. *Id.* For the term "trumpet-like," Petitioner asserts only that the prior art discloses the limitation regardless of its exact metes and bounds. *Id.* Patent Owner asserts that the former claim phrase is limiting. Prelim. Resp. 17. As for the latter phrase, Patent Owner only notes the construction Petitioner proposed in district court, without taking a position on it. *Id.* at 18.

We do not find that an express construction of either claim term is necessary for purposes of rendering this Decision. *See Wellman, Inc. v. Eastman Chem. Co.*, 642 F.3d 1355, 1361 (Fed. Cir. 2011) ("[C]laim terms need only be construed 'to the extent necessary to resolve the controversy.'") (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999)).

Patent Owner additionally provides a discussion of the claim phrase "proximal portion of the stent member," recited in claim 1. Prelim. Resp. 18. According to Patent Owner, the parties agree that "the proximal portion is that portion that is closer to the user of the stent member (as opposed to closer to the heart, which is the distal portion)." *Id.* (citing Pet. 29). Patent Owner asserts, however, that Petitioner incorrectly reads the proximal portion as anywhere from 1/2 to 3/4 of the length of the stent member. *Id.* Patent Owner's position is that a stent has three separate portions because the '294 patent Specification refers to the proximal, central, and distal portions of the stent. *Id.* (citing Ex. 1001, 14:2–3, 14:22–23, 14:42–43). According to Patent Owner, "each portion should only

encompass approximately 1/3 of the length of the stent member, and should not overlap with any adjacent portion." *Id.* Patent Owner asserts further that even if one were to believe that only a distal and proximal portion exist, it would be unreasonable to recognize a construction permitting the distal portion to encroach upon half of the proximal portion. *Id.* at 19.

Petitioner does not address this claim term in its claim construction discussion. However, Petitioner does address the term in its obviousness analysis. Thus, for purposes of this Decision, we address the parties' contentions regarding this claim term in context of the claim challenges in our discussion below, in Section II.C.2.

C. The Garrison Grounds

Petitioner asserts that claims 1–4 are rendered obvious by (a) Garrison alone; (b) Garrison in view of Leonhardt; (c) Garrison in view of Cox; and (d) Garrison in view of Leonhardt and Cox. Pet. 21–48. Patent Owner challenges each of those contentions. Prelim. Resp. 37–59.

1. Garrison

Garrison is "directed to methods and devices for implanting replacement cardiac valves." Ex. 1005, 1:5–6. The implantation system includes a delivery catheter, a cardiac valve, and a valve displacer. *Id.* at 4:14–15. Garrison's valve has an expandable support structure which moves from a collapsed position to an expanded position. The support structure is preferably formed with first and second elongate members which are wound to form windings around the circumference of the valve. The elongate members of the support structure form three posts extending from the support structure. Garrison's Figures 10 and 11 are set forth below:

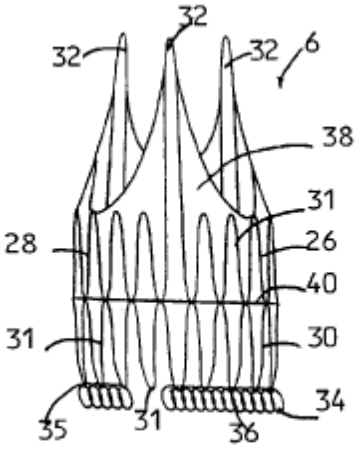


FIG. 10

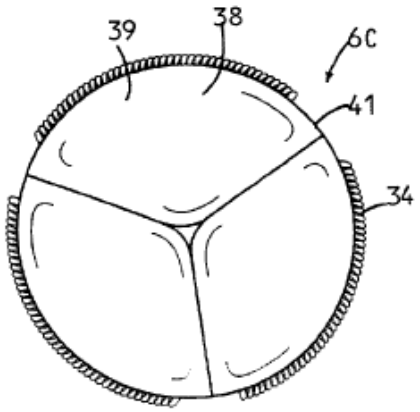


FIG. 11

Garrison's Figure 10 depicts Garrison's valve in a collapsed position. *Id.* at 3:11. Garrison's Figure 11 depicts a plan view of the valve showing the valve leaflets. *Id.* at 3:12.

The Specification explains,

> The posts 32 support a valve portion 38 which performs the functions of the patient's malfunctioning native valve. Referring to FIGS. 10 and 11, the valve portion 38 is preferably a stentless tissue valve such as a tri-leaflet 39 stentless porcine valve. The valve portion 38 has a base 41 which is secured to the support structure 26 with sutures (not shown).

Id. at 5:42–48.

2. Discussion

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 the 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) if in the record, objective evidence of nonobviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966). Consideration of the *Graham* factors "helps inform the ultimate obviousness determination." *Apple Inc. v. Samsung Elecs. Co.*, 839 F.3d 1034, 1048 (Fed. Cir. 2016) (en banc).

Petitioner provides a claim chart identifying the disclosures in Garrison that it relies on for each limitation of claim 1 and its dependent claims 2–4. Pet. 26–40. Petitioner combines Leonhard, and/or Cox, in the other Garrison grounds "to the extent further disclosure is required beyond Garrison" to address certain claim elements. The first step of the method recited by independent claim 1 requires obtaining a replacement heart valve device, wherein the device includes "a valve . . . attached to a proximal portion of the stent member," i.e., the "attachment limitation." Ex. 1001, 13:41–43, 14:1–3. For each of the Garrison grounds, Petitioner relies only upon Garrison as teaching that limitation. *See* Pet. 29, 41–48. In other words, Petitioner does not rely on the combined teachings of Garrison and Leonhardt and/or Cox to reach that limitation. Patent Owner challenges, among other things, Petitioner's reliance on Garrison for that disclosure. Prelim. Resp. 37–42. As we find this issue to be dispositive, we focus our analysis on whether Petitioner has demonstrated sufficiently for institution that Garrison discloses a valve attached to a proximal portion of the stent member, as required by independent claim 1.

To begin, Petitioner asserts that Garrison discloses a valve replacement device having a valve portion mounted within an expandable support structure. Pet. 21. Petitioner identifies those and other elements in its first annotated version of Garrison's Figures 10 and 11, set forth below:

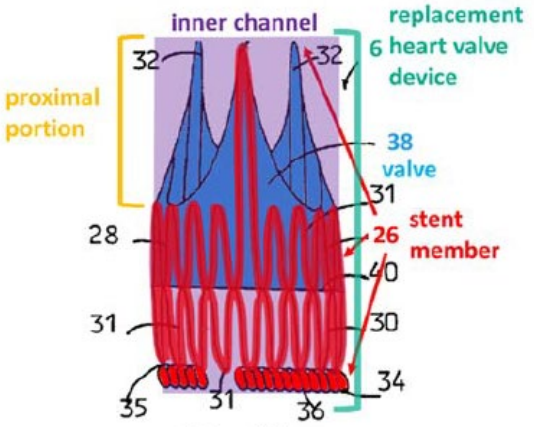


FIG. 10

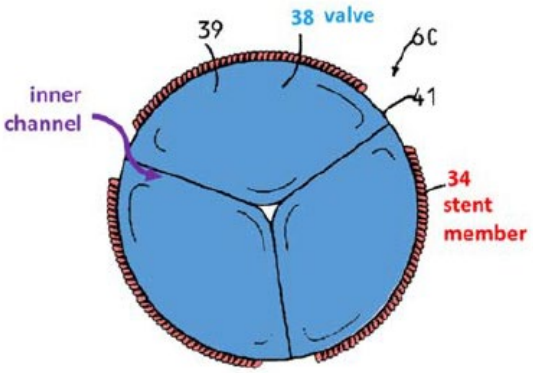


FIG. 11

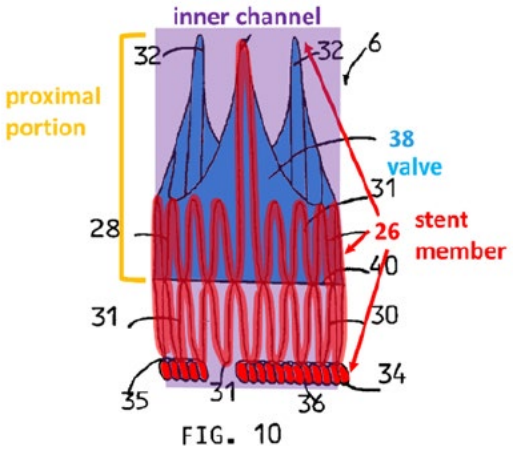
Petitioner first annotated version of Garrison's Figure 10 is color coded to show: the replacement heart valve device (labeled and bracketed as element 6 in turquoise); the heart valve 38 (labeled and colored in blue); the stent member (labeled and colored in red, along with added red arrows extending from the stent, i.e., "support structure 26" to the stent posts 32 and the stent protrusion 34/coil 36); the inner channel of the stent (labeled and colored in purple), and the proximal portion of the stent (labeled and bracketed in yellow). *Id.* Petitioner's annotated version of Garrison's Figure 11 is similarly color coded to show the valve, stent member, and inner channel. *Id.* Referring to these annotated figures, Petitioner asserts that Garrison's valve and its leaflets are entirely within (both radially and axially) the stent's inner channel. *Id.* (citing Ex. 1005, 5:42–43; 6:42–48; Ex. 1002 ¶¶ 69–70).

Petitioner addresses the limitation in claim 1 requiring the valve to be "attached to a proximal portion of the stent member" in its claim chart. *Id.* at 29–31. Petitioner asserts that Garrison discloses that the valve portion 38 is attached to the support structure 26, including posts 32 as shown in Garrison's Figure 10. *Id.* at 29. According to Petitioner, Garrison's valve

portion 38 is "sutured to both the base and posts 32 of 'support structure 26.'" *Id.* (citing Ex. 1005, 5:42–50). Petitioner contends,

> [a]s shown in Figs. 10 and 14, the posts are on the proximal portion (closer to the user) of the stent member. [Ex. 1005], 5:42-50. And even if proximal were wrongly read to mean closer to the heart, the valve's lower portion is also attached to the stent's proximal portion as shown in Fig.10. The "valve portion 38" is attached to the internal surface of "support structure 26," and resides entirely within the inner channel formed by "support structure 26," as shown in Figs. 10-11.

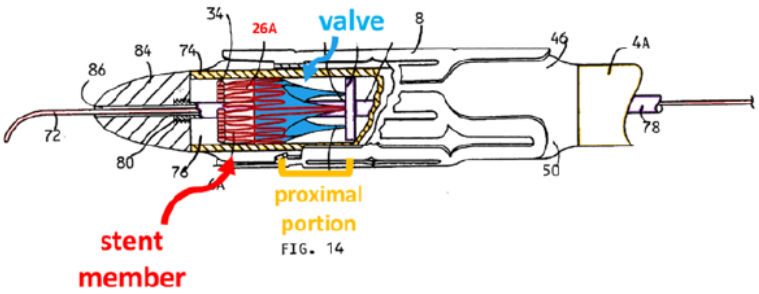
Pet. 29. To support those contentions, Petitioner provides a second annotated version of Garrison's Figure 10, set forth below:



Petitioner's second annotated version of Garrison's Figure 10 is color coded as in its first annotated version of the figure to show: the heart valve 38 (labeled and colored in blue); the stent member (labeled and colored in red, along with added red arrows extending from the stent, i.e., "support structure 26" to the stent posts 32 and the stent protrusion 34/coil 36); the inner channel of the stent (labeled and colored in purple), and the proximal portion of the stent (labeled and bracketed in yellow). *Id.* at 30. However, in this second annotated version of Garrison's Figure 10, Petitioner extends

what it labels as the proximal portion of the stent to include the location in the stent that contains the base of the valve. *Id.*

Petitioner also refers to its annotated version of Garrison's Figure 14, set forth below, to support its contentions. *Id.* at 29, 31.



Petitioner's annotated version of Garrison's Figure 14 is color coded to show: the valve (labeled and colored in blue); the stent member 26A (labeled and colored in red); and the proximal portion of the stent (labeled and colored in yellow).

Patent Owner asserts that Petitioner's contentions rely on a misreading of Garrison and conflate Garrison's use of the term "support" with the claim's recitation of "attached." Prelim. Resp. 38. Patent Owner notes that Garrison discloses only that its "posts 32 *support* a valve portion 38," without describing that support as an attachment. *Id.* (quoting Ex. 1005, 5:42–43) (emphasis added by Patent Owner). According to Patent Owner, such support is not an attachment, as Garrison distinctly describes only the valve portion 38 as being "*secured to the support structure 26 with sutures* (not shown)." *Id.* (quoting Ex. 1005, 5:46–48) (emphasis added by Patent Owner). Patent Owner asserts that "the valve of Garrison is not sutured, secured, or attached to the posts. It is supported by them." *Id.*

Patent Owner asserts further that Petitioner's "fallback" argument, i.e., in the event that the proximal "wrongly read to mean closer to the heart, the valve's lower portion is also attached to the stent's proximal portion,"

Pet. 29, relies on an annotated version of Garrison's Figure 10 that improperly identifies 3/4 of the stent member as the "proximal portion," and leaves only 1/4 of the stent to serve as both the central and distal portions of the stent member, Prelim. Resp. 39–40. According to Patent Owner, "even with Petitioner's lopsided labeling of Figure 10, the attachment of the valve to the stent member occurs at the valve's base (bottom line of the blue valve 38 shown in Figure 10, above) which is not in the proximal portion, but rather in the distal portion." *Id.* at 41 (citing Ex. 1005, 5:46–48).

Based upon our review of the arguments and evidence, we agree with Patent Owner that Petitioner has not shown that Garrison teaches or suggests that its valve is "attached to the proximal portion of the stent member," as required by claim 1. Petitioner does not propose an express construction for the term "attached" or "proximal portion." However, to show that Garrison's valve is attached to the proximal portion of the stent, i.e., support structure, Petitioner refers to Garrison's disclosure at Ex. 1005, 5:42–50, and asserts that the valve is "sutured to both the base and posts 32 of 'the support structure 26.'" Pet. 29; Ex. 1002 ¶ 92. According to Petitioner, "the posts are on the proximal portion (closer to the user) of the stent member." *Id.* As Patent Owner has recognized, both parties agree that the proximal portion of the stent member is the portion closer to the user, i.e., the end with the post 32 portion of the stent member. *Id.*; Prelim. Resp. 18, 40. The problem with Petitioner's reliance on Garrison as disclosing the valve being attached via sutures to the posts in the proximal portion of the stent is that Garrison does not describe the valve portion being attached to those posts, by suturing, or by any other means. Instead, the disclosure in Garrison that Petitioner relies upon describes only that the base of the valve is secured to the support structure/stent with sutures. Ex. 1005, 5:42–50 ("The valve

portion 38 has a base 41 which is secured to the support structure 26 with sutures . . . ."). Garrison describes the posts by merely stating, "[p]osts 32 *support* a valve portion 38." *Id.* at 5:42 (emphasis added). Critically missing in the Petition is any showing by Petitioner that Garrison's use of the term "support" means "attach." Petitioner does not even allege as much. Instead, Petitioner mistakenly relies on Garrison as disclosing that the valve is sutured to the posts of the support structure. But, as may be plainly seen in the disclosure relied upon by Petitioner, that is not the case.

Insofar as Petitioner asserts that "the valve's lower portion is also attached to the stent's proximal portion as shown in Fig. 10," Pet. 29, we remain unpersuaded. As noted by Patent Owner, Petitioner conspicuously and inexplicably extends what it identifies as the "proximal portion" of the stent member in its second annotated version of Garrison's Figure 10, so that the base of the valve now falls within the identified "proximal portion" of the stent member. Petitioner does not support that second annotation with any teaching in Garrison. While Garrison discloses that the base of the valve portion is secured to the support structure, Garrison does not describe the location of that attachment as being in the *proximal portion* of the support structure. Ex. 1005, 5:46–48.

The testimony of Petitioner' declarant, Dr. Drasler, also does not support Petitioner's attempt to extend the proximal portion from the stent posts to the base of the valve. In his declaration, Dr. Drasler explains that he "interpret[s] 'proximal' to refer to a portion of the stent that is located closer to the catheter's proximal end (i.e., the user) during delivery." Ex. 1002 ¶ 52. He illustrates what he considers to be the proximal portion of Garrison's stent in annotated versions of Garrison's Figures 10 and 14. *Id.* ¶¶ 69, 92. In both of those figures, Dr. Drasler labels the proximal portion to

include the same portion of the stent that Petitioner identifies in Petitioner's first annotated version of Garrison's Figure 10, and in Petitioner's annotated version of Garrison's Figure 14, set forth above, which do not extend the proximal portion from the stent posts to the base of the valve. *Id.* Petitioner's second annotated version of Garrison's Figure 10 does not appear in Dr. Drasler's declaration. Nor does he describe the proximal portion in the manner depicted in Petitioner's second annotated version of Garrison's Figure 10.

Significantly, Dr. Drasler appears to recognize that the attachment of the valve base to the stent is not in the proximal portion of the stent when the proximal portion of the stent is correctly viewed to be located near the user. He states, "[t]he fact that the valve is also attached at its base, 40 or 41, does not change this analysis: the posts are still attached to the valve, and the claim does not require attachment at only the proximal portion of the stent." Ex. 1002 ¶ 92. Thus, Dr. Drasler considers the attachment limitation to be met by the valve alleged attachment to the posts despite there being an alleged second attachment the valve base at a location other than the proximal portion of the stent. Dr. Drasler then explains that "even if 'proximal' is found to refer to the opposite side of the support structure, the valve is attached to the opposite side at base 41 (40 in Figure 10) as well." *Id.* In other words, Dr. Drasler declares that the valve base would be considered to be attached to the proximal portion of the stent, if the proximal portion of stent is on the opposite side of what Petitioner, Patent Owner, and Dr. Drasler consider to be the actual proximal side of the stent. Indeed, Petitioner acknowledges the same by stating, "if proximal were wrongly read to mean closer to the heart, the valve's lower portion is also attached to the stent's proximal portion . . . ." Pet. 29. As we do not consider where the

attachment of the valve to the stent occurs based upon an undisputedly incorrect labeling of the proximal side of the stent, Petitioner has not shown that the valve base is attached to the proximal portion of the stent.

Because Petitioner has failed to show that Garrison teaches or suggests the replacement heart valve "attached to a proximal portion of the stent member," as required by independent claim 1, we determine that Petitioner has not shown a reasonable likelihood of prevailing on its assertion that claim 1 is rendered obvious by Garrison. Petitioner does not rely on any of the other art cited in the remaining Garrison grounds to address this attachment limitation. Thus, we determine that Petitioner has not shown a reasonable likelihood of prevailing on its assertion that independent claim 1 would have been rendered obvious by the combined teachings of Garrison and Leonhard, and/or Cox. For at least the same reasons, we also determine that Petitioner has not shown a reasonable likelihood of prevailing on its assertion that dependent claims 2–4 would have been rendered obvious by Garrison alone or in combination with Leonhard, and/or Cox.

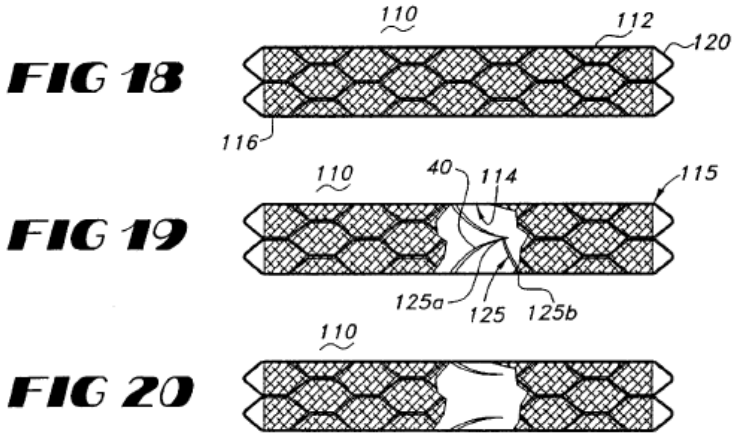
D. The DiMatteo Grounds

Petitioner asserts that claims 1–3 are rendered obvious over the combination of DiMatteo and Limon. Pet. 48–68. Petitioner asserts that claim 4 is rendered obvious over the combination of DiMatteo, Limon, and Gabbay or Phelps. *Id.* at 69–72. Patent Owner challenges those contentions. Prelim. Resp. 59–67.

1. DiMatteo

DiMatteo is directed to "providing a fully prosthetic valve having leafs formed from a covered valve leaf frame and which may be implanted

using a minimally-invasive, endoscopic technique." Ex. 1007, 2:23–26. The valve "provides a device for regulating and maintaining the direction of a pulsating fluid flow through the body lumen." *Id.* at 2:29–32. DiMatteo Figures 18–20 are set forth below:



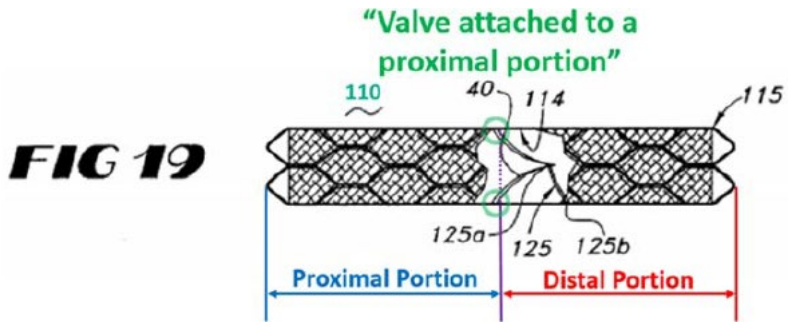
DiMatteo Figure 18 shows an embodiment of the invention "in which a number of deflectable valve leafs are attached within the fluid-conducting passageway to a radially-expandable prosthetic support structure." *Id.* at 6:9–12. DiMatteo Figure 19 shows a partial cut-away of a prosthetic valve of the invention, wherein "the valve leaflets are in a closed, flow-restricting configuration." *Id.* at 6:13–15. DiMatteo Figure 20 shows a partial cut-away of a prosthetic valve of the invention, wherein "the valve leafs [are] in an open, flow-conducing configuration." *Id.* at 6:16–18. DiMatteo explains that "the valve leafs of an implantable prosthetic valve 110 are attached to the interior luminal surface 114 of a second radially collapsible tubular fluid conduit 112." *Id.* at 13:52–56.

2. Discussion

Petitioner provides a claim chart identifying the disclosures in DiMatteo and Limon that it relies on for each limitation of independent claim 1 and its dependent claims 2 and 3. Pet. 54–69. For the limitation in

claim 1 requiring "a valve . . . attached to a proximal portion of the stent member," Ex. 1001, 14:1–3, i.e., the "attachment limitation," Petitioner relies only upon DiMatteo as teaching or suggesting that limitation. Pet. 49–50, 58. Petitioner combines Limon to address other limitations of those claims. *See id.* at 54–69. Patent Owner challenges, among other things, Petitioner's reliance on DiMatteo for the attachment limitation. Prelim. Resp. 59–64. As we find this issue to be dispositive, we focus our analysis on whether Petitioner has demonstrated sufficiently for institution that DiMatteo teaches or suggest a valve attached to a proximal portion of the stent member, as required by independent claim 1.

Petitioner provides an annotated version of DiMatteo's Figure 19, set forth below:



Petitioner's annotated version of DiMatteo's Figure 19 is labeled to show what Petitioner asserts to be: the proximal portion (labeled in blue) and the distal portion (labeled in red) of DiMatteo's stent; and the location where the valve is attached to a proximal portion of the stent (labeled "valve attached to a proximal portion" in green with the attachment points encircled in green). Pet. 49. According to Petitioner, a person of ordinary skill in the art "would have understood and at a minimum found it obvious that the valve is attached to the stent's proximal portion (closer to the catheter user) in order to implant the valve in the direction of desired fluid flow for delivery via

certain paths." *Id.* (citing Ex. 1002 ¶¶ 166–167); *see also* Pet. 58–59 (citing Ex. 1002 ¶¶ 168, 194). In addition to citing to Dr. Drasler's declaration, Petitioner seeks to supports it contention by citing: (a) DiMatteo's teaching that known stent designs may be used, Ex. 1007, 5:3–7; (b) McGuckin's[8] teaching that "valve can be attached at the proximal end, distal end, or intermediate the proximal and distal end," Ex. 1014, 15:55–59 and Figs. 38–40; and (c) Leonhardt's description of a "valve/stent 'loaded either end first' such that implanted valve properly oriented," Ex. 7:17–20. Pet. 50. According to Petitioner, a skilled artisan would have been "motivated to attach the valve to the stent's proximal portion to achieve the advantageous result of more easily recovering the valve/stent after partial deployment—otherwise the bulkier portion with the valve would be deployed first." *Id.* (citing Ex. 1002 ¶ 168).

Patent Owner asserts that Petitioner has mislabeled the proximal and distal portions in its annotated version of DiMatteo's Figure 19. Prelim. Resp. 60. According to Patent Owner, because DiMatteo is directed to a "fluid flow check valve for a body lumen," when the valve is placed in the aortic position, as required by the challenged claims, blood will flow in the opposite direction, meaning that the hinges where the valve attaches to the stent, i.e., at 40 in DiMatteo's Figure 19, are in what Petitioner labels as the distal portion of the stent. *Id.*

Additionally, Patent Owner asserts that Petitioner's labeling of the portions of the stent omits a central portion. *Id.* According to Patent Owner, the '294 patent describes a stent having three portions: proximal, central, and

[8] McGuckin et al., US 6,676,698 B2, issued Jan. 13, 2014 ("McGuckin," Ex. 1014).

distal. *Id.* (citing Ex. 1001, 14:2–3 ("proximal portion of stent"); *id.* at 14:22–23 ("distal portion" of stent and valve device); *id.* at 14:42–43 ("central portion" of stent)). Patent Owner contends that when properly considered, the stent depicted in DiMatteo's Figure 19 includes a central portion, and it is in that portion where the valve attaches to the stent. Prelim. Resp. 62.

Further, Patent Owner asserts that Petitioner has failed to support its obviousness allegations. *Id.* at 63. In particular, Patent Owner contends that "Petitioner fails to identify even a single instance in the prior art that a [person having ordinary skill in the art] would have thought it desirable to choose to attach the valve to the stent's proximal portion, as opposed to the central or distal attachment options." *Id.*

Based upon our review of the arguments and evidence, we agree with Patent Owner that Petitioner has not shown sufficiently for institution that DiMatteo teaches or suggests that its valve is "attached to the proximal portion of the stent member," as required by claim 1. At most, DiMatteo describes proximal and distal ends of the valve itself, wherein "[e]ach leaf frame 52 is joined to scaffold 30 at a flexible hinge 60 defined by the junction of the proximal ends 54a and 56b of each leg component with scaffold 30." Ex. 1007, 9:29–32. The attachment limitation in challenged claim 1, however, does not recite an attachment at the proximal portion of the valve, but instead at a proximal portion of the stent member. Neither Petitioner nor its declarant, Dr. Drasler, has explained why they consider the proximal portion of the stent to include the entire length of the left half of the stent body such that the proximal portion of the stent includes the proximal end of the valve. *See* Pet. 49; Ex. 1002 ¶¶ 165–166. Instead, the Petitioner and Dr. Drasler refer to DiMatteo's disclosure of the proximal and

distal ends of the valve leafs and then annotate Figure 19 to depict proximal and distal halves of the stent. DiMatteo does not describe the proximal end of the valve leaf being positioned or hinged, i.e., attached, in the proximal portion of the stent. And DiMatteo does not refer to proximal and distal halves of its stent. Further, as Patent Owner has asserted, Petitioner's annotated version of DiMatteo's Figure 19 does not provide for a central portion. Petitioner and Dr. Drasler have not addressed their choice to omit a central portion, despite recognizing elsewhere that stents have this third portion, *see* Pet. 50 (referring to McGuckin's stent having a proximal end, intermediate portion, and distal end), and in view of the challenged claims identifying three stent portions, *see* claims 1 and 4 (reciting proximal, distal and central stent portions).

Thus, based upon our review of the arguments and evidence, we disagree with Petitioner that a person having ordinary skill in the art would have understood that DiMatteo discloses a valve attached to the stent's proximal portion.

Insofar as Petitioner asserts that a skilled artisan would have found it obvious to attach DiMatteo's valve to the stent's proximal portion, we remain unpersuaded. Pet. 49–50. According to Petitioner and Dr. Drasler, a skilled artisan would have been motivated to make that modification "to implant the valve in the direction of desired fluid flow for delivery via certain paths," and "to achieve the advantageous result of more easily recovering the valve/stent after deployment . . . ." *Id.* at 49–50 (citing Ex. 1002 ¶¶ 166–168. Petitioner and Dr. Drasler, however, have not adequately explained or supported such alleged motivation. For example, they have not explained why attaching the valve to the proximal portion of the stent, as opposed to a central portion, would uniquely allow implantation

of the valve in the direction of desired fluid flow or provide the advantage of an easy recovery of the device.

Moreover, Petitioner's reference to McGuckin only demonstrates that valves can be attached at any location in the stent. *Id.* at 49. Petitioner's reference to Leonhardt addresses loading either end first of device and not the location of the valve attachment to the stent. *Id.* Petitioner's reference to DiMatteo's teaching that "the second fluid conduit may be selected from many known stent and covered stent designs known in the art," does not teach or suggest a design wherein the valve leafs are attached to a proximal portion of the stent member. *Id.*

Thus, based upon our review of the arguments and evidence, we do not find that Petitioner has adequately demonstrated for institution that a person having ordinary skill in the art would have been motivated to attach DiMatteo's valve to the proximal portion of the stent instead of maintaining the attachment at what DiMatteo appears to depict in its figures as a more central portion of the stent.

Petitioner does not rely on Limon to address the attachment limitation. Because Petitioner has failed to show sufficiently for institution that DiMatteo teaches or suggests the replacement heart valve "attached to a proximal portion of the stent member," as required by independent claim 1, we determine that Petitioner has not shown a reasonable likelihood of prevailing on its assertion that claim 1, or its dependent claims 2 and 3, are rendered obvious over the combination of DiMatteo and Limon.

In the remaining DiMatteo grounds challenging claim 4, which depends from claim 1, Petitioner continues to rely only on DiMatteo for the attachment limitation in claim 1. Therefore, we determine that Petitioner has not shown a reasonable likelihood of prevailing on its assertion that claim 4

would have been rendered obvious by the combined teachings of DiMatteo, Limon and Gabbay or Phelps for the same reasons as claim 1.

III. CONCLUSION

For the foregoing reasons, we deny the Petition and decline to institute the requested *inter partes* review.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that Petitioner's request for an *inter partes* review of claims 1–4 of the '294 patent is *denied*.

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