

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 Petitioner's Request for Rehearing
37 C.F.R. § 42.71

I. INTRODUCTION

Medtronic CoreValve LLC (“Petitioner”) requests a rehearing of the Decision Denying Institution (“Decision”) of an *inter partes* review of claims 1–4 of U.S. Patent No. 8,900,294 B2 (Ex. 1001, “the ’294 patent”) entered on March 5, 2021 (Paper 11, “Dec.”). Paper 12 (“Reh’g Req.”).

In the Petition (Paper 2, “Pet.”) Petitioner raised the following challenges to those claims:

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
1–3	103(a)	DiMatteo, Limon ⁵
4	103(a)	DiMatteo, Limon, Gabbay ⁶
4	103(a)	DiMatteo, Limon, Phelps ⁷

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 Sept. 28, 1999 (“Leonhardt,” Ex. 1006).

⁴ Cox, US 5,713,950, issued Feb. 3, 1998 (“Cox,” Ex. 1021).

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).

As in the Decision, 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 relied on the Declaration of William J. Drasler, Ph.D. (Ex. 1002) for its patentability challenges. Colibri Heart Valve LLC (“Patent Owner”) filed a Preliminary Response to the Petition. Paper 6.

Upon consideration of the Petition, Preliminary Response, and evidence of record, we determined that Petitioner failed to demonstrate a reasonable likelihood that it would prevail in showing the unpatentability of at least one challenged claim. Dec. 2. In the Rehearing Request, Petitioner seeks a reconsideration of that determination. *See* Reh’g Req. 1.

II. DISCUSSION

“When rehearing a decision on petition, a panel will review the decision for an abuse of discretion.” 37 C.F.R. § 42.71(c). “The burden of showing a decision should be modified lies with the party challenging the decision. The request must specifically identify all matters the party believes the Board misapprehended or overlooked, and the place where each matter was previously addressed in a motion, an opposition, or a reply.” *Id.* § 42.71(d). Because Petitioner has not met its burden, as discussed below, the Rehearing Request is *denied*.

Independent claim 1 recites a method of controlled release of a percutaneous replacement heart valve at a location of a native heart valve in a patient. Ex. 1001, 13:38–14:37. The method comprises, in part, obtaining a replacement heart valve device and a delivery and implantation system, wherein the replacement heart valve device includes “a valve residing entirely within an inner channel of the stent member and attached to a proximal portion of the stent member.” *Id.* at 13:41–14:3. As in the

Decision, we refer to the limitation requiring the valve to be “attached to a proximal portion of the stent member” as the “attachment limitation.”

Dec. 13, 22. In the Decision, we determined that Petitioner failed to demonstrate that the cited prior art teaches or suggests that attachment limitation. In the following discussion, we address Petitioner’s rehearing contentions regarding that determination for the Garrison grounds and the DiMatteo grounds, in turn.

A. The Garrison Grounds

Petitioner asserts that the Decision “overlooks and does not address Garrison’s Figures, which, as explained in the Petition and by Dr. Drasler, teach that the valve is attached to a proximal portion from the perspective of a POSITA [a person of ordinary skill in the art].” Reh’g Req. 10. Petitioner argues in the Rehearing Request that Garrison’s Figures 9, 10, and 14 depict to a POSITA that the valve is attached to the proximal end of posts 32. *Id.* at 12–13. Petitioner also refers to the testimony of Dr. Drasler that the valve is attached to a proximal portion of the stent member because it is attached, by suture, to posts 32. *Id.* (citing Ex. 1002 ¶¶ 70, 91–93). According to Petitioner, “[r]egardless of whether Garrison separately discusses how the valve is attached to posts 32, the Figures themselves demonstrate to a POSITA that the limitation is met.” *Id.* at 14. Petitioner asserts further that Garrison’s description of the valve’s base as being sutured to the stent does not preclude the valve from also being attached to the posts 32. *Id.* at 14–15.

We disagree with Petitioner’s assertion that our Decision overlooks and does not address Garrison’s Figures. Indeed, in the Decision we set forth, describe, and discuss Garrison’s Figures 10 and 11, as well as Petitioner’s first and second annotated versions of Garrison’s Figure 10, Petitioner’s annotated version of Garrison’s Figure 11, and Petitioner’s

annotated version of Garrison's Figure 14. Dec. 11–16. In the Decision, we also address Petitioner's contention and Dr. Drasler's testimony that Garrison's valve is attached to the post portion of the stent member. *Id.* at 17–20. In doing so, we noted in the Decision, as we do again here, that Petitioner's contention that the valve in Garrison's Figure 10 is attached to the post was based upon Petitioner's assertion that Garrison disclosed that the valve is sutured to the post. *Id.* at 14–15, 17–18; Pet. 29 (citing Ex. 1005, 5:42–50). We did not find that assertion to be supported by Garrison's disclosure. The disclosure in Garrison referenced by Petitioner states,

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 45 stentless porcine valve. The valve portion 38 has a *base 41 which is secured to the support structure 26 with sutures (not shown)*. The valve portion 38 may be stored separately from support structure 26 and attached to the support structure 26 before the procedure.

Ex. 1005, 5:42–50 (emphasis added). As we explained in the Decision, 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." *Id.* (citing 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.

Dec. 17–18.

Similarly, we addressed Dr. Drasler’s opinion that the valve portion in Garrison is attached to the posts. *Id.* at 17 (citing Ex. 1002 ¶ 92). The rationale that Dr. Drasler provides for his opinion that the valve is attached to, and not merely supported by, the posts is his assertion that, “[a]s illustrated in Figures 10-11 and 14, the valve portion (annotated in blue) is supported by the posts via sutures (not shown) described as used to secure the valve to the support structure (Garrison 5:42–47) at the proximal portion of the supporting structure (annotated in red).” Ex. 1002 ¶ 92. Thus, Dr. Drasler relies not on what is shown in Garrison’s figures, but in his mistaken belief that the quoted language from Garrison set forth above describes that the valve is secured to the posts via sutures. *Id.* (citing Ex. 1005, 5:42–47). As we discuss above, and in the Decision, Garrison does not describe the valve being secured to the posts via sutures, or by any other means. Dec. 17–18.

B. The DiMatteo Grounds

Petitioner does not dispute our determination that it failed to show sufficiently for institution that DiMatteo discloses a replacement heart valve attached to a proximal portion of the stent member. Dec. 25; *see* Reh’g Req. 5–6. Rather, Petitioner contends that we erred in determining that Petitioner did not adequately explain why a POSITA would have been motivated to modify DiMatteo’s valve/stent configuration to attach the valve to the proximal portion of the stent instead of maintaining the attachment at what DiMatteo depicts as a more central portion of the stent. Reh’g Req. 6.

To begin, Petitioner asserts that “the Decision erred as a matter of law in requiring Petitioner to demonstrate that the benefits of attachment to the proximal portion must be ‘unique’ relative to the other options.” *Id.* (citing Dec. 25–26). We disagree as that argument mischaracterizes the Decision.

In the Decision, we considered Petitioner’s and Dr. Drasler’s position that a skilled artisan would have been motivated to attach DiMatteo’s valve to the stent’s proximal portion. Dec. 25. According to Petitioner and Dr. Drasler, a POSITA would have made 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 partial deployment—otherwise the bulkier portion with the valve would be deployed first.” Pet. 49–50 (citing Ex. 1002 ¶¶ 166–168). That was the extent of Petitioner’s discussion in the Petition regarding a motivation for modifying DiMatteo’s valve/stent configuration.

Upon considering that asserted basis for the proposed modification of DiMatteo, we explained that such alleged motivation was inadequately explained. Dec. 25. Our statement that Petitioner and Dr. Drasler “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,” was not an application of some heightened standard for obviousness motivation. *Id.* at 25–26. Rather, it was a finding focused on the rationale relied upon by Petitioner and Dr. Drasler for modifying DiMatteo, i.e., to obtain an advantage or benefit from doing so. Thus, it is misleading for Petitioner to allege that the Board erred in requiring Petitioner to demonstrate the benefits of attaching the valve to the proximal portion of the stent, as our analysis focused on the rationale that Petitioner relied on for its proposed obviousness modification.

Further, Petitioner asserts that the Board overlooked and did not address Petitioner’s and Dr. Drasler’s explanation of how attaching the valve to the stent’s proximal portion advantageously facilitates an easier recovery

of the valve/stent after partial deployment, i.e., “otherwise the bulkier portion with the valve would be deployed first.” Reh’g. Req. 8–9. We disagree. The explanation in the Petition that Petitioner asserts we overlooked is limited to Petitioner’s assertion that “a POSITA 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.” Pet. 50 (citing Ex. 1002 ¶ 168).

As Petitioner acknowledges in the Rehearing Request, that “full passage from the Petition is cited in the Decision’s summary of Petitioner’s arguments.” Reh’g. Req. 10 (citing Dec. 23). Yet, Petitioner takes issue with how we referred back to that statement subsequently in our Decision by quoting only a portion of it and using an ellipses for the end of the passage. *Id.* (citing Dec. 25). That manner of referring to Petitioner’s assertion does not demonstrate that we overlooked Petitioner’s assertion that “the bulkier portion with the valve would be deployed first,” which we expressly quoted earlier. Nor does it demonstrate that we erred in determining that Petitioner and Dr. Drasler failed to adequately support that contention for institution.

For additional clarity, we note here that it is unclear what Petitioner and Dr. Drasler meant by their statement in the Petition that “otherwise the bulkier portion with the valve would be deployed first.” Pet. 50. The term “first” is a relative term that remains undefined in the Petition and Dr. Drasler’s testimony. Dr. Drasler’s testimony that “with the non-valve end of the stent partially deployed, the operator could confirm the accuracy of the placement of the prosthesis, and recover the valve/stent if needed for repositioning,” Ex. 1002 ¶168, appeared to be based on an assumption that the only alternative to a proximal valve/stent attachment is a distal

valve/stent attachment. However, as we discuss in the Decision, “DiMatteo does not refer to proximal and distal halves of its stent.” Dec. 25. Rather, DiMatteo’s stent may be considered to have a central portion between the proximal and distal portions. *Id.* And DiMatteo’s figures appears to depict the valve attachment at a more central portion of the stent. *See id.*; Ex. 1007, Figs. 19–20. Thus, Petitioner and Dr. Drasler’s explanation for why attaching the valve to the stent’s proximal portion achieves “the advantageous result of more easily recovering the valve/stent after partial deployment—otherwise the bulkier portion with the valve would be deployed first,” Pet. 50, was insufficient and unpersuasive for institution, *see* Dec. 25 (“Petitioner and Dr. Drasler, however, have not adequately explained or supported such alleged motivation.”).

III. CONCLUSION

Because Petitioner has not demonstrated that we misapprehended or overlooked matters raised in the Petition, we conclude Petitioner has not shown that the Board abused its discretion in denying institution of the challenged claims. *See* 37 C.F.R. § 42.71(d).

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that Petitioner’s Request for Rehearing is *denied*.

IPR2020-01453
Patent 8,900,294 B2

For PETITIONER:

James L. Davis, Jr.
James.l.davis@ropesgray.com

Scott McKeown
Scott.mckeown@ropesgray.com

Cassandra Roth
Cassandra.roth@ropesgray.com

For PATENT OWNER:

Sarah Spires
sspires@skkiermontderby.com