

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MEDTRONIC COREVALVE LLC,
EDWARDS LIFESCIENCES CORPORATION, AND
EDWARDS LIFESCIENCES LLC,
Petitioner,

v.

COLIBRI HEART VALVE LLC,
Patent Owner.

IPR2020-01454¹
Patent 9,125,739 B2

Before ERICA A. FRANKLIN, JAMES A. TARTAL, and
ERIC C. JESCHKE, *Administrative Patent Judges*.

TARTAL, *Administrative Patent Judge*.

JUDGMENT
Final Written Decision
Determining All Challenged Claims Unpatentable
35 U.S.C. § 318(a)

¹ Edwards Lifesciences Corporation and Edwards Lifesciences LLC filed a petition in IPR2021-00775 and are joined as petitioner in this proceeding.

We have jurisdiction to conduct this *inter partes* review under 35 U.S.C. § 6. This Final Written Decision is issued pursuant to 35 U.S.C. § 318(a) (2018) and 37 C.F.R. § 42.73 (2020). For the reasons discussed below, we determine Medtronic CoreValve LLC, Edwards Lifesciences Corporation, and Edwards Lifesciences LLC (“Petitioner”)² has shown by a preponderance of the evidence that claims 1–5 (“the Challenged Claims”) of U.S. Patent No. 9,125,739 B2 (Ex. 1001, “the ’739 patent”) are unpatentable.

I. INTRODUCTION

A. Summary of Procedural History

Medtronic CoreValve LLC filed a Petition on September 2, 2020, pursuant to 35 U.S.C. §§ 311–319, requesting an *inter partes* review of the Challenged Claims. Paper 2 (“Pet.”). On March 10, 2021, we instituted an *inter partes* review of the Challenged Claims on all grounds of unpatentability asserted in the Petition. Paper 11. Within one month of institution of review, on April 6, 2021, Edwards Lifesciences Corporation and Edwards Lifesciences LLC filed a petition in IPR2021-00775 substantively identical to the Petition in this proceeding, along with a motion for joinder to this proceeding. IPR2021-00775, Papers 2 and 3. We instituted trial in IPR2021-00775 and granted the motion joining Edwards Lifesciences Corporation and Edwards Lifesciences LLC as petitioner to this proceeding. Paper 17.

² Medtronic CoreValve LLC identifies Medtronic Inc. as an additional real party in interest. Pet. 7. Edwards Lifesciences Corporation and Edwards Lifesciences LLC identify no additional real parties in interest. IPR2021-00775, Paper 2, 7.

Colibri Heart Valve LLC (“Patent Owner”)³ filed a Patent Owner Response. Paper 14 (“Resp.”). Petitioner filed a Reply to the Patent Owner Response. Paper 18 (“Reply”). Patent Owner filed a Sur-reply in support of the Patent Owner Response. Paper 19 (“Sur-reply”).

Following oral argument, we entered a transcript of the hearing in the record. Paper 25 (“Tr.”). Petitioner bears the burden of proving unpatentability of each claim it has challenged by a preponderance of the evidence, and the burden of persuasion never shifts to Patent Owner. *See* 35 U.S.C. § 316(e) (2018); 37 C.F.R. § 42.1(d); *Dynamic Drinkware, LLC v. Nat’l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015).

B. Related Matters

The ’739 patent is also challenged in *Edwards Lifesciences Corp. and Edwards Lifesciences LLC v. Colibri Heart Valve LLC*, IPR2020-01649 (filed September 18, 2020), in which a final written decision is issued contemporaneous with this Decision. The parties identify the ’739 patent as a subject of *Colibri Heart Valve LLC v. Medtronic CoreValve LLC*, No 8:20-cv-847 (C.D. Cal., filed May 4, 2020) (the “CDCA Case”). Pet. 7; Paper 4, 1. In addition to the ’739 patent, U.S. Patent No. 8,900,294 (“the ’294 patent”) is also a subject of the CDCA Case. The ’739 patent and the ’294 patent each issued from applications that are continuations of U.S. Application No. 13/675,665, and have substantially the same specification. The ’294 patent was challenged in a petition for *inter partes* review that was denied. *Colibri Heart Valve LLC v. Medtronic CoreValve LLC*, IPR2020-001453, Paper 11 (PTAB Mar. 5, 2021).

³ Patent Owner identifies no additional real parties in interest. Paper 4, 1.

C. The '739 Patent

The '739 patent, titled “Percutaneous Replacement Heart Valve and a Delivery and Implantation System,” issued September 8, 2015, from Application No. 14/253,650, filed April 15, 2014, which claims priority back to Application No. 10/037,266, filed on January 4, 2002. Ex. 1001, codes (21), (22), (45), (54), (63). The replacement heart valve device described by the '739 patent “comprises a stent made of stainless steel or self-expanding nitinol and a completely newly designed artificial biological tissue valve disposed within the inner space of the stent.” *Id.* at 4:64–5:1.

Figure 5 of the '739 patent is reproduced below.

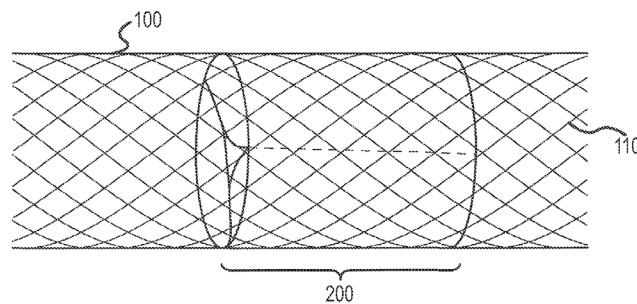


FIG.5

Figure 5 illustrates a side view of a replacement heart valve device mounted within a self-expanding stent in the expanded position. *Id.* at 6:31–34. “The replacement heart valve device comprises a stent member 100 and a flexible valve means 200.” *Id.* at 6:55–57. “The stent member 100 includes a length of wire 110 formed in a closed zigzag configuration.” *Id.* at 7:32–33. The stent member may be a meshwork of nitinol wire formed into a tubular structure that “flares markedly at both ends in a trumpet-like configuration.” *Id.* at 7:55–63. The “trumpet-like configuration” is not illustrated in Figure 5, or in any other figure of the '739 patent.

The valve means comprises “a generally tubular portion” and, “preferably, a peripheral upstanding cusp or leaflet portion.” *Id.* at 6:61–64. 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 8:28–35. 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 cusp or leaflet portion of the valve means is “formed by folding the pericardium material used to create the valve.” *Id.* at 8:44–46. “The starting material is preferably a flat dry sheet, which can be rectangular or other shaped.” *Id.* at 8:47–49. The cusps/leaflets “open in response to blood flow in one direction and close in response to blood flow in the opposite direction.” *Id.* at 8:49–51.

Figure 8 of the '739 patent is reproduced below.

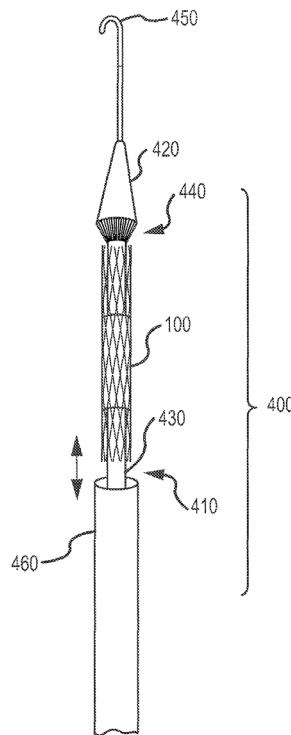


FIG.8

Figure 8 illustrates the “delivery and implantation system of the replacement artificial heart valve,” including “flexible catheter 400 which may be inserted into a vessel of the patient and moved within that vessel.” *Id.* at 11:40–44. The ’739 patent further explains as follows:

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.

D. Illustrative Claims of the '739 Patent

Petitioner challenges claims 1–5 (all claims) of the ’739 patent. Pet. 1. Claim 1 is independent and claims 2–5 depend from claim 1. Ex. 1001, 14:2–38. Claims 1 and 5 are illustrative of the claimed subject matter and are reproduced below.

1. An assembly to treat a native heart valve in a patient, the assembly for use in combination with a guidewire, the assembly comprising:
 - a prosthetic heart valve including:
 - a stent member having an inner channel, the stent member collapsible, expandable and configured for transluminal

- percutaneous delivery, wherein the stent member includes a tubular structure away from a central portion that flares at both ends in a trumpet-like configuration; and
- a valve means including two to four individual leaflets made of fixed pericardial tissue, wherein the valve means resides entirely within the inner channel of the stent member, and wherein no reinforcing members reside within the inner channel of the stent member;
- a delivery system including a pusher member and a moveable sheath, the pusher member including a guidewire lumen, wherein the pusher member is disposed within a lumen of the moveable sheath, wherein the prosthetic heart valve 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, wherein a distal end of the prosthetic heart valve is located at a distal end of the moveable sheath, and wherein the valve means resides entirely within the inner channel of the stent member in said collapsed configuration and is configured to continue to reside entirely within the inner channel of the stent member upon deployment in the patient.

Id. at 14:2–29.

5. The assembly of claim 1, wherein the pusher member includes a controlled release mechanism that can be activated.

Id. at 14:37–38.

E. References and Testimony

Below we provide an abbreviated summary of the qualifications of Dr. William J. Drasler, who provides testimony in support of Petitioner, and Dr. Lakshmi Prasad Dasi, who provides testimony in support of Patent Owner. We also provide a table identifying the primary references relied upon by Petitioner, as well as the exhibits corresponding to the declarations and deposition testimony in the record for Dr. Drasler and Dr. Dasi.

Dr. Drasler indicates he received a Ph.D. in Biomedical Engineering in 1983, was employed by various medical device companies between 1983 and 2008 where he worked on interventional cardiology devices, founded and served as Chief Technology Officer from 2008 to 2015 for a company that developed a product for Transcatheter Aortic Valve Replacement procedures, and currently works as a consultant for a medical device company on a product for such procedures. Ex. 1002 ¶¶ 11–18.

Patent Owner argues that Dr. Drasler applied “an incorrect standard to his obviousness analysis,” because “he required a combination to produce unexpected results in order to be non-obvious.” Resp. 8 (citing Ex. 2020, 19:13–20:16, 24:5–17). We find Patent Owner’s argument unpersuasive because, in addition to Dr. Drasler not having been offered as an expert in patent law, Patent Owner’s description of Dr. Drasler’s testimony is a misrepresentation of what was said during the deposition, as follows:

Q. Sure. Do you have an understanding as to whether an unexpected result is required for the combination of two references to not be obvious?

A. Yeah I -- I believe that that type of question is -- goes beyond what I was asked to do here as an expert, and as a result, I think it -- it perhaps is -- is beyond -- beyond where I should make my comment. I think that there’s probably other -- other reasons that I can’t go into because I’m not a patent attorney that would make something obvious other than the unexpected result.

Ex. 2020, 21:1–14 (objection omitted). The other portions of Dr. Drasler’s testimony cited by Patent Owner are not to the contrary. *See id.* at 19:13–20 (in response to questions about “hindsight” Dr. Drasler stated “let’s say there was two things that were out there, and you’re going to combine them in a --

a nonobvious way, in a way that is not -- gives an unexpected result, then I think it would not be obvious”), 24:5–17 (Dr. Drasler confirmed his opinion that “[i]f components are brought together in a manner that does not provide any unexpected result *and would be obvious to someone skilled in the art at the time*, then it would not be a patentable device” (emphasis added)); *see also* Reply 28 (discussing examples from Dr. Drasler’s testimony to show that he understood “that unexpected results were *not* the only way something could be nonobvious”).

Next, Patent Owner argues that Dr. Drasler’s testimony “should be entitled to little, if any, weight,” because he purportedly “admitted to opining based on his own perspective, rather than from the perspective of a [person of ordinary skill in the art].” Resp. 8–9 (citing Ex. 2020, 22:18–23:4). The testimony cited by Patent Owner is as follows:

Q. Fair. I’ll clarify the question.

So in reaching the opinions you set forth in your declaration, did you apply all of the experience that you set forth in your CV up to the January 4th, 2002, date?

A. I have a -- I believe the answer is yes. I -- I would use anything and everything I knew up to that point in 2002.

Ex. 2020, 22:18–23:4 (objection omitted). We find no clear inconsistency between Dr. Drasler’s testimony and his declaration, which expressly states as follows:

I understand that obviousness is determined from the perspective of a hypothetical person of ordinary skill in the art and that the asserted claims of the patent should be read from the point of view of such a person at the time the claimed invention was made.

Ex. 1002 ¶ 24. Dr. Drasler did not state in his deposition or elsewhere that he was applying his personal perspective in place of what a person of

ordinary skill in the art would have known at the time of the invention, or that a person of ordinary skill in the art at the time of the invention would have known “anything and everything” he knew in 2002. To the contrary, Dr. Drasler expressly explained that “[i]n rendering the opinions set forth in this declaration, I was asked to consider the patent claims and the prior art through the eyes of a person of ordinary skill in the art at the time of the alleged invention,” and further articulated what the qualifications he considered a person of ordinary skill in the art would have had at the relevant time. *Id.* at ¶¶ 30, 31. Further, as Petitioner shows, Patent Owner disregards numerous other instances during the deposition when Dr. Drasler addressed his opinion in the context of what would have been known to a person of ordinary skill in the art at the time of the invention, not his own perspective at the time of the invention. Reply 28 (citing Ex. 2020, 23:10–24:17, 58:13–59:10). Lastly, Patent Owner does not dispute Petitioner’s proposed level of ordinary skill in the art, which we adopt below, and which includes a minimum level of education and experience, but not a maximum level. *See infra* Section II.B. Thus, Patent Owner fails to articulate a factual basis to support its argument that Dr. Drasler’s qualifications in 2002 were outside of the level of ordinary skill in the art. *See Kyocera Senco Indus. Tools Inc. v. Int’l Trade Comm’n*, 22 F.4th 1369 (Fed. Cir. 2022) (“To offer expert testimony from the perspective of a skilled artisan in a patent case . . . a witness must *at least* have ordinary skill in the art.”) (emphasis added).

Both parties discuss *Neutrino Development Corp. v. Sonosite, Inc.*, 410 F. Supp. 2d 529 (S.D. Tex. 2006). Resp. 9; Reply 28. In *Neutrino*, the district court rejected an attempt to exclude expert testimony, noting that the witness “never asserts that he applied his own perspective” to his unpatentability analysis and recognized that the expert’s “opinions as to the

level of ordinary skill in the art are necessarily based on his own experience.” 410 F. Supp. at 550. We find the same reasoning applies to Dr. Drasler’s testimony in this case. As Dr. Drasler’s qualifications are otherwise undisputed, we also determine that Dr. Drasler is qualified to opine on the issues in this proceeding from the perspective of a person of ordinary skill in the art. Ex. 1002, App’x B (Dr. Drasler’s curriculum vitae).

Dr. Dasi indicates he received a Bachelor’s of Technology in Civil Engineering in 1998 from the Indian Institute of Technology, received a Master’s of Science in Civil and Environmental Engineering in 2000 from the Georgia Institute of Technology, completed a Ph.D. in Civil and Environmental Engineering in 2004, and was a Postdoctoral Fellow in the Department of Biomedical Engineering at the Georgia Institute of Technology in 2004 to 2005. Ex. 2027, 4–5. We note that at the time of the invention of the ’739 patent, which claims priority back to 2002, Dr. Dasi was not yet working in the field of heart valve replacement. Ex. 1001, code (63), 1:20–21; *see also infra* Section II.B (discussing the qualifications of a person of ordinary skill).

Dr. Dasi states he is a professor in the Department of Biomedical Engineering at the Georgia Institute of Technology, a Fellow of the American College of Cardiology, a Fellow of the American Institute of Medical and Biological Engineering, has directed a research program in heart valve engineering, and is a named inventor on three U.S. patents in the field of cardiovascular devices, with additional applications pending. Ex. 2019 ¶¶ 7–17. As his current qualifications in the pertinent art are undisputed, we determine that Dr. Dasi is qualified to opine on the issues in this proceeding from the perspective of a person of ordinary skill in the art. Ex. 2027 (Dr. Dasi’s curriculum vitae).

References and Witness Testimony⁴	Date	Ex. No.
U.S. Patent No. 6,425,916 B1 (“Garrison”)	July 30, 2002	1005
U.S. Patent No. 5,957,949 (“Leonhardt”)	Sept. 28, 1999	1006
U.S. Patent No. 5,961,549 (“Nguyen”)	Oct. 5, 1999	1020
U.S. Patent No. 5,840,081 (“Andersen”)	Nov. 24, 1998	1013
U.S. Patent No. 6,077,295 (“Limon”)	June 20, 2000	1008
U.S. Patent No. 7,025,780 B2 (“Gabbay”)	Apr. 11, 2006	1009
WO 00/15147 (“Phelps”)	Mar. 23, 2000	1010
Declaration of William J. Drasler, Ph.D. in Support of Petition for Inter Partes Review of U.S. Patent No. 9,125,739	Sept. 1, 2020	1002
Declaration of William J. Drasler in Support of Petitioner’s Reply to Patent Owner Response	Aug. 25, 2021	1041
Deposition Transcript of William J. Drasler, Ph.D.	May 19, 2021	2020
Declaration of Dr. Lakshmi Prasad Dasi	June 2, 2021	2019

F. Asserted Grounds of Unpatentability

Petitioner asserts that the Challenged Claims are unpatentable based on the following grounds:

Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
1–5	103(a)	Garrison
1–5	103(a)	Garrison, Leonhardt
1–5	103(a)	Garrison, Nguyen
1–5	103(a)	Garrison, Leonhardt, Nguyen

⁴ The table identifies only a select number of documents particularly pertinent to this Decision. *See, e.g.*, Paper 23 (Patent Owner’s List of Exhibits); Paper 24 (Petitioner’s Updated Exhibit List). A complete identification of the papers and exhibits that form the record of this case is available in the docket of this proceeding.

Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
1–3, 5	103(a)	Andersen, Limon, Gabbay
1–3, 5	103(a)	Andersen, Limon, Phelps
1–3, 5	103(a)	Andersen, Limon, Phelps, Nguyen
4	103(a)	Andersen, Limon, Gabbay, Garrison
4	103(a)	Andersen, Limon, Phelps, Garrison
4	103(a)	Andersen, Limon, Phelps, Nguyen, Garrison

Pet. 10–11. We refer to the grounds based on Garrison, alone or in combination with Leonhardt and/or Nguyen (i.e., the first four grounds in the table above) as the “Garrison Grounds,” and the six grounds including Andersen and Limon as the “Andersen/Limon Grounds.”

II. ANALYSIS

A. Legal Standards of Obviousness

Petitioner contends under ten grounds that the Challenged Claims are unpatentable based on obviousness.⁵ Pet. 10–11. As set forth in 35 U.S.C. § 103(a),

[a] patent may not be obtained . . . if the differences between the subject matter sought to be patented 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.

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

⁵ 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 ’739 patent issued has an effective filing date prior to March 16, 2013, the pre-AIA version of § 103 applies.

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 evidence of nonobviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

An obviousness analysis “need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007). However, Petitioner cannot satisfy its burden of proving obviousness by employing “mere conclusory statements.” *In re Magnum Oil Tools Int’l, Ltd.*, 829 F.3d 1364, 1380 (Fed. Cir. 2016). Instead, Petitioner must articulate a reason why a person of ordinary skill in the art would have combined the prior art references. *In re NuVasive*, 842 F.3d 1376, 1382 (Fed. Cir. 2016); *see also Pers. Web Tech., LLC, v. Apple, Inc.*, 848 F.3d 987, 993–94 (Fed. Cir. 2017) (“[O]bviousness concerns whether a skilled artisan not only *could have made* but *would have been motivated to make* the combinations or modifications of prior art to arrive at the claimed invention”) (quoting *Belden Inc. v. Berk-Tek LLC*, 805 F.3d 1064, 1073 (Fed. Cir. 2015)).

B. 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)). In determining the level of ordinary skill in the art, various factors may be considered, including the “type of problems encountered in the art; prior art solutions to those problems; rapidity with which innovations are made; sophistication of the technology; and

educational level of active workers in the field.” *In re GPAC Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995) (citation omitted).

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.

Pet. 23 (citing Ex. 1002 ¶¶ 30–33). Patent Owner does not dispute Petitioner’s definition of a person of ordinary skill in the art. Resp. 2.

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 ’739 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))).

C. Claim Construction

We apply 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). 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. 23. Petitioner discusses three claim terms as follows. *Id.* at 24–25.

1. “*flares at both ends in a trumpet-like configuration*”

Claim 1 recites “wherein the stent member includes a tubular structure away from a central portion that flares at both ends in a trumpet-like configuration.” Ex. 1001, 14:8–11. The Specification of the ’739 patent does not otherwise describe a “trumpet-like configuration” and provides no illustration of such a configuration. *See id.* at 7:62–63 (the only mention of “trumpet-like” in the Specification of the ’739 patent outside of claim 1 states that “[a]way from its central portion, the tubular structure flares markedly at both ends in a trumpet-like configuration”).

For the term “trumpet-like,” Petitioner asserts only that the prior art discloses the limitation regardless of its exact metes and bounds. Pet. 24 (citing Ex. 1002 ¶¶ 61–63). Patent Owner states that it has applied the construction adopted in related district court proceedings construing “‘flares at both ends in a trumpet-like configuration’ to mean ‘having, at each end, a widening that resembles the bell of a conventional musical trumpet.’” Resp. 7 (citing Ex. 2025, 46; Ex. 2026; Ex. 2019 ¶¶ 72, 73). We discern no dispute over the meaning of “trumpet-like” that requires an express construction. *See Reply 1. 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)).

2. “a valve means”

Claim 1 recites “a valve means.” Ex. 1001, 14:11. Petitioner argues that “valve means” is not a means-plus-function limitation because the remainder of the limitation “does not recite a function.” Pet. 24. Alternatively, if it is construed to be a means-plus-function limitation, Petitioner asserts “the function/structure would be the function and structure of a valve.” *Id.* (citing Ex. 1001, 3:18–4:32). Patent Owner states that it has applied the construction adopted in related district court proceedings construing “‘valve’ and ‘valve means’ to mean ‘portions of the replacement heart valve device that allow the one-way flow of blood.’” Resp. 7–8 (citing Ex. 2025, 15; Ex. 2026; Ex. 2019 ¶¶ 74, 75). We discern no dispute over the meaning of “valve means” that requires an express construction. *See* Reply 1.

3. “controlled release mechanism”

Claim 5, which depends from claim 1, recites “wherein the pusher member includes a controlled release mechanism that can be activated.” Ex. 1001, 14:37–38. Petitioner argues “controlled release mechanism” is not a means-plus-function limitation, because it does not recite “means for.” Pet. 25. Alternatively, if it is construed to be a means-plus-function limitation, Petitioner asserts as follows:

[T]he function would be: controlling release of device during deployment; and the corresponding structure would be: a pusher member that can be activated by pushing out the pusher member and the prosthetic heart valve partially from the sheath such that

the stent member partially expands, but is restrained so it doesn't pop out.

Id. (citing Ex. 1001, 11:51–59, 12:24–28).

Patent Owner states that it has applied the definition of “controlled release” purportedly provided by Dr. Drasler as “that ‘the operator can control when the valve . . . is released,’ including ‘control [of the valve’s release] so that [the valve] doesn’t just arbitrarily pop out . . . when [the operator] do[es]n’t want it to.’” Resp. 8 (quoting Ex. 2020, 87:7–18) (alterations in original). The complete exchange Patent Owner cites is as follows:

Q. And so I think, in paragraph 69 of your declaration -- let me turn there really quickly. In that paragraph, you're talking about -- that paragraph and the one above it, you're talking about the meaning of controlled release mechanism?

A. Yes.

Q. And so I think you -- you sort of set forth a meaning of that in paragraph 69, and so I wanted to see if I understand what you're saying. Is it the case that, to one of ordinary skill in the art, you would view controlled release meaning that the operator can control when the valve of Garrison is released from the sheath?

A. Control when it's released, and control it so that it doesn't just arbitrarily pop out, so it has some frictional aspect to it so that it doesn't want to just go outwards and -- when you don't want it to, yes.

Ex. 2020, 87:1–18. Thus, Dr. Drasler's full testimony makes clear that in his opinion a frictional force is sufficient to act as the mechanism for controlled release of the valve. Further, Paragraph 69 of Dr. Drasler's Declaration, referenced in the deposition exchange above, provides the same definition of “controlled release” provided in the Petition, as discussed

above, not what Patent Owner purports to be the definition “provided by Dr. Drasler” taken from a shortened excerpt from his deposition. Ex. 1002 ¶ 69. We therefore reject Patent Owner’s argument that Dr. Drasler’s deposition testimony provided a definition of “controlled release mechanism” different from what is provided in the Petition, because Patent Owner’s argument misrepresents Dr. Drasler’s testimony.

Petitioner further argues in reply that “as Dr. Drasler testified, there must be some mechanism to control the valve’s release—which is simply the term’s plain and ordinary meaning.” Reply 2 (citing Ex. 1041 ¶¶ 13, 14). According to Petitioner, an express construction is unnecessary because “under the plain and ordinary meaning, any reasonable construction and [Patent Owner’s] construction,” the limitation is taught by the asserted art. *Id.* Thus, we discern no dispute over the meaning of “controlled release mechanism” that requires an express construction.

4. Additional Claim Terms

We find that no other claim term requires an express construction for purposes of rendering this Decision. *See Wellman*, 642 F.3d at 1361.

D. Scope and Content of the Asserted Art Under the Garrison Grounds

Under the Garrison grounds, Petitioner also relies on Leonhardt and Nguyen. Pet. 27–52. Each of these references is summarized in relevant part below.

1. Summary of Garrison

Garrison is “directed to methods and devices for implanting replacement cardiac valves.” Ex. 1005, 1:5–6. Garrison explains that “[a]n object of the present invention is to provide additional devices and methods which reduce the trauma associated with conventional open-chest methods and devices for implanting cardiac valves.” *Id.* at 1:49–52. Figures 1–12 of

Garrison illustrate features of “a system for implanting a cardiac valve.” *Id.* at 2:60–3:15.

Figure 2 of Garrison is reproduced below.

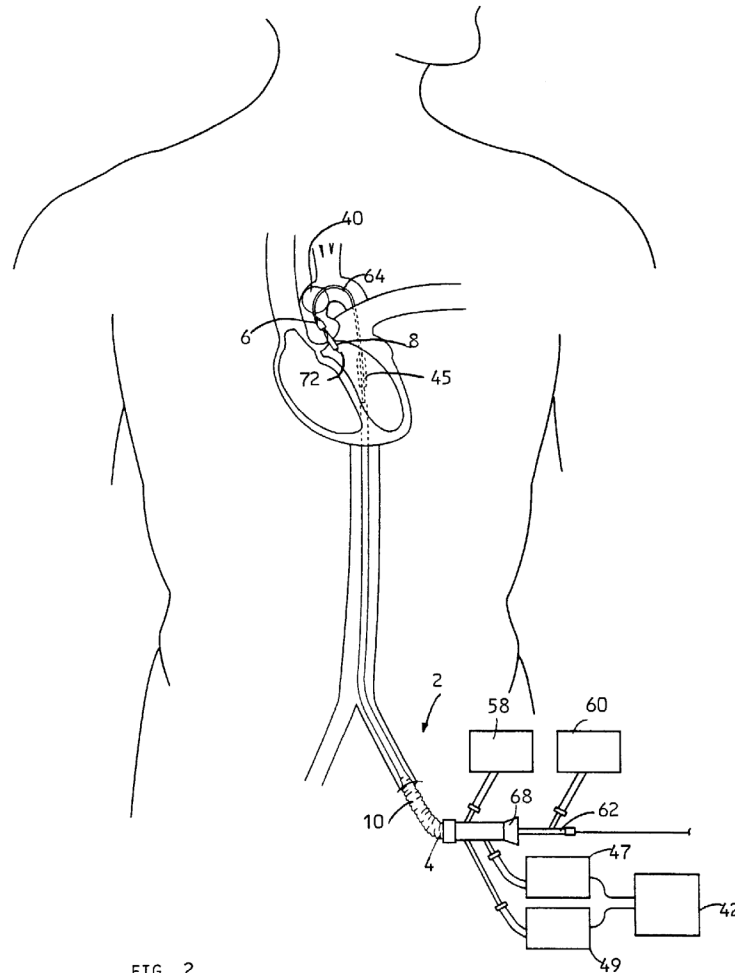


FIG. 2

Figure 2 illustrates “a system for implanting a cardiac valve,” with a sheath retracted to expose the cardiac valve, a valve displacer and a temporary valve mechanism. According to Garrison, system 2 includes delivery catheter 4, cardiac valve 6, valve displacer 8, and protective sheath 10, which “covers the delivery catheter 4, cardiac valve 6 and valve displacer 8 during introduction to prevent contact between the blood vessel and the cardiac valve 6 and valve displacer 8.” *Id.* at 4:14–19. Garrison states

“valve displacer 8 is expanded within the native valve to hold the native cardiac valve leaflets 6 open,” but further provides that the native valve may be removed “rather than using the valve displacer 8.” *Id.* at 4:46–52. Garrison further states “valve displacer 8 and cardiac valve 6 may be integrated into a single structure and delivered together rather than separately,” and “[t]hus, all features of any valve displacer described herein may also form part of any of the cardiac valves described herein.” *Id.* at 4:52–56.

Figures 7 and 8 of Garrison are reproduced below.

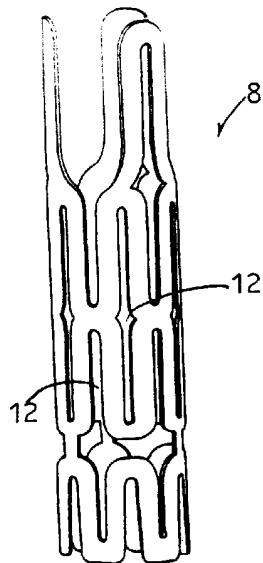


FIG. 7

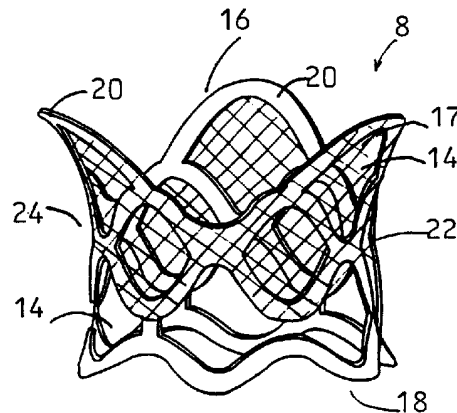
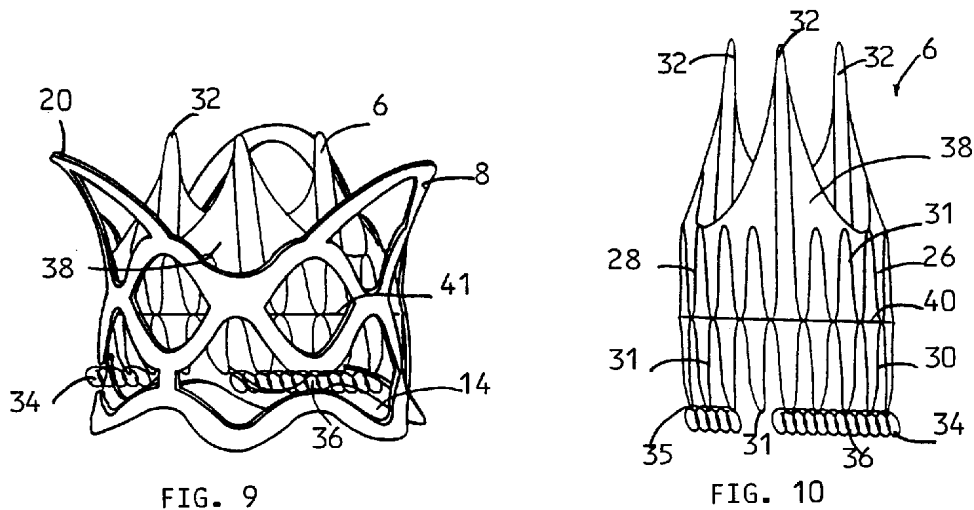


FIG. 8

Figures 7 and 8 illustrate valve displacer 8 in the collapsed condition and the expanded condition, respectively. *Id.* at 4:58–60. According to Garrison, “first and second ends 16, 18 of the valve displacer 8 flare outwardly to form a circumferential recess 24 at a central section 22,” and Garrison provides that although the flared ends are preferred, “valve displacer 8 may have any other suitable shape which holds the leaflets open.” *Id.* at 4:66–5:1, 5:11–14.

Figures 9 and 10 of Garrison are reproduced below.



Figures 9 and 10 illustrate cardiac valve 6, including expandable support structure 26 with protrusions 34 in an expanded condition and a collapsed condition, respectively. *Id.* at 5:20–22, 30–32. “Protrusions 34 engage the openings 14 in the valve displacer 8 as shown in [Figure] 9 to secure the cardiac valve 6 to the valve displacer 8.” *Id.* at 5:32–34. “[S]upport structure 26 may also have barbs to secure the cardiac valve 6 to the valve displacer 8 or to the blood vessel wall.” *Id.* at 5:36–39. A delivery catheter with first and second expandable members is used to deploy valve displacer 8 and cardiac valve 6, respectively. *Id.* at 6:36–38; Figs. 3–6; *see also id.* at 7:49–8:9 (detailing that valve displacer 8 is placed between the valve leaflets and expanded to hold the native valve leaflets open, after which a “second catheter” is advanced until valve 6 is positioned adjacent valve displacer 8 where the second catheter is manipulated to until protrusions 34 of valve 6 engage openings 14 in displacer 8).

Figures 13–15 of Garrison illustrate features of “another system for implanting another cardiac valve.” *Id.* at 3:16–3:22. Figures 13 and 14 of Garrison are reproduced below.

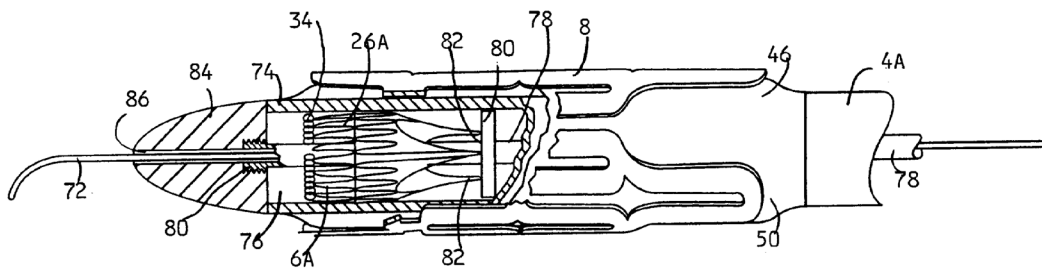
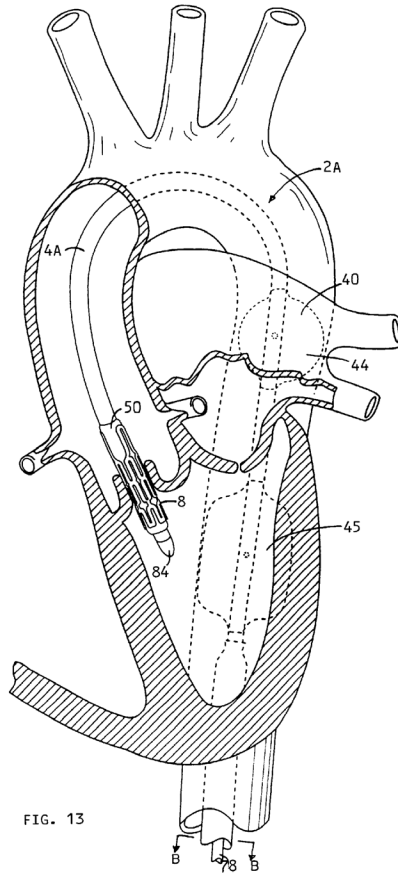


Figure 13 illustrates “another system for implanting another cardiac valve,” and Figure 14 illustrates a “partial cut-away view of the catheter” of Figure 13 “with the valve contained in a chamber.” *Id.* at 3:16–20. Cardiac

valve 6A is similar to cardiac valve 6 described above; however, cardiac valve 6A “is self-expanding and, therefore, does not require an independent expansion mechanism.” *Id.* at 8:13–16. “[C]atheter 4A has the expandable member 46, which is preferably the balloon 50, for expanding the valve displacer 8.” *Id.* at 8:21–23. Garrison explains as follows:

The cardiac valve 6A is contained within an outer wall 74 of the delivery catheter 4A. The cardiac valve 6A is advanced out of a chamber 76 in the delivery catheter 4A by advancing a rod 78 having a pusher element 80 attached thereto. The pusher element 80 engages the posts 82 on the cardiac valve 6A to move the cardiac valve 6A out of the chamber 76. The rod 78 has threaded connections 80, 82 with a tip 84 and the pusher element 80 to facilitate assembling the delivery catheter 4A and loading the cardiac valve 6A in the chamber 76. The rod 78 has a guidewire lumen 86 for receiving the guidewire 72.

Id. at 8:24–34. “The cardiac valve 6A is implanted in substantially the same manner as the cardiac valve 6.” *Id.* at 8:45–47; *see also id.* at 8:53–64 (describing how valve 6A is placed and secured after displacer 8 is expanded in place). Two additional systems for “implanting a cardiac valve” are shown in Garrison in Figures 16–22 and in Figures 23–30, respectively, and “another system for delivering a cardiac valve” is shown Figures 31–38. *Id.* at 3:23–4:6.

2. Summary of Leonhardt

Leonhardt, titled “Percutaneous Placement Valve Stent,” describes an artificial valve, including “a tubular graft having radially compressible annular spring portions for biasing proximal and distal ends of the graft into conforming fixed engagement with the interior surface of a generally tubular passage.” Ex. 1006, codes (54), (57).

Figures 2 and 4 of Leonhardt are reproduced below.

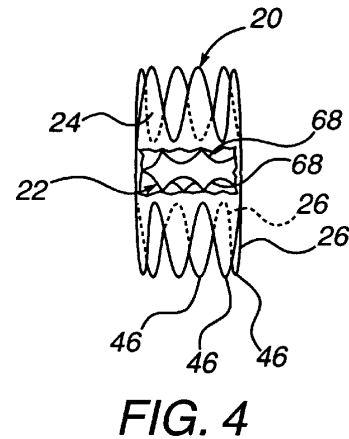
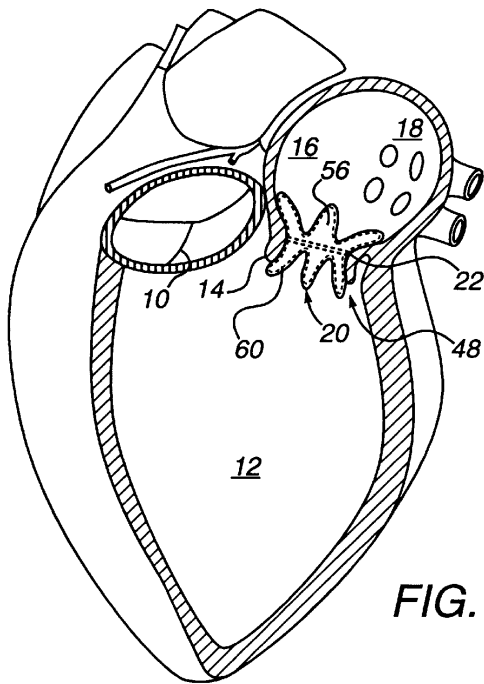


Figure 2 illustrates a “valve stent fully deployed within the mitral valve,” and Figure 4 illustrates a sectional view of a “biological valve within the stent.” *Id.* at 3:57–58, 3:61–62. As shown in Figure 4, valve stent 20 includes stent 26, biological valve 22, and graft material 24. *Id.* at 4:15–17. According to Leonhardt, as shown in Figure 2, “[s]tent 26 biases the proximal and distal ends of valve stent 20 into conforming and sealingly fixed engagement with the tissue of mitral valve 14,” and the “deployed valve stent 20 creates a patent one way fluid passageway.” *Id.* at 5:48–52.

3. Summary of Nguyen

Nguyen, titled “Multi-Leaflet Bioprosthetic Heart Valve,” relates “to methods and apparatuses for selecting individual pericardial leaflets for a multi-leaflet heart valve prosthesis. Ex. 1020, code (54), 1:5–9. In relevant part, Nguyen teaches as follows:

Bio-prosthetic valves may be formed from an intact, multi-leaflet porcine (pig) heart valve, or by shaping a plurality of

individual leaflets out of bovine pericardial tissue and combining the leaflets to form the valve. The pericardium is a sac around the heart of vertebrate animals, and bovine (cow) pericardium is commonly used to make individual leaflets for prosthetic heart valves. The bovine pericardium is first harvested from the animal and then chemically fixed to crosslink collagen and elastin molecules in the tissue and increase the tissue durability, before being cut into leaflets. Various physical characteristics of the tissue may be examined before or after fixation.

Id. at 1:28–39.

E. Alleged Obviousness over Garrison Alone

Petitioner contends the Challenged Claims would have been obvious over Garrison. Pet. 26–46; Reply 3–14. Petitioner’s contentions are supported by Dr. Drasler. Ex. 1002 ¶¶ 73–131. Patent Owner disputes Petitioner’s contentions with the support of Dr. Dasi. Resp. 8–36; Sur-reply 1–11, 22–25; Ex. 2019 ¶¶ 97–159.

Below we address first Patent Owner’s argument, which we reject, that Dr. Drasler “disclaimed” many of Petitioner’s contentions. Next, after reviewing the entire record developed at trial, we explain our determination that Petitioner has shown, by a preponderance of the evidence, that Garrison teaches or suggests each limitation of the Challenged Claims. We then discuss our determination that Petitioner has shown, by a preponderance of the evidence, that a person of ordinary skill in the art would have had sufficient reasons to modify Garrison and would have had a reasonable expectation of success in doing so. Finally, we consider all of the *Graham* factors and conclude that Petitioner has shown by a preponderance of the evidence that the Challenged Claims would have been obvious over Garrison.

1. Whether Dr. Drasler “Disclaimed” Contentions Based on Garrison Made by Petitioner

As a preliminary issue we address Patent Owner’s argument that Dr. Drasler “disclaimed” various contentions of Petitioner concerning the grounds based on Garrison. *See, e.g.*, Resp. 10–21. In short, Patent Owner’s argument has no merit.

Patent Owner recognizes that Garrison describes what Patent Owner calls a “two-component” system for cardiac valve replacement comprised of a valve displacer and a replacement cardiac valve. *Id.* (citing Ex. 1005, 1:55–2:22). Garrison also states that the valve displacer and cardiac valve “may be integrated into a single structure and delivered together rather than separately.” Ex. 1005, 4:52–53; *see also id.* at 2:36–37 (stating in regard to the delivery system that “[a]lternatively, the valve displacer and valve may be mounted to a single catheter”). Patent Owner also acknowledges that “Petitioner repeatedly cites to and relies upon Garrison’s two-component system.” Resp. 10–11. Patent Owner then asserts that “every argument in which Petitioner relies on Garrison’s two-component system—including those arguments upon which the PTAB relied in instituting IPR—should be disregarded,” because, according to Patent Owner, Dr. Drasler, in response to a deposition question, “specifically disclaimed any reliance on Garrison’s two-component valve replacement system.” *Id.* (citing Ex. 2020, 74:11–17, 75:10–76:4); *see also* Sur-reply 22 (asserting that “Petitioner’s expert proceeded to very clearly disclaim all but one of these embodiments [of Garrison] in his deposition”). Patent Owner’s assertion is not accurate.

During his deposition Dr. Drasler was first asked at length about Leonhardt. *See* Ex. 2020, 65:1–73:3. Dr. Drasler was then directed to Garrison, and specifically to Figure 14 of Garrison, which illustrates a

catheter as a delivery device with the replacement valve in a chamber of the device. *Id.* at 73:4–12; Ex. 1005, 3:19–20. Dr. Drasler then testified in response to Patent Owner’s questioning as follows:

Q. Once the Garrison valve displacer is in place, if the shape of the valve displacer creates any -- in the native valve creates any mating problems with the valve that’s going to be inserted, would that have to be addressed by open heart surgery?

A. Likely not. The -- the initial -- first of all, let me just say that the -- *the two-component system that you are referring to here, namely support -- valve support inside of a displacer, is not what we're proposing here in this declaration as -- as the device structure that -- that could be used as taught by Garrison.*

But to answer your question, you would first put the -- the displacer in -- in one embodiment, right? In one embodiment of the invention, you would first put in the displacer, and then it would expand out to a significantly larger diameter, and there would be plenty of room to place your second component within it. And then it would move out and mate with this first component.

You would like to design your first component, the displacer, so that it was in a final configuration that would have a structure that would allow you to mate easily with it in this embodiment that we're talking about now.

Q. *Okay. And you said that you're not proposing in your declaration that the device -- using the two-component device taught by Garrison with Leonhardt; is that right?*

A. *That's right.* We’re -- we’re focusing in on the statement made by Garrison that -- that the valve support structure can have any and all of the properties found in this --

Q. I’m sorry. I couldn't understand --

A. Can have any and all of the properties found in the displacer. And that the -- the two components, the -- the support structure -- the valve support structure and the displacer can be integrated into one device. And that then provides the device that has the features that this declaration focuses on.

Q. So focusing instead on the integrated device of Garrison, if I understand it correctly, Garrison describes inverting the valve so that it's not damaged during delivery and then pulling it back into its intended position by sutures that pull the valve device into place. Is that right for the integrated device in Garrison?

A. No. It -- that -- that is incorrect. So Garrison does indeed describe an embodiment of an integrated device that has the features that you just described and is shown in, for example, figures 31, 32, and perhaps others as well. That -- that is not the form of the integrated device that is being proposed here in the declaration. When Garrison says in his specification somewhere -- I think it's in column 4. I can't remember the line.

Q. That's okay.

A. That -- that you can indeed use any of the aspects of the displacer in the valve support structure and -- and you can integrate them. Integrate would mean to me that you can take, for example, the valve leaflets of the valve support structure and put it into the displacer, which then becomes your new valve support structure.

When you say that the -- that these two components can have the same structure and properties as the other one, you would then say, therefore, the valve support structure can be -- have the shape of the valve displacer, can look like the valve displacer, and we can put -- we can integrate -- we can put the valve into it.

So the final design being proposed here and taught by Garrison -- proposed in the declaration, taught by Garrison is that you would then have a one-component device with a valve located in a stent that looks like the displacer. And the properties of the displacer to hold and push back the leaflets would be, therefore, bound in this new valve support structure, and it would have the same shape as the displacer, and it would function as a stent valve, one component.

Ex. 2020, 74:4–78:4 (objections to form omitted) (emphases added to identify the only portions quoted by Patent Owner in its Response). There is nothing in Dr. Drasler's testimony that amounts to him having broadly

“disclaimed any reliance on Garrison’s two-component valve replacement system,” as Patent Owner argues, which would have been contrary to his own declaration and the Petition. *See generally* Pet.; Ex. 1002.

Of particular note in the deposition exchange reproduced above, Dr. Drasler explained in his response that “the two components, the -- the support structure – the valve support structure and the displacer can be integrated into one device,” and “that then provides the device that has the features that this declaration focuses on.” Ex. 2020, 75:15–76:4. Thus, Dr. Drasler expressly relied on Garrison’s teaching of “two components” in combination with Garrison’s further teaching that the two components may be integrated. *Id.* To the extent any of Dr. Drasler’s testimony at deposition is inconsistent with his opinion in his declaration, we consider that in assessing the weight afforded his testimony. It is not a basis for Patent Owner to broadly assert “every argument in which Petitioner relies on Garrison’s two-component system . . . should be disregarded,” which is a proposition Patent Owner fails to support with any legal authority. *See* Resp. 10–11.

Additionally, we note that Dr. Dasi, in support of the Patent Owner Response, states “I further understand that Petitioner’s expert has disclaimed reliance on Garrison’s two-component valve replacement system in favor of an embodiment not actually disclosed in Garrison.” Ex. 2019 ¶ 99.

Presumably, Dr. Dasi’s understanding comes from Patent Owner’s unfounded “disclaimed” argument, which we take into consideration as an unsupported assumption upon which at least portions of Dr. Dasi’s testimony is founded. *See, e.g., id.* ¶ 134 (Dr. Dasi offering an opinion “in the event that Petitioner attempts to rely on the two-component, valve-only, or integrated valve/displacer embodiments that I understand Petitioner’s expert has disclaimed”).

2. Differences Between the Subject Matter of Independent Claim 1 and Garrison

Garrison teaches or suggests each limitation of claim 1, as shown by Petitioner, for the reasons below based on the supporting cited evidence of record. *See* Pet. 32–34; Reply 3–13. Patent Owner’s arguments to the contrary are not persuasive because they are insufficiently supported by the cited evidence of record or misapply legal precedent.⁶ Resp. 8–36; Sur-reply 1–12, 22–25.

An assembly to treat a native heart valve in a patient, the assembly for use in combination with a guidewire, the assembly comprising:

To the extent the preamble of claim 1 is limiting, Garrison teaches, as shown by Petitioner, “devices for implanting replacement cardiac valves,” including a delivery catheter 4A with a guidewire lumen 86 (corresponding to “an assembly to treat a native heart valve . . . for use in combination with a guidewire”). Pet. 32–33; Ex. 1002 ¶¶ 89–91; Ex. 1005, 1:5–6, 3:5–6, 8:25–34, Fig. 6).

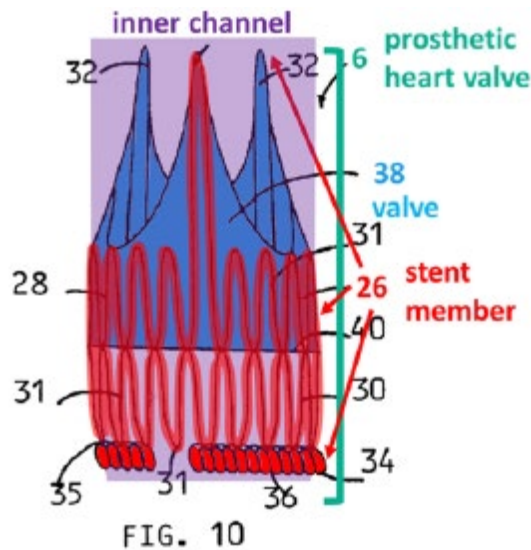
*a prosthetic heart valve including:
a stent member having an inner channel, the stent member
collapsible, expandable and configured for
transluminal percutaneous delivery,*

Garrison teaches, as shown by Petitioner, cardiac valves 6 and 6A (each corresponding to a “prosthetic heart valve”) with valve portion 38 and support structure 26 and 26A (each corresponding to “a stent member”), respectively. Pet. 33; Ex. 1002 ¶ 94; Ex. 1005, 5:42–48, 8:10–16. Garrison explains with regard to cardiac valve 6A (shown in Figures 13 and 14) that it

⁶ We separately address Patent Owner’s arguments directed to Petitioner’s reasons for modifying Garrison after addressing how Garrison teaches each limitation. *See infra* Section II.E.7.

is “similar to cardiac valve 6,” that “the same or similar reference numbers refer to the same or similar structures,” and that unlike cardiac valve 6, cardiac valve 6A does not require “an independent expansion system” because it is “self-expanding.” Ex. 1005, 8:16.

Petitioner further identifies the relevant features of the prosthetic heart valve of Garrison through an annotated and colorized version of Figure 10 of Garrison illustrating cardiac valve 6, which we find apply equally to cardiac valve 6A. *See id.* Petitioner’s annotated and colorized version of Figure 10 of Garrison is reproduced below:



Petitioner’s annotated and colorized version of Figure 10 illustrates cardiac valve 6 with expandable support structure 26 (shown in red) in a collapsed condition, surrounding valve portion 38 (shown in blue) and an inner channel (shown as a purple shaded region). Pet. 33, 34; Ex. 1002 ¶ 94; Ex. 1005, 5:20–22, 5:30–32. In Figure 10, cardiac valve 6 is shown configured in a collapsed condition for transluminal percutaneous delivery, as required by claim 1. Pet. 33; Ex. 1005, 3:12, 4:24–35.

wherein the stent member includes a tubular structure away from a central portion that flares at both ends in a trumpet-like configuration;

Petitioner contends that Garrison teaches or suggests a stent member with a “that flares at both ends in a trumpet-like configuration.” Pet. 35–36. Patent Owner argues to the contrary, asserting, for example, that “Petitioner provides no allegations regarding how a [person of ordinary skill in the art] would successfully implement a flared stent in Garrison.” Resp. 29–30.

To better understand the arguments of the parties, we begin by noting that neither claim 1 nor the Specification of the ’739 patent limits the assembly recited or described (respectively) to applications requiring the removal of the native heart valve. The ’739 patent states as follows:

The replacement heart valve device of the present invention is *preferably* used in surgical procedures involving the percutaneous and transluminal removal of the diseased or defective heart valve and the percutaneous and transluminal implantation of the new heart valve described above.

Ex. 1001, 10:56–60 (emphasis added).

Similarly, the teachings of Garrison are not limited to procedures where the native heart valve is not removed. Although Garrison describes the use of a “valve displacer” when the native heart valve is left in place, Garrison’s teachings are not limited to such procedures, and Garrison states as follows:

The valve displacer 8 is expanded within the native valve to hold the native cardiac valve leaflets 6 open. An advantage of the system 2 and method of the present invention is that the native valve does not need to be removed. The replacement cardiac valves described herein may, of course, also be used when removing the native valve rather than using the valve displacer 8. Furthermore, the valve displacer 8 and cardiac valve 6 may be integrated into a single structure and delivered together rather than separately. Thus, *all features of any valve*

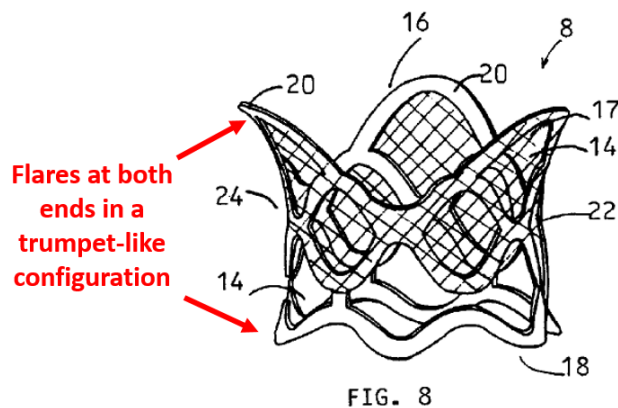
displacer described herein may also form part of any of the cardiac valves described herein without departing from the scope of the invention.

Ex. 1005, 4:46–57 (emphasis added). It is this disclosure that Petitioner relies upon in large part to support its contention that Garrison teaches or suggests a stent member with a trumpet-like configuration, as explained below. Pet. 35–36. With regard to the excerpt from Garrison above, Patent Owner argues that, because the last sentence begins with “[t]hus,” it only applies to the “immediately-proceeding disclosure” of an integrated valve displacer and cardiac valve. Resp. 16–17 (citing Ex. 2019 ¶ 118). We find this argument not persuasive because the sentence preceding the sentence that begins with “[t]hus” begins with “[f]urthermore,” indicating that it is in addition to what precedes it, not separate from, as Patent Owner argues. Nor is there any ambiguity in the disclosure, which explicitly states “all features of *any valve displacer* described herein may also form part of *any of the cardiac valves described herein*.”

We have further considered Patent Owner’s argument that Garrison’s teaching that “all features of any valve displacer described herein may also form part of any of the cardiac valves described herein” does not apply to any integrated valve other than the one depicted in Figure 31–38 (which pertains to an embodiment Petitioner does not rely upon), and find it is unsupported by the language at issue, and, therefore, not persuasive. *Id.* at 14–17. Thus, we reject Patent Owner’s argument that a person of ordinary skill in the art would have understood the teachings of Garrison to only encompass the purported three embodiments in Garrison that have

“detailed descriptions and figures.”⁷ *Id.* at 16–17; *see also* Reply 8–9 (asserting that Patent Owner’s “attempt to limit Garrison’s disclosure to three, siloed embodiments runs contrary to Garrison’s express teachings . . . and excludes the vast majority of Garrison’s teachings”). In light of Petitioner’s showing that a stent member with a trumpet-like configuration was well known in the art, as explained below, we find, contrary to Patent Owner’s assertion, that a person of ordinary skill in the art would have known “how to use Garrison’s disclosures” to make a “fourth embodiment” in which “which Garrison’s ‘valve (including its support structure)’ has ‘the same features of the valve displacer.’” Resp. 14, 17 (citing, e.g., Ex. 2019 ¶¶ 120, 121); *see also* Reply 6 (arguing that Garrison is presumed enabled).

Garrison teaches, as shown by Petitioner, valve displacer 8 flared at both ends in a “trumpet-like configuration,” as shown in Petitioner’s annotated version of Figure 8 reproduced below:



Pet. 36. The annotated version of Figure 8 shows valve displacer 8 with flares at both ends in a trumpet-like configuration. Garrison explains in

⁷ To the extent arguments raised by Patent Owner suggest that a person of ordinary skill in the art would not have understood Garrison to teach a stent member with a trumpet-like configuration, we address those arguments below in our discussion of reasons supporting obviousness over Garrison (*see infra* Section II.E.7). *See* Resp. 26–33.

detail the trumpet-like configuration as a notable feature of valve displacer 8 as follows:

[A] valve displacer is used to hold the native valve leaflets open so that the native valve does not need to be removed. The valve displacer is preferably introduced into the patient in a collapsed condition and expanded to displace and hold the leaflets open. The valve displacer may either be expanded with an expansion mechanism, such as a balloon, or may be self-expanding. In a preferred embodiment, the valve displacer has a first end, a second end and a central section between the first and second ends. *The first and second ends are preferably flared outwardly to form a circumferential recess around the central portion.* The native leaflets are trapped within the recess when the valve displacer is deployed.

Ex. 1005, 1:66–2:11 (emphasis added). Garrison broadly refers to “all features” of the valve displacer in regard to what may form “part of any of the cardiac valves,” and as noted above a significant feature of the valve displacer is a trumpet-like configuration in which its “first and second ends are preferably flared outwardly.” *Id.* Petitioner reasons, and we agree, that because Garrison states “all features of any valve displacer described herein may also form part of any of the cardiac valves described herein,” a person of ordinary skill in the art would have understood Garrison to teach, or at least suggest, a stent member that flares outwardly at both ends in a trumpet-like configuration in an identical manner to Garrison’s flared valve displacer 8 “to advantageously conform the valve to the valve displacer or vessel walls.” Pet. 35 (citing, e.g., Ex. 1003 ¶¶ 98–99). That is, if the native valve is left in place and a valve displacer is used, Garrison suggests that the replacement cardiac valve may also have flared ends in a trumpet-like configuration. As Petitioner shows, this applies whether the valve displacer and replacement cardiac valve are separate components, or are integrated

into a single structure, as expressly taught by Garrison. *Id.* at 35; Ex. 1005; *see also id.* at 4:52–54 (stating that “the valve displacer 8 and cardiac valve 6 may be integrated into a single structure”). Additionally, if the native valve is removed and a valve displacer is not necessary, Garrison teaches that the replacement cardiac valve may have flared ends in a trumpet-like configuration, a feature of the valve displacer that Garrison teaches “may also form part of any of the cardiac valves” described in Garrison.

As additional support, Petitioner shows that applying the flared ends of Garrison’s valve displacer to Garrison’s stent member, as taught by Garrison, is merely what a person of ordinary skill in the art would have known at the time, as shown by various references that use a stent member with a “trumpet-like configuration.” Pet. 29–30 (citing Ex. 1002 ¶ 78; Ex. 1006, 5:45–48, 6:17–22, 10:53–64, Fig. 2; Ex. 1009, 2:5–15, 3:36–4:8, 8:14–43, Fig. 2; Ex. 1010, 10:7–17, 10:25–29, Fig. 8; Ex. 1012, 9:7–9, 9:19–21, Figs. 3a, 3b). Because Petitioner’s arguments are supported by the cited evidence of record, which we adopt as our own findings, we are persuaded that a preponderance of the evidence shows that Garrison teaches a “stent member” (the support structure of a cardiac valve) with a “trumpet-like configuration” (the trumpet-like configuration feature of Garrison’s valve displacer, which Garrison states “may also form part of any of the cardiac valves”).

a valve means including two to four individual leaflets made of fixed pericardial tissue, wherein the valve means resides entirely within the inner channel of the stent member, and wherein no reinforcing members reside within the inner channel of the stent member;

Garrison teaches, as shown by Petitioner, valve portion 38 (illustrated in annotated Figure 9 above) corresponding to the recited “valve means.” Pet. 36–39 (citing, e.g., Ex. 1005, 5:42–50, Figs. 10, 11; Ex. 1002 ¶ 103). In particular, Petitioner shows that Figures 10 and 11 of Garrison illustrate valve 38 residing entirely within the inner channel of the stent member. *Id.* at 38. Garrison further states that “valve portion 38 is preferably a stentless tissue valve such as a tri-leaflet [] stentless porcine valve.” Ex. 1005, 5:42–46; *see also id.* at 5:50–52 (stating that “[a]lthough it is preferred to provide a tissue valve for the valve portion 38, the valve portion 38 may also be made of a flexible, synthetic material”). Thus, Garrison broadly teaches a valve means that may be made of tissue or synthetic material, and identifies a “porcine valve” as a specific example, but does not expressly teach the use of “fixed pericardial tissue.” *See id.* at 5:42–52.

The ’739 patent discusses in its Specification under “Background of the Invention,” “Description of Related Art,” the construction of “tissue valves” using “pig aortic valves” and “the pericardial sac,” as follows:

Most tissue valves are constructed by sewing the leaflets of pig aortic valves to a stent to hold the leaflets in proper position, or by constructing valve leaflets from the pericardial sac of cows or pigs and sewing them to a stent. The porcine or bovine tissue is chemically treated to alleviate any antigenicity. The pericardium is a membrane that surrounds the heart and isolates it from the rest of the chest wall structures. The

pericardium is a thin and very slippery, which makes it difficult for suturing in a millimetrically precise way.

Ex. 1001, 3:41–49.⁸

Thus, both Garrison and the '739 patent describe a “tissue valve” as a valve means, and the '739 patent explains as background that “most tissue valves” are made of either “pig aortic valves” or “the pericardial sac.” *Id.*; Ex. 1005, 5:42–46. Additionally, there is no dispute between the parties that “fixed” tissue is tissue that has been chemically treated to eliminate antigenicity and was well known in the art. *See, e.g.*, Tr. 30:17–24 (Patent Owner stating that “all natural valves are chemically fixed,” that “[t]hey have to be to alleviate antigenicity,” and that “[t]his is something that has been known for decades”); Ex. 1001, 3:33–35 (explaining in the context of natural valves from cadavers that the valve is “typically fixed in glutaraldehyde to eliminate antigenicity”), 5:23–25 (stating “[t]he endovascular stented-valve, in a preferred embodiment, is a glutaraldehyde fixed mammal pericardium”); Ex. 1002 ¶ 87 (Dr. Drasler explaining that “person of ordinary skill in the art would have found it advantageous to have used “a natural tissue valve constructed from chemically treated (aka ‘fixed’) pericardial tissue in implementing Garrison’s cardiac valve to alleviate antigenicity and thus reduce the risk of an adverse immune response”).

⁸ We note that the '739 patent further states that it solves the problem of the pericardium being thin, slippery, and difficult to suture “through a process that includes drying and compressing the pericardium using photo-mechanical compression in such a way that makes it possible to handle and fold the material more easily.” Ex. 1001, 3:49–54. The Challenged Claims, however, only recite a valve made of “fixed pericardial tissue,” and do not recite any feature tied to the purportedly novel process described in the '739 patent of “drying and compressing” the tissue.

Petitioner has shown by a preponderance of the evidence that the use of fixed pericardial tissue to construct the “tissue valve” taught by Garrison was well known and within the common knowledge of a person of ordinary skill in the art prior to the priority date of the ’739 patent. First, the “Description of Related Art” in the ’739 patent discussed above reflects the general knowledge of a person of ordinary skill in the art that “fixed pericardial tissue” was a common, well-known material for use in a tissue valve. *See Qualcomm Inc. v. Apple Inc.*, 24 F.4th 1367, 1376 (Fed. Cir. 2022) (holding that applicant admitted prior art may not be the basis of a ground of unpatentability in an *inter partes* review, but may be used in an *inter partes* review in a similar way “[a]s a patentee’s admission about the scope and content of the prior art [to] provide a factual foundation as what a skilled artisan would have known at the time of invention”). Second, we credit the testimony of Dr. Drasler in this regard, who provides additional evidence showing that the use of pericardial tissue in tissue valves was well known, and further explains as follows:

[T]he ’739 patent concedes the use of fixed pericardial tissue was well-known general knowledge for a person of ordinary skill in the art, stating that “[m]ost tissue valves are constructed...by constructing valve leaflets from the pericardial sac of cows or pigs and sewing them to a stent. The porcine or bovine tissue is chemically treated to alleviate any antigenicity.” [Ex. 1001], 3:41–56; [Ex. 1009], 3:38–48 (“If the valve portion 12 is formed of a natural tissue material, such as an animal heart valve, a venous valve, or a composite valve manufactured of natural tissue, the valve should be chemically fixed, such as in a suitable solution of glutaraldehyde in a closed condition (as is known in the art)...), 7:4–7 (“natural tissue pericardium”); [Ex. 1021], 4:35–45 (“Most tissue valves are constructed by sewing the leaflets of pig aortic valves to a stent (to hold the leaflets in proper position), or by constructing valve leaflets from the pericardial sac (which surrounds the heart) of

cows or pigs and sewing them to a stent....The porcine or bovine tissue is chemically treated to alleviate any antigenicity (i.e., to reduce the risk that the patient's body will reject the foreign tissue).”), 25:39–46; Ex. 1021, 1:28–39.

Ex. 1002 ¶ 86 (some alterations in original). In sum, although not expressly stated in Garrison, Petitioner has shown that a person of ordinary skill in the art would have known from general knowledge of the use of fixed pericardial tissue in forming a tissue valve, as taught by Garrison. Pet. 38–39 (citing Ex. 1002 ¶¶ 100–106; *see also id.* ¶ 86 (discussing references that teach the well-known use of natural tissue that is chemically fixed to alleviate antigenicity); *see also Fleming v. Cirrus Design Corp.*, No. 2021-1561, 2022 WL 710549, at *6 (Fed. Cir. March 10, 2022) (stating that “it is appropriate to consider the knowledge, creativity, and common sense of a skilled artisan in an obviousness determination,” so long as these considerations are not used “as a wholesale substitute for reasoned analysis and evidentiary support”) (internal quotations and citations omitted).

Patent Owner does not dispute that Garrison teaches a valve means with the features recited in claim 1, aside from the use of pericardial tissue. *See generally* Resp. Patent Owner also does not dispute that the use of fixed pericardial tissue in the construction of a valve means was well known in the art to a person of ordinary skill.⁹ *Id.* Because Petitioner's arguments are supported by the cited evidence of record, which we adopt as our own findings, we are persuaded that a preponderance of the evidence shows that

⁹ We address Patent Owner's arguments directed to whether a person of ordinary skill in the art would have had reason to use fixed pericardial tissue below in our discussion of reasons supporting obviousness over Garrison (*see infra* Section II.E.7). *See* Resp. 21–25.

Garrison, in light of the knowledge of a person of ordinary skill in the art, teaches a “valve means” as required by claim 1.

a delivery system including a pusher member and a moveable sheath, the pusher member including a guidewire lumen, wherein the pusher member is disposed within a lumen of the moveable sheath, wherein the prosthetic heart valve 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, wherein a distal end of the prosthetic heart valve is located at a distal end of the moveable sheath, and

Garrison teaches delivery catheter 4A (corresponding to a “delivery system”), as shown by Petitioner in a colorized and annotated version of Figure 14 of Garrison, reproduced below:

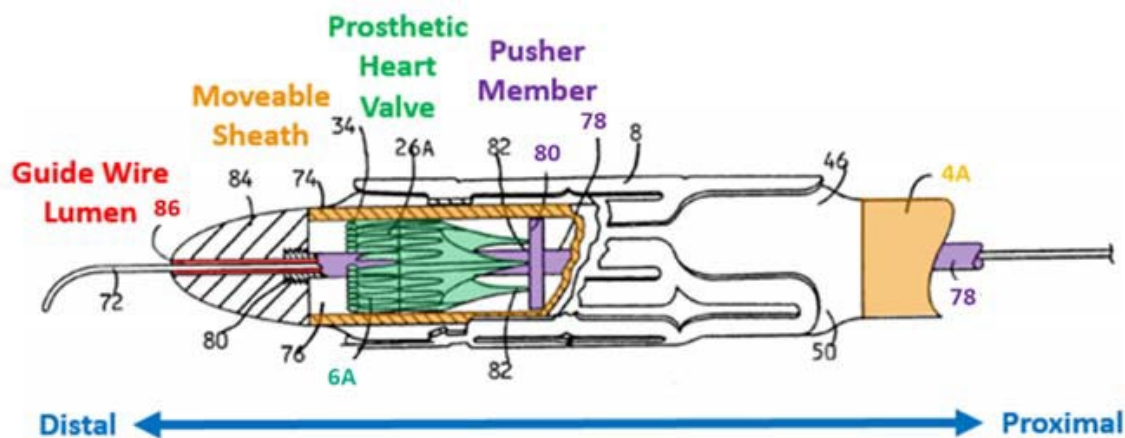


FIG. 14

Pet. 39–42; Ex. 1005, Fig. 14. As further shown by Petitioner and illustrated in Figure 14, Garrison teaches that delivery catheter 4A includes rod 78 with pusher element 80 (together, corresponding to the “pusher member” (shown in purple)), outer wall 74 of delivery catheter 4A (corresponding to the “moveable sheath” (shown in yellow)), and guidewire lumen 86 (corresponding to the “guidewire lumen” (shown in red)). Pet. 39–42; Ex. 1002 ¶ 110; Ex. 1005, 6:57–59, 7:29–33, 8:24–44, 8:53–58, 8:65–9:1,

9:51–53. As can be seen from Figure 14, rod 78 and pusher element 80 are disposed within a lumen of moveable outer wall 74 of delivery catheter 4A. As further shown in Figure 14, Garrison teaches cardiac valve 6A (corresponding to a “prosthetic heart valve” (shown in green)) collapsed onto rod 78 and pusher element 80 and restrained in a collapsed configuration by outer wall 74 of delivery catheter 4A. Pet. 41–42; Ex. 1002 ¶¶ 113–114; Ex. 1005, code (57), 8:24–44, Fig. 14. Patent Owner does not dispute that cardiac valve 6A is “collapsed onto” a pusher member (rod 78 and pusher member 80) “to reside in a collapsed configuration on the pusher member,” as required by claim 1. *See generally* Resp. Petitioner further shows that in Figure 14 “the distal end of the valve is located at the distal end of the moveable sheath in the loaded configuration, wherein distal refers to the direction away from the user.” Pet. 41; Ex. 1002 ¶¶ 113–114.

Patent Owner does not dispute that Garrison teaches a delivery system with the features recited in claim 1.¹⁰ *See generally* Resp. Because Petitioner’s arguments are supported by the cited evidence of record, which we adopt as our own findings, we are persuaded that a preponderance of the evidence shows that Garrison teaches a “delivery system” as required by claim 1.

¹⁰ We address Patent Owner’s arguments directed to how a person of ordinary skill in the art would have used Garrison’s delivery system in our discussion of reasons supporting obviousness over Garrison (*see infra* Section II.E.7). *See* Resp. 17–21, 33–36.

wherein the valve means resides entirely within the inner channel of the stent member in said collapsed configuration and is configured to continue to reside entirely within the inner channel of the stent member upon deployment in the patient.

Garrison teaches, as shown by Petitioner, that valve portion 38 (corresponding to the “valve means”) resides within the inner channel of support structure 26, both when the valve portion is collapsed and after it is deployed. Pet. 42–43 (citing Ex. 1002 ¶¶ 116–119; Ex. 1005, 3:53–56, 5:42–50, 8:3–4, 8:45–47; Figs. 9–11, 14). Patent Owner does not dispute Petitioner’s contentions in this regard. *See generally* Resp.

3. Differences Between the Subject Matter of Dependent Claim 2 and Garrison

Claim 2 further recites that “the stent member is self-expanding.” Ex. 1001, 14:29–30. Petitioner shows, and Patent Owner does not dispute, that Garrison teaches a self-expanding support structure, corresponding to the recited “stent member.” Pet. 44 (citing Ex. 1002 ¶¶ 120–122; Ex. 1005, 5:19–21, 8:13–22, 8:45–47); *see generally* Resp. Specifically, Garrison teaches that cardiac valve 6A, with support structure 26A, is “self-expanding.” Ex. 1005, 8:13–16. Based on the cited evidence of record, which we adopt as our own findings, Petitioner has shown that Garrison teaches the additional limitations of claim 2.

4. Differences Between the Subject Matter of Dependent Claim 3 and Garrison

Claim 3 requires that “the stent member comprises nitinol.” Ex. 1001, 14:31–32. Petitioner shows, and Patent Owner does not dispute, that Garrison teaches support structure 26A, corresponding to the recited “stent member,” may be made of nitinol. Pet. 44 (citing Ex. 1005, 8:16–21; Ex. 1002 ¶¶ 123, 124); *see generally* Resp. Specifically, Garrison states

“support structure 26A may be made of any suitable material and preferred materials are stainless steel or shape-memory alloys such as nitinol.”

Ex. 1005, 8:18–21. Based on the cited evidence of record, which we adopt as our own findings, Petitioner has shown that Garrison teaches the additional limitations of claim 3.

5. Differences Between the Subject Matter of Dependent Claim 4 and Garrison

Claim 4 recites that “the stent member includes two circles of barbs on an outer surface of the stent member.” Ex. 1001, 14:34–36. As shown by Petitioner, Garrison states that “[as] will be described below, the support structure 26 may also have barbs to secure the cardiac valve 6 to the valve displacer 8 or to the blood vessel wall.” Pet. 45; Ex. 1005, 5:36–39.

Garrison then states further below as follows: “The cardiac valve 6C is similar to the cardiac valves 6[,] 6A except that the cardiac valve 6C has barbs 100 which extend outwardly from the cardiac valve 6C in the expanded condition of FIG. 30,” and “[t]he barbs 100 secure the cardiac valve 6C to the valve displacer 8 or directly to the vessel wall.” Ex. 1005, 9:64–10:1, 12:64–67. Figures 29 and 30 of Garrison illustrate cardiac valve 6C with barbs 100 arranged as two circles on an outer surface of a stent member. *Id.* at 9:58–10:9, Figs. 29, 30. Based on the cited evidence of record, which we adopt as our own findings, Petitioner has shown, and Patent Owner does not dispute, that Garrison teaches the additional limitations of claim 4. *See generally* Resp.

6. Differences Between the Subject Matter of Dependent Claim 5 and Garrison

Claim 5 recites that “the pusher member includes a controlled release mechanism.” Ex. 1001, 14:37–38. The only discussion in the Specification

of the '739 patent related to a controlled release mechanism outside of claim 5 states as follows:

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 11:48–62.

Garrison teaches, as shown by Petitioner, that rod 78 with pusher element 80 (together, corresponding to the “pusher member”) of delivery catheter 4A includes a mechanism to control the release of the replacement heart valve (corresponding to a “controlled release mechanism”) in accordance with the description of such a mechanism in the '739 patent Specification. Pet. 46–47 (citing Ex. 1002 ¶¶ 129–131; Ex. 1005, 8:25–44, 8:48–64). Specifically, Garrison states as follows:

The valve 6A preferably remains coupled to the catheter 4A while the protrusions 34 are exposed for manipulation of the valve 6A until the valve 6A engages the valve displacer 8. After the valve 6A has engaged the valve displacer 8, the rod 78 is then advanced far enough to completely release the cardiac valve 6A. Ex. 1005, 8:58–64. Because it is supported by this express disclosure in Garrison, we find persuasive Dr. Drasler's explanation that in Garrison “the rod and pusher element have a controlled release mechanism that is activated by distally moving the rod/pusher element to partially deploy the

valve,” whereby “a portion of the valve remains collapsed on the rod inside the catheter and the valve remains coupled to the catheter,” until the valve is completely released by “pushing the valve out further.” Ex. 1002 ¶ 131 (citing Ex. 1005, 8:51–64).

Patent Owner argues that “Garrison does not teach a [person of ordinary skill in the art] how to make a working mechanism that can be activated for controlled release.” Resp. 33–36 (citing, e.g., Ex. 2019 ¶ 151). Garrison, however, is presumed enabled and Patent Owner has made no showing to overcome that presumption. *See Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1355 (Fed. Cir. 2003). Patent Owner also argues that Petitioner “provides no explanation as to how its purported integrated embodiment from Garrison would function with Garrison’s separate Figure 14 embodiment.” *Id.* at 34. As discussed above, Petitioner does not rely only on an “integrated embodiment.” *See supra* Section II.E.1. Moreover, Patent Owner does not identify what “function” Petitioner must explain that turns on whether the displacer and valve are integrated or not. Garrison makes clear that the valve “remains coupled” to the delivery catheter, which is the only way any valve (whether “integrated” or not) could be delivered to a desired location. The mechanism by which the ’739 patent indicates a controlled release is achieved is identical to the mechanism taught by Garrison, and requires no more than a valve that is restrained by a catheter until a pusher member is activated to release the valve at a desired location. *See* Ex. 1001, 11:48–62; Ex. 1005, 8:58–64.

Patent Owner further argues that “Garrison’s Figure 14 embodiment includes a self-expandable valve device 6A, but describes no mechanism for keeping the valve device from popping out during delivery.” Resp. 34. Patent Owner’s argument is contrary to the express disclosure of Garrison,

as well as the '739 patent, which both rely on the same mechanism of controlled release, as explained above. Relatedly, Patent Owner's argument that a friction fit "does not meet the definition of 'controlled release' that Petitioner's expert applied," is likewise unpersuasive because Patent Owner mischaracterizes Dr. Drasler's testimony, as explained above. *See supra* Section II.C.3. We further credit the reply testimony of Dr. Drasler in this regard, in which he states as follows:

As I explained during my deposition, "there is a[] frictional force between the stent and the outer sheath that's holding it" similar to the preferred embodiment of the '739 itself. [Ex. 2020,] 85:21–86:22. The '739 itself does not disclose any mechanism for a controlled release beyond a frictional force between the stent and outer sheath that would hold the valve in. *See, e.g.,* [Ex. 1001,] 11:51–59, Fig. 8. Patent Owner mischaracterizes my testimony on this point by claiming that my purported definition of "controlled release" . . . is not met by Garrison. But, in my testimony that Patent Owner purports to provide the definitional language I use for "controlled release mechanism," Patent Owner omits my explanation that the "frictional aspect" of Garrison provides the controlled release of the valve from the sheath, "so that it doesn't just arbitrarily pop out." [Ex. 2020,] 87:14–18.

Ex. 1041 ¶ 42 (first alteration in original). We have considered the testimony of Dr. Dasi in this regard and find it unsupported and, therefore, not persuasive. Ex. 2019 ¶¶ 153–157. The thrust of Dr. Dasi's opinion suggests claim 5 of the '739 patent requires some mechanism beyond friction to control release that is neither described in the '739 patent nor required by the broad scope of claim 5. For example, according to Dr. Dasi "[b]ecause Garrison lacks any attachment mechanism between the valve device and the delivery system, a person of skill would have understood that friction is the only force keeping the valve device inside the catheter." *Id.* ¶ 157. Claim 5, however, does not require an "attachment mechanism," and

does not preclude friction between components from being the mechanism that provides for controlled release, just as the '739 patent, itself, suggests. Tellingly, Dr. Dasi does not explain what he thinks the recited “controlled release mechanism” requires that is not taught by Garrison, but instead merely repeats Patent Owner’s assertion that Garrison doesn’t meet the definition that “Petitioner’s expert applied,” which is an assertion we reject as explained above (*see supra* Section II.C.3). *Id.*

Next, Patent Owner faults the design of Garrison, arguing that Garrison’s stent includes posts that would buckle under pressure from the pusher member, causing the stent to “pop out of the catheter more uncontrollably and unpredictably.” Resp. 35–36 (citing Ex. 2019 ¶ 158). Patent Owner’s argument relies on Dr. Dasi’s opinion, which we find not reliable because it is unsupported, conclusory, and contrary to the disclosure of Garrison. As Petitioner explains, “Figure 14 depicts ‘system 2A for implanting...valve 6A,’ which ‘is self-expanding’—demonstrating it works with self-expanding valves.” Reply 14 (citing Pet. 39–40; Ex. 1005, 8:10–23; Ex. 1041 ¶ 43) (alteration in original).

Lastly, Patent Owner argues that Figure 14 of Garrison is described as being used only “with valve displacers that are balloon expandable,” and that a person of ordinary skill in the art would have understood “that an integrated balloon-expandable device would not have the ability to have controlled release.” Resp. 36 (citing Ex. 2019 ¶ 135). As explained in detail by Dr. Drasler, Patent Owner’s argument is not supported by Garrison. We find persuasive, and credit Dr. Drasler’s testimony over Dr. Dasi, because Dr. Drasler’s testimony is supported by Garrison as follows:

Garrison teaches that both valves and displacers may be “self-expanding” as discussed above in Section IV.B.1. Garrison 2:3–

5, 2:14–16. Moreover, “[r]eferring to FIGS. 13 and 14,” Garrison explains that the “cardiac valve 6A is self-expanding and, therefore, does not require an independent expansion mechanism,” and that for “expanding the valve displacer 8” the “expandable member 46 ... is *preferably* the balloon 50.” Garrison 8:14-22. Nowhere does Garrison limit the Figure 14 embodiment” to “valve displacers that are balloon expandable.” Notably, Garrison concludes by acknowledging that “[a]lthough the foregoing invention has been described by way of illustration and example of preferred embodiments changes and modifications to the preferred embodiments may be incorporated without departing from the scope of the invention. For example, ... the expansion mechanism may be a mechanical mechanism rather than a balloon.” Garrison 11:35-44. Thus, the delivery mechanism of deploying the valve displacer and the valve (in the two-component system) or the integrated valve displacer/valve from a sheath as taught in Figure 14 would apply to the self-expanding embodiments taught in Garrison. There is simply no basis for Patent Owner’s and Dr. Dasi’s incorrect assertion that displacers would need to be balloon-expanded, or that the exemplary embodiments in Garrison would be limited to displacers that are balloon-expanded. The displacer of Garrison is described in Figs. 17, 18, and 21 as being self-expanding. Garrison, 8:65–9:5.

Ex. 1041 ¶ 44 (alterations in original). Based on the cited evidence of record, which we adopt as our own findings, Petitioner has shown that Garrison teaches the additional limitations of claim 5.

7. Reasons Supporting Obviousness Over Garrison

As a preliminary matter, Petitioner shows that both the ’739 patent and Garrison are in the same field, “percutaneously, transluminally implantable cardiac prosthetic devices,” and that Garrison is “reasonably pertinent to the alleged problem(s) identified in the ’739 patent of transluminally implanting heart prosthesis.” Pet. 32 (citing, e.g., Ex. 1001, code (57); Ex. 1002 ¶ 85; Ex. 1005, code (57)); *see also id.* at 76 (asserting that “Garrison is analogous art”). In light of the record evidence cited by

Petitioner, we agree, and Patent Owner does not dispute, that Garrison is analogous art to the '739 patent. *See generally* Resp. We also find that, to the extent the system shown in Figures 13–15 of Garrison is considered a separate embodiment from the system shown in Figures 1–12 of Garrison, Petitioner shows a person of ordinary skill in the art would have had sufficient reason to combine those teachings, namely because Garrison explains both embodiments illustrate systems with “the same or similar reference numbers” that “refer to the same or similar structures.” Pet. 33; Ex. 1005, 8:13–16; *see also* Ex. 1002 ¶ 74 (Dr. Drasler explaining that “Garrison Figures 10–11 are equally applicable to self-expanding support structure 26A in cardiac valve 6A (citing Ex. 1005, 8:10–16, 8:45–47)).

We find for the reasons provided below that Petitioner has shown by a preponderance of the evidence persuasive reasons the subject matter of the Challenged Claims, as a whole, was taught or suggested by Garrison in light of the knowledge of a person of ordinary skill in the art. We further find that, to the extent a feature of Garrison relied upon by Petitioner would have required modification to correspond to a feature of a Challenged Claim, Petitioner has shown by a preponderance of the evidence a person of ordinary skill not only could have made the modification, but would have had reason to do so. We focus our discussion below on the issues in dispute, addressing in particular the limitations regarding a “trumpet-like configuration,” “fixed pericardial tissue,” and a “delivery system.”

a. “trumpet-like configuration” (claim 1)

Garrison teaches a “stent member” (support structure 26A of cardiac valve 6A) with a “trumpet-like configuration” (the trumpet-like configuration feature of Garrison’s valve displacer that Garrison states “may also form part of any of the cardiac valves,” which includes valve 6A with

stent member 26A). *See supra* Section II.E.2. Thus, Garrison requires no “modification,” as it teaches all required features of the recited “stent member.” To the extent a reason is needed for why a person of ordinary skill in the art would have applied the trumpet-like configuration of the valve displacer of Garrison to support structure 26A of Garrison, Garrison expressly teaches that any feature of the valve displacer may also form part of the cardiac valve. *See* Pet. 28–30 (arguing that a person of ordinary skill in the art “would have understood Garrison to disclose, or at minimum it would have been obvious to implement, a support structure 26A with flared ends . . . to achieve the advantageous and predictable result of ensuring the valve device conforms to the valve displacer or directly to the vessel wall”) (citing Ex. 1002 ¶¶ 76–79); Reply 5. Petitioner also shows a person of ordinary skill would have had a reasonable expectation of success in this regard because the use of stents with a trumpet-like configuration was well known in the art. Pet. 29–30 (citing Ex. 1002 ¶ 78; Ex. 1006, 5:45–48, 6:17–22, 10:53–64, Fig. 2; Ex. 1009, 2:5–15, 3:36–4:8, 8:14–43, Fig. 2; Ex. 1010, 10:7–17, 10:25–29, Fig. 8; Ex. 1012, 9:7–9, 9:19–21, Figs. 3a, 3b).

Petitioner’s reasoning applies whether the valve displacer and valve are separate components or are integrated, and regardless of whether the native valve remains, or is removed (where, in the latter case, the valve must conform to the vessel wall in the absence of a valve displacer). We find persuasive Dr. Drasler’s testimony, supported by evidence of record, that “a person of skill in the art would have understood a flared shape to work as expected, because that flared shape with a valve entirely inside was well-known as enabling the device to better engage the surrounding structure with a similar shape (e.g., the valve displacer and/or the vasculature) and prevent

movement of the device.” Ex. 1002 ¶ 78 (discussing Exs. 1006, 1009, 1010, 1012).

Patent Owner’s arguments in opposition are not persuasive. Resp. 26–33. First, Patent Owner argues that Petitioner’s rationale relies on modifying a valve to have the trumpet-like configuration of a separate valve displacer, and that Dr. Drasler “disclaimed any reliance on Garrison’s two-component embodiment using a valve displacer.” *Id.* at 26. We reject Patent Owner’s argument for the reasons provided above. *See supra* Section II.E.1. Additionally, as explained above, Petitioner’s rationale does not require a valve displacer separate from the valve, nor is Garrison’s teaching of a trumpet-like configuration limited to a valve displacer separate from the valve. *See* Pet. 35–36; Ex. 1005, 4:46–57.

Second, Patent Owner argues that a person of ordinary skill in the art “would not have wanted to use a valve device that modified Garrison’s stent into a flared shape,” because that person “would have expected a flared Garrison valve device to perform worse than the non-flared version that Garrison teaches.” Resp. 26–29 (citing, e.g., Ex. 2019 ¶ 132). Patent Owner’s argument is not persuasive because it disregards that Garrison itself expressly teaches applying the flared, trumpet-like configuration of the valve displacer to the support structure of its valve, as explained above. *See* Pet. 35–36; Ex. 1005, 4:46–57. Moreover, Patent Owner’s argument relies only on the opinion of Dr. Dasi, which is unsupported and speculative. Ex. 2019 ¶ 64. The notion that a flared stent is more likely to leak is supported by no more than Dr. Dasi stating that the wires of the stent would be “further apart . . . giving more space between the stent’s winding’s for blood to leak through.” *Id.* Dr. Dasi does not state more blood would necessarily leak through, does not explain why “more space” equates to

greater blood leakage, and does not support his statements with any evidence. We find more persuasive in this regard Dr. Drasler’s testimony in reply, who explains that “[a] stent—by its nature—is not water-tight; it is the valve attached to the stent, for example, that would or would not leak, and there is nothing inherent about a flared stent that causes leakage,” and further notes that “the valve-device seals at the valve base.” Ex. 1041 ¶ 33. Further, Dr. Drasler shows that “Garrison expressly provides the preferred number of windings (‘12–18’) that would give a person of ordinary skill in the art sufficient guidance as to ensure the valve (including its support structure) is not leaky.” *Id.*; *see also* Ex. 1005, 5:21–25 (describing the support structure with two elongate members that are wound to form “preferably 12–18 windings”).

Third, Patent Owner argues the references Petitioner relies on to show that a stent member with a trumpet-like configuration was well known in the art do not contain “a stent that, like Garrison, is made from wire that is ‘wound to form windings . . . around the circumference of the valve.’” Resp. 29 (citing Ex. 1005, 5:22–26, Fig. 10) (alteration in original). According to Patent Owner, “none of these references teaches a [person of ordinary skill in the art] how to successfully implement a flared structure in Garrison, where adding a flared shape to Garrison’s winding conformation would result in the bends of the wire being too far apart, resulting in an excessive amount of space for blood to leak through.” *Id.* (citing Ex. 2019 ¶ 137). Patent Owner suggests that the proposed modification is motivated by hindsight. *Id.* We disagree.

The other references discussed by Dr. Drasler reflect that a person of ordinary skill in the art would have had reason to have known that the support structure of the valve of Garrison may include the “trumpet-like”

configuration feature of Garrison's valve displacer because valves with a trumpet-like configuration were well known in the art. Patent Owner disregards again Garrison's express teaching both of a trumpet-like configuration for a valve displacer, and that any feature of the valve displacer may be applied to the support structure, which refute the notion that the proposed modification is improper hindsight. Further, as explained above, Petitioner has not shown support for the notion that flaring the support member of Garrison would result in "an excessive amount of space for blood to leak through," making Patent Owner's premise that "Garrison's winding conformation would result in the bends of the wire being too far apart," unsupported and not persuasive.

Fourth, Patent Owner argues that Garrison fails to disclose "any method to ensure alignment" between a flared device and the native leaflets. Resp. 30. Patent Owner further argues that "Petitioner provides no allegations regarding how a [person of ordinary skill in the art] would successfully implement a flared stent in Garrison," and proceeds to argue that a person of ordinary skill in the art "would not have been motivated to use a flared version of Garrison's displacer (or integrated device)" for various reasons. *Id.* at 29–33. For example, Patent Owner contends that flaring the ends of the support structure of Garrison's valve "would cause significant increased loads on the commissural attachment points, as well as increased deflections of the posts during each heartbeat." *Id.* at 30–31 (further asserting that Dr. Drasler's opinion "should be entitled to little, if any weight," because he purportedly "did not consider how the prior art combinations he utilizes in his analysis would impact the durability of his proposed valve").

Patent Owner’s arguments attacking Garrison are insufficiently supported and fail to overcome the presumption that Garrison is enabled. As Dr. Drasler explains, Garrison expressly teaches implanting the valve displacer into the aortic valve. Ex. 1041 ¶ 38 (citing Ex. 1005, 2:16–22); *see also id.* (further noting that the ’739 patent “does not provide disclosure regarding alignment”). We also find persuasive Dr. Drasler’s testimony that “the repeated disclosures in the art of stents with this very shape [(i.e., a trumpet-like configuration)] further confirm that a person of ordinary skill in the art would have understood that such an arrangement would indeed work.” *Id.*

Moreover, Patent Owner again disregards the express teachings of Garrison and that neither Petitioner nor Dr. Drasler relies on a modification of Garrison that Garrison does not, itself, teach. In this regard, we agree with Petitioner’s argument in its Reply, which states as follows:

[D]espite Garrison’s teachings of flared valve-devices and flared displacer/valve-devices, [Patent Owner] wrongly insinuates a [person of ordinary skill in the art] would not have known how to implement such structures. [Resp.] 10–21. But prior art patents are presumptively enabled and [Patent Owner] must put forward evidence of “nonenablement”—though it does not even attempt to analyze the *Wands* factors. *Amgen Inc. v. Hoechst Marion Roussel*, 314 F.3d 1313, 1355 (Fed. Cir. 2003); *Johns Manville Corp. v. Knauf Insulation, Inc.*, IPR2015-01402, Paper 45, *14–16. Moreover, “as enablement of the prior art is not a requirement to prove invalidity under § 103,” *Amgen*, 314 F.3d at 1357, [Patent Owner]’s conclusory specters of misaligned valves or invasive procedures ([Resp.] 12, 20) are irrelevant.

Reply 6.

We have considered all of Patent Owner’s remaining arguments and find them not persuasive because they are based only on Dr. Dasi’s

unsupported conclusory testimony or are contradicted by the underlying record. *See* Resp. 30–33 (arguing that a person of ordinary skill in the art “would not have been motivated to use a flared version of Garrison’s displacer (or integrated device),” as *expressly* taught by Garrison, because it “would create an unacceptably high risk of coronary artery obstruction,” which Dr. Drasler purportedly did not consider; arguing that “in Garrison’s two-component system, the valve device portion that mates with the flared displacer is not flared, the flaring of the displacer must have no hemodynamic role;” and arguing that a person of ordinary skill in the art “would not have believed that utilizing a flared shape for Garrison’s valve device would outweigh any benefits received from this flared shape”) (citing, e.g., Ex. 2019 ¶¶ 110, 134, 137). In this regard, Patent Owner’s arguments are persuasively addressed at length by Petitioner in its Reply at pages ten to thirteen, which we adopt as our own findings. *See* Reply 10–13. We conclude that Petitioner has shown, for the reasons provided above, that enabling the support structure to advantageously conform to the displacer or the vasculature would have provided a person of ordinary skill in the art sufficient reason and motivation to modify the support structure taught by Garrison to include the “trumpet-like” configuration of Garrison’s valve displacer with a reasonable expectation of success.

b. “fixed pericardial tissue” (claim 1)

Petitioner has shown that a person of ordinary skill in the art would have had reason to make the valve portion of Garrison out of fixed pericardial tissue for the reasons below. Garrison teaches a “valve portion” that “is preferably a stentless tissue valve such as a tri-leaflet [] stentless porcine valve,” but does not expressly describe the use of “fixed pericardial tissue” to make a tissue valve. Ex. 1005, 5:44–46. Petitioner has shown that

the use of fixed pericardial tissue to make a tissue valve was well known in the art, as explained above. *See supra* Section II.E.2. As Dr. Drasler further explains, “the details of forming the tissue valve are left [by Garrison] to the person of ordinary skill in the art.” Ex. 1002 ¶ 86 (citing Ex. 1005, 5:42–50). Dr. Drasler further explains reasons why a person of ordinary skill in the art would have had reason to use fixed pericardial tissue for the valve taught by Garrison, as follows:

A person of ordinary skill in the art would have found it advantageous to apply these teachings of using a natural tissue valve constructed from chemically treated (aka “fixed”) pericardial tissue in implementing Garrison’s cardiac valve to alleviate antigenicity and thus reduce the risk of an adverse immune response to the prosthetic device using one of the most common ways of making a tissue valve and also to advantageously use a construction material that is very strong, with a low profile, and easy to manipulate into the valve’s shape. Indeed, as the ’739 [patent] admits, a fixed pericardial tissue valve was one of the most common ways of forming a valve at the time and a person of ordinary skill in the art would have been motivated to use this easily accessible and common approach to forming a valve. A person of skill in the art would have known that pericardial tissue is strong for its relatively low profile (thickness), and is more easily manipulated (e.g., folded, shaped, etc) than some other available materials. And given its ubiquity in the art and known benefits, a person of ordinary skill in the art would have had a reasonable expectation of success in applying these teachings to Garrison’s valve.

Id. ¶ 87; *see also id.* ¶ 106 (same); Pet. 31–32, 38–39 (discussing the known benefits of the use of fixed pericardial tissue in a valve).

Having considered the full record, we find not persuasive Patent Owner’s numerous arguments in opposition to Petitioner’s reasons supporting the use of fixed pericardial tissue for Garrison’s expressly disclosed “tissue valve.” *See* Resp. 21–25; Sur-reply 4–12. A common

theme among Patent Owner's arguments is to disregard what Garrison expressly discloses and to mischaracterize Petitioner's contentions as requiring the replacement of one element (Garrison's "tissue valve") with a purportedly entirely different element (a "tissue valve" made of fixed pericardial tissue, as was well known in the art) purportedly without reason. *See id.* Garrison, however, expressly states, for example, in its Abstract that it addresses a "valve implantation system" wherein "[t]he valve is a *tissue valve* mounted to an expandable support structure." Ex. 1005, code (57) (emphasis added). Garrison expressly addresses "a tissue valve such as a tri-leaflet [] stentless porcine valve," but does not also expressly address as an example a tissue valve made of "fixed pericardial tissue." However, the '739 patent itself explains as background knowledge that one category of replacement heart valves are "tissue valves," and that "most tissue valves" are made of either "pig aortic valves" or "the pericardial sac of cows or pigs." Ex. 1001, 3:18–20, 3:41–44. Thus, the issue is whether Petitioner has shown a person of ordinary skill in the art would have had a reason to use fixed pericardial tissue for Garrison's tissue valve.

Rather than address straightforward what is at issue, Patent Owner instead argues that the porcine valve of Garrison "already has leaflets attached and so has no need for additional or replacement leaflets;" that a person of ordinary skill in the art "would *not* modify a valve device like Garrison's with functioning leaflets—to replace the existing leaflets with those of another material;" that "Petitioner has not alleged how a person of ordinary skill in the art would make this valve device out of fixed pericardium, especially without adding sutured leaflets to the device;" that "Garrison's valve device already has its own leaflets;" and that there was no motivation "to *remove these existing leaflets* in order to use fixed pericardial

leaflets with Garrison.” Resp. 21–23, 22 n.2 (emphasis omitted from first quote).

We agree with Petitioner that Patent Owner “misconstrues the Grounds as requiring bodily incorporation of pericardial tissue leaflets onto Garrison’s existing leaflets, but the Grounds do not propose adding ‘additional or replacement leaflets’ as [Patent Owner] asserts.” Reply 3 (citing Resp. 21–22). Patent Owner’s arguments suggest that Garrison disclosure is limited to a porcine valve, however, as explained above, Garrison uses a “tissue valve” and identifies a porcine valve only as an example of a “tissue valve.” And Petitioner has shown that a person of ordinary skill in the art “would have been motivated to apply known teachings having known benefits (advantageous construction from fixed pericardial tissue) to implement—not replace—Garrison’s valve.” *Id.* at 3–4 (citing, e.g., Pet. 31, 32, 36, 37; Ex. 1002 ¶¶ 87, 88, 104–106; Ex. 1041 ¶¶ 18–20).

Patent Owner cites *Winner International Royalty Corp. v. Wang*, for the proposition that a finding of “nonobviousness” was supported “where ‘there was no apparent disadvantage’ to the prior art mechanism.” Resp. 23 (quoting 202 F.3d 1340, 1349–50 (Fed. Cir. 2000)); *see also* Sur-reply 5 (arguing that Petitioner fails to identify “disadvantages” of Garrison’s “valve devices which might prompt a [person of ordinary skill in the art] to begin evaluating options and tradeoffs”). In this case the “prior art mechanism” is a “tissue valve” expressly disclosed by Garrison, and Petitioner does not propose replacing the tissue valve of Garrison with anything else. In other words, a “tissue valve” is still a “tissue valve,” whether it is made out of a porcine valve, as identified as an example in Garrison, or out of fixed pericardial tissue, as was well known in the art.

Further, according to Patent Owner, “Petitioner’s allegation would suffer from a lack of motivation to replace a single-piece stentless porcine valve device—and the advantages that come with using such a valve device,” as well as “from the fact that . . . a [person of ordinary skill in the art] would not want to introduce sutured leaflets in a valve device that did not require a suture line.” *Id.* at 22 n.2, 23–24. According to Patent Owner, “suturing leaflets to a valve device introduces a point of weakness into the valve device at the suture line,” a factor Patent Owner alleges Dr. Drasler did not consider that would impact durability. *Id.* at 23–24. Patent Owner further argues that Petitioner “ignores the disadvantages of fixed pericardial tissue,” (i.e., that the ’739 patent describes it as “thin and very slippery,” making it difficult to suture), does not alleged the use of fixed pericardial tissue would have been an improvement, and has not sufficiently addressed all of the “non-trivial considerations” necessary “in order to use leaflets made of fixed pericardial tissue with Garrison.” *Id.* at 24–25 (citing, e.g., Ex. 1001, 3:47–49; Ex. 2019 ¶ 149); Sur-reply 5–12.

We find Patent Owner’s arguments not persuasive for the reasons explained by Petitioner based on the evidence of record. Petitioner notes that “Garrison’s natural valves are also sutured—posing similar risks” to the sutures Patent Owner asserts are required with a fixed pericardial tissue valve. Reply 4 (citing Ex. 1005, 5:46–48; Ex. 1041 ¶ 21). We note, Patent Owner subsequently argues in its Sur-reply that fixed pericardial tissue valves require “additional sutures.” Sur-reply 4. Petitioner, however, explains, and we agree, that the mere existence of tradeoffs “between using natural valves or ones formed of pericardial tissue” does not mean a person of ordinary skill in the art “would not have been motivated to apply the admitted prior art’s teachings in implementing Garrison’s valve.” Reply 4

(citing *Randall Mfg. v. Rea*, 733 F.3d 1355, 1363 (Fed. Cir. 2013); *In re Mouttet*, 686 F.3d 1322, 1330 (Fed. Cir. 2012)).

Lastly, Patent Owner takes issue with Petitioner’s reference to a person of ordinary skill having been motivated to used fixed pericardial tissue for a tissue valve to “achieve properly sized/configured valves.” Sur-reply 11–12 (citing Reply 5). In this regard, Dr. Drasler states as follows in his Reply Declaration:

Indeed, Patent Owner’s and Dr. Dasi’s own exhibits (relied on to show that using pericardial tissue requires sutures that are a point of weakness) acknowledge that using pericardial tissue has advantages. *See, e.g.*, Ex. 2021 (Fisher), 105 (acknowledging that by 1987 “pericardial bioprosthesis has been used clinically for over 13 years with good clinical follow-up results”); Ex. 2022 (Rygg), 2:5–12 (acknowledging that fixed “porcine pericardium . . . have the advantages in common that follow from the application of a heterologous material, viz. that they remain thin and movable, and that no deposits are formed on the them that may get loose and cause thrombi”). This is a significant benefit over trying to find a pig with a native valve of the right size: “[e]verybody would have known that pig valves vary in size, in accordance with the size of the pig.” [Ex. 2020,] 91:21–92:1.

Ex. 1041 ¶ 22. Patent Owner argues that no reference in this proceeding “mentions any advantage over being able to control the size of the valve as opposed to finding a correctly-sized natural pig valve among the roughly 130 million pigs that are sacrificed each year in the U.S. alone,” and that “Petitioner’s new, unsupported argument additionally fails because it improperly attempts to provide a new and previously undisclosed motivation to combine on Reply.” Sur-reply 11–12. Our determination in this case does not rely on the testimony of Dr. Drasler in paragraph 22 of his Reply

Declaration or on Petitioner's reference to the ability to "achieve properly sized/configured valves" as a motivation supporting obviousness.

c. "delivery system" (claim 1)

Petitioner has shown, as explained above, that Garrison teaches delivery catheter 4A that, without modification, includes all features of the "delivery system" recited in claim 1. *See supra* Section II.E.2. Premised on Patent Owner's argument that Dr. Drasler "disclaimed any reliance on Garrison's two-component valve replacement system," Patent Owner argues that Petitioner "provides no explanation for how a [person of ordinary skill in the art] would have used Garrison's" delivery catheter 4A (illustrated in Figure 14) "without a separate valve displacer." Resp. 19. Patent Owner then refers to what it calls Petitioner's "proposed integrated device embodiment" and argues that Petitioner failed to consider "what material" it would be composed of, "how it would function," and whether "the device or delivery system" needed to be modified. *Id.* According to Patent Owner, "the only delivery system that Garrison discloses for an integrated device embodiment is disclosed with respect to Garrison's Figures 31–38, upon which Petitioner's expert has disclaimed any reliance." *Id.* at 19–20 (citing Ex. 2019 ¶¶ 123, 135; Ex. 1005, 10:37–51; Ex. 2020, 76:5–78:4). Patent Owner further argues that Garrison "does not teach a [person of ordinary skill in the art] how to properly align any integrated valve with the native leaflets, rather than to engage the valve displacer" and that "Garrison would not have known how to use Garrison's Figure 14 delivery device with the purported integrated embodiment." *Id.* at 20–21 (citing Ex. 2019 ¶¶ 121–124).

To begin, as explained above, we reject Patent Owner's argument that Dr. Drasler "disclaimed" any reliance on a two-component system, which

renders Patent Owner's argument unpersuasive because it is founded on a faulty premise. The thrust of Patent Owner's argument suggests that Garrison's delivery catheter may only be used with Garrison's teaching of a valve displacer separate from the valve. As explained above, Petitioner has shown that even with this "two-component" system, the required "stent member . . . with a trumpet-like configuration" was taught by Garrison. *See supra* Sections II.E.2 and II.E.7.a. Petitioner has shown that delivery catheter 4A includes all recited features of the recited "delivery system" and may be used with such a "two-component" system. *See supra* Section III.E.2. Moreover, as Petitioner has shown, delivery catheter 4A of Garrison is not limited to a "two-component system." Petitioner explains as follows:

Garrison teaches various delivery mechanisms and materials for valve 6 using "the same or similar reference numbers [to] refer to the same or similar structures" across teachings—including operating "delivery catheter 4A" to deploy valve 6A (a self-expanding valve-device made of, e.g., shape-memory alloys such as nitinol). Pet. 28–31, 39–40; [Ex. 1002] ¶¶107–110; [Ex. 1005] Figs. 13–14, 8:10–34, 8:45–47, 8:65–9:10. Garrison further teaches a self-expanding displacer. [Ex. 1005] 9:2–10; Pet. 29; [Ex. 1002] ¶¶74, 78.

These teachings apply with equal force to Garrison's valve-device and displacer/valve-device. Thus, the integrated displacer/valve-device is delivered the same way as Garrison's self-expanding displacer. Pet. 35; [Ex. 1002] ¶99; [Ex. 1041] ¶31; [Ex. 1005] Figs. 13–14, 4:49–57, 8:10–34, 8:44–47, 8:65–9:10. And the self-expanding, flared valve-device is deployed either into the previously deployed displacer or directly onto the vasculature. Pet. 29–30, 35; [Ex. 1002] ¶¶77, 79, 99; [Ex. 1041] ¶31.

Reply 9. We credit Dr. Drasler's testimony in this regard as it is supported by Garrison.

Dr. Drasler explains as follows:

As explained in the Petition and as I explained in my Declaration, Garrison teaches particular delivery mechanisms and materials for the valve 6 using “the same or similar reference numbers [to] refer to the same or similar structures”—including “delivery catheter 4A” for deploying valve 6A (*i.e.*, a self-expanding valve made of a suitable material, such as “shape-memory alloys such as nitinol,” that is otherwise “similar” to valve 6). Pet. 28–31, 39–40; [Ex. 1002], ¶¶107–110; [Ex. 1005,] Figs. 13–14, 8:10–34, 8:45–47, 8:65–9:10. Garrison further teaches the valve displacer can also be self-expanding. [Ex. 1005,] 9:2–10; Pet. 29; [Ex. 1002] ¶¶74, 78. Garrison further teaches how the delivery catheter operates as extensively described in the Petition. Pet. 30–31, 39–40. These teachings apply with equal force to Garrison’s teachings of integrating the support structure of valve 6 and the valve displacer 8 as well as applying features of the valve displacer to the support structure. Where the valve and valve displacer are integrated, the integrated structure is delivered the same way a valve displacer is using the self-expanding material. Pet. 35; [Ex. 1002] ¶99; [Ex. 1005,] Figs. 13–14, 4:49–57. Specifically, Garrison, describing Figures 13 and 14, explains the “cardiac valve 6A” can be delivered via “catheter 4A” which has “an expandable member for expanding the valve displacer” (*e.g.*, using a balloon). [Ex. 1005,] 8:10–23, Fig. 13, Fig. 14. Garrison further explains that the delivery of the valve is accomplished by “advancing a rod 78 having a pusher element” to “move the cardiac valve 6A out of the chamber” of the catheter. [Ex. 1005,] 8:24–38. Separately, Garrison describes a delivery method using self-expanding valve displacer which “does not require an independent expansion mechanism.” [Ex. 1005,] 8:65–9:10. Where the support structure has the flared shape of the valve displacer and is made of the self-expanding material, it is either deployed into the previously-deployed valve displacer or directly onto the vasculature, *e.g.*, onto the tissues of the native valve. Pet. 29–30, 35; [Ex. 1002] ¶¶77, 79, 99.

Ex. 1041 ¶ 31 (alteration in original). Additionally, Patent Owner fails to provide any sufficient analysis to show that Garrison lacks enablement. *See*

Resp. 21; Reply 6 (arguing that “prior art patents are presumptively enabled and [Patent Owner] must put forward evidence of “nonenablement”—though it does not even attempt to analyze the *Wands* factors”) (citing, e.g., *Amgen Inc. v. Hoechst Marion Roussel*, 314 F.3d 1313, 1355 (Fed. Cir. 2003)). Likewise, Patent Owner’s argument that a [person of ordinary skill in the art] “would not have selected Garrison as a starting point to make a heart valve device as claimed in the ’739 patent” is not persuasive. Resp. 21 (citing Ex. 2019 ¶ 125). Petitioner isn’t required to prove that the reference it relies upon to show obviousness would have been superior to any other reference available at the time of the invention. See *Infineum USA L.P. v. Chevron Oronite Co.*, 844 F. App’x 297, 305 (Fed. Cir. 2021) (explaining that obviousness does not turn on whether a person of ordinary skill in the art would have been motivated to select “to select one prior art disclosure over another”); *In re Mouttet*, 686 F.3d 1322, 1334 (Fed. Cir. 2012) (stating that “just because better alternatives exist in the prior art does not mean that an inferior combination is inapt for obviousness purposes”).

8. *Collective Consideration of the Graham Factors*¹¹

Based upon consideration of the entire record, and for the reasons discussed above, we determine Petitioner has shown by a preponderance of the evidence that Garrison teaches each limitation of the Challenged Claims and has also shown that an ordinarily skilled artisan would have had reason to modify Garrison, and would have had a reasonable expectation of success when doing so. On the whole, we find that the information provided by Petitioner and Patent Owner in consideration of the *Graham* factors

¹¹ The parties did not provide or discuss objective evidence of nonobviousness. See generally Pet.; Resp.

collectively demonstrates that Petitioner has shown by a preponderance of the evidence that the Challenged Claims are unpatentable under 35 U.S.C. § 103(a) as obvious over Garrison.

F. Alleged Obviousness over Garrison and Leonhardt

Petitioner contends the Challenged Claims would have been obvious over Garrison and Leonhardt. Pet. 47–52; Reply 15–18. Petitioner’s contentions are supported by Dr. Drasler. Ex. 1002 ¶¶ 132–150. Patent Owner disputes Petitioner’s contentions.¹² Resp. 37–46.

To the extent Garrison, alone, is insufficient, Leonhardt teaches, as shown by Petitioner, a replacement stent device with biological valve 22 and stent 26, that, when deployed, includes ends of the stent that “flair sufficiently to conform and seal to the tissue,” corresponding to “a stent member . . . that flares at both ends in a trumpet-like configuration.” Pet. 48; Ex. 1006, 6:17–22, Fig. 2. Leonhardt also teaches, as shown by Petitioner, biological valve 22 (corresponding to a “valve means”), which resides entirely within an inner channel of the stent member in both collapsed and deployed configurations. *Id.* at 51 (citing Ex. 1006, 6:23–31, Figs. 2, 4; Ex. 1002 ¶¶ 146–150). Petitioner has shown that Garrison teaches all other limitations of the Challenged Claims for the same reasons discussed above with respect to unpatentability over Garrison, alone. *See supra* Section II.E.2–6.

Patent Owner argues in regard to the required trumpet-like configuration that “Garrison in view of Leonhardt does not meet this limitation,” but Patent Owner’s arguments are directed to whether Petitioner

¹² Patent Owner does not directly address the combination of Leonhardt with Garrison in its Sur-reply. *See generally* Sur-reply.

provides a sufficient reason in support of the combination, and do not dispute that Leonhardt and Garrison, together, teach “a stent member . . . that flares at both ends in a trumpet-like configuration,” as Petitioner contends. Resp. 44–46. Based on the cited evidence of record, which we adopt as our own findings, Petitioner has shown that the combination of Garrison and Leonhardt teaches every limitation of the Challenged Claims. Pet. 47–52.

In support of combining the teachings of Leonhardt and Garrison, Petitioner shows as a preliminary matter that, like Garrison, “Leonhardt is in the same field” as the ’739 patent of “transluminally implanting heart prosthesis,” and is “reasonably pertinent” to the alleged problems identified in the ’739 patent. *Id.* at 32, 47–50 (citing, e.g., Ex. 1002 ¶ 137; Ex. 1006, codes (54), (57), 1:4–16, 2:5–6, 3:15–17, 9:63–67). In light of the record evidence cited by Petitioner, we agree, and Patent Owner does not dispute, that Leonhardt is analogous art to the ’739 patent. *See generally* Resp.

As discussed above, Garrison, itself, provides an express reason for a person of ordinary skill to modify support structure 26A to have a “trumpet-like” configuration, which is because Garrison expressly teaches that any feature of the valve displacer may also form part of the cardiac valve. *See supra* Section II.E.7.a. Leonhardt also provides an express reason to modify Garrison’s support structure to include flared ends with a trumpet-like configuration, as shown by Petitioner: “valve stent 20 . . . will flair sufficiently to conform and seal to the tissue.” Pet. 50–51; Ex. 1006, 6:17–22. We further credit the testimony of Dr. Drasler in this regard, who explains that “a person of ordinary skill in the art would have been motivated to apply Leonhardt’s teaching of a cylindrical stent shape that flares outwardly at both ends of the stent in implementing Garrison’s support

structure to advantageously conform and seal support structure 26A to the valve displacer or surrounding vasculature.” Ex. 1002 ¶ 140 (citing Ex. 1006, 6:20–23). Dr. Drasler further notes that “this flared valve structure was known and its benefits in securing a prosthetic valve to surrounding structure or tissue is discussed in a number of references that were available at the time.” *Id.* (citing Exs. 1009, 1010, 1012); *see also id.* ¶ 78 (citing the same exhibits and discussing how each discloses a flared stent).

Petitioner further reasons, and we agree, that a person of ordinary skill “would have been motivated to apply Leonhardt’s teachings of placing the valve axially and radially inside the stent to Garrison’s support structure 26A such that the valve portion 38 is advantageously protected by the support structure—avoiding valvular damage caused by the valve residing outside the stent’s more protected inner channel and increasing the surface area over which the support structure presses and seals against the valve displacer to better secure the prosthesis.” Pet. 51–52 (citing, e.g., Ex. 1005, 4:15–20; Ex. 1006, 7:10–20; Ex. 1002 ¶ 150).

Patent Owner argues that a person of ordinary skill in the art would not have been motivated to combine Garrison and Leonhardt and would not have reasonably expected this combination to have been successful. Resp. 37–46. In particular, Patent Owner argues that “[b]ecause of the numerous differences between the needs for a replacement heart valve in the aortic position versus in the mitral position, a [person of ordinary skill in the art] would not have been motivated to combine a reference directed at aortic heart valve devices such as Garrison with a reference for mitral heart valve devices such as Leonhardt.” *Id.* at 37 (citing, e.g. Ex. 2019 ¶¶ 31–41, 163–170).

Patent Owner's argument is not persuasive because the premise upon which it is based is contrary to the express teachings of Garrison and Leonhardt. As Petitioner shows, Garrison expressly states that it is not limited to aortic valves ("the method is described in connection with replacing the aortic valve, however, the method may also be applied to other [] cardiac valves such as the mitral, tricuspid and pulmonary valves" (Ex. 1005, 7:10–13)) and Leonhardt expressly states that it is not limited to the mitral heart valve (illustrating "the valve stent fully deployed within the aorta above the aortic valve" and discussing "[i]f the placement sight is in the aorta or aortic valve" (Ex. 1006, 3:59–60, 9:63–67, Fig. 3)). Patent Owner's attempt to avoid the express disclosures of the asserted references by arguing that a person of ordinary skill in the art would have understood both Garrison and Leonhardt "would not, in fact, work" is not persuasive because it is supported by no more than the conclusory testimony of Dr. Dasi. Resp. 43 (citing Ex. 2019 ¶ 164).

Patent Owner further details various purported problems with the stent of Leonhardt if it were bodily incorporated into the prosthetic heart valve of Garrison. *Id.* at 39–44. According to Patent Owner, the asserted combination could "even kill the patient because having the leaflets oriented in the wrong direction would prevent the mitral valve device from regulating blood flow" and "positioning the Leonhardt device . . . in the aortic valve, would lead to an unacceptably high risk for coronary obstruction because the fingers would push the native leaflets toward the coronary ostia." *Id.* "The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference." *In re Keller*, 642 F.2d 413, 425 (CCPA 1981). "Rather, the test is what the combined teachings of the references would have suggested to

those of ordinary skill in the art.” *Id.* To the extent additional explanation is necessary, we adopt as our own determination, based on the cited evidence of record, Petitioner’s discussion in its Reply at pages 15 to 18 as showing that a person of ordinary skill in the art would have been motivated to apply Leonhard’s teaching of a stent member that “includes a tubular structure away from a central portion that flares at both ends in a trumpet-like configuration” and “a valve residing entirely within an inner channel of the stent member” to Garrison.

Patent Owner’s additional arguments duplicate arguments addressed above under this ground or are the same as the arguments it asserts with regard to obviousness over Garrison alone. *See* Resp. 41–46. We find these arguments not persuasive for the same reasons, based on the same evidence, as discussed above. Based upon consideration of the entire record, and for the reasons discussed above, we determine Petitioner has shown by a preponderance of the evidence that Garrison in light of Leonhardt teaches each limitation of the Challenged Claims and has also shown that an ordinarily skilled artisan would have had a reason to modify Garrison in light of Leonhardt, as asserted by Petitioner, and would have had a reasonable expectation of success when doing so. On the whole, we find that the information provided by Petitioner and Patent Owner in consideration of the *Graham* factors collectively demonstrates that Petitioner has shown by a preponderance of the evidence that the Challenged Claims are unpatentable under 35 U.S.C. § 103(a) as obvious over Garrison and Leonhardt.

*G. Alleged Obviousness over Garrison and Nguyen or
Garrison, Leonhardt, and Nguyen*

Petitioner contends the Challenged Claims would have been obvious over Garrison and Nguyen or over Garrison, Leonhardt, and Nguyen. Pet. 77–78; Reply 18–19. Petitioner’s contentions are supported by Dr. Drasler. Ex. 1002 ¶¶ 151–153. Patent Owner disputes Petitioner’s contentions. Resp. 46–48; Sur-reply 9–11.

To the extent Garrison, alone, is insufficient, Nguyen is directed to “methods for selecting leaflets for use in a prosthetic heart valve” and teaches, as shown by Petitioner, the use of “leaflets made of fixed pericardial tissue,” corresponding to the requirement of claim 1 that the “valve means” are “made of fixed pericardial tissue.” Pet. 77 (citing Ex. 1020, 1:28–39); *see also* Ex. 1020, 1:5–9 (addressing the “Field of the Invention”). Petitioner further reasons that a person of ordinary skill “would have been motivated to apply Nguyen’s teachings of leaflets made of fixed pericardial tissue to Garrison’s leaflets . . . to advantageously improve durability using a material well-known to be suited for replacement heart valves.” *Id.* (citing Ex. 1020, 1:28–39, 1:51–54; Ex. 1002 ¶ 153).

Patent Owner argues that “Nguyen teaches nothing about a valve device with leaflets made of fixed pericardial tissue.” Resp. 47. Patent Owner’s argument is unsupported and contrary to Nguyen, which states that “[t]he present invention relates to methods for selecting *leaflets* for use in a *prosthetic heart valve*, and, more particularly, to methods and apparatuses for selecting individual *pericardial leaflets* for a *multi-leaflet heart valve* prothesis.” Ex. 1020, 1:5–9 (emphases added). Patent Owner then proceeds to quote a portion of Nguyen that discusses harvesting pericardium and chemically fixing the tissue to “increase the tissue durability” before the

tissue is “cut into leaflets.” Resp. 47 (quoting Ex. 1020, 1:28–39). Patent Owner argues, and we agree, that the increase in “durability” described in Nguyen applies to “the durability of the fixed pericardium as opposed to unfixed pericardium.” *Id.*; *see also* Ex. 2019 ¶ 190 (Dr. Dasi explaining that “[o]ne of skill would understand that Nguyen’s disclosure of chemically fixing the pericardium ‘to increase the tissue durability’ is a statement about increasing the durability of the fixed pericardium as opposed to unfixed pericardium”). From this, Patent Owner argues that Petitioner has not shown that leaflets made of fixed pericardial tissue were known to be more durable than the porcine valve of Garrison, and, therefore, purportedly fails to provide a person of ordinary skill in the art “with motivation to modify a valve device like Garrison’s—that already has leaflets attached—by replacing existing leaflets of Garrison’s valve device with fixed pericardium leaflets.” *Id.* at 48 (citing Ex. 2019 ¶¶ 265–271). Patent Owner also argues that the use of fixed pericardial tissue would have required additional sutures and “there are very real safety-related reasons” a person of ordinary skill in the art “would not choose to alter” the valve of Garrison. Sur-reply 10–11.

Patent Owner’s argument is not persuasive. Petitioner relies on the teachings of Nguyen in combination with Garrison to provide additional express support to show a person of ordinary skill in the art would have known to implement the “tissue valve” of Garrison with fixed pericardial tissue, as required by claim 1. Pet. 77–78; Reply 18–19; *see also* Ex. 1005, code (57), 5:42–46 (stating that “[t]he valve is a tissue valve mounted to an expandable support structure,” and providing as an example, “such as a tri-leaflet [] porcine valve”). Thus the issue is not whether a person of ordinary skill would have had reason to remove and replace Garrison’s porcine valve with a valve made of fixed pericardial tissue, as taught by Nguyen, because

Garrison teaches the use of a tissue valve, and, as Dr. Drasler explains, Garrison leaves “the details of forming the tissue valve . . . to the person of ordinary skill in the art.” Ex. 1002 ¶ 86. Dr. Dasi’s statement testimony that “a person of skill would not modify a valve like that in Garrison—that already has leaflets attached—to replace the existing leaflets with those of another material,” is directed to the wrong issue and disregards Garrison’s express teaching that use of a porcine valve was only one example of a material that could be used. *See* Ex. 2019 ¶ 191; *see also id.* ¶¶ 192–193 (opining that Petitioner fails to allege a person of ordinary skill would have been “motivated to remove the already-existing leaflets from Garrison’s tri-leaflet stentless porcine valve, and replace those already-existing leaflets by suturing fixed pericardial leaflets to Garrison’s tri-leaflet stentless porcine valve” (emphasis omitted)). *See Keller*, 642 F.2d at 425.

Garrison and Nguyen, together, suggest the use of fixed pericardial tissue to form a valve in a replacement heart valve. The only recited feature of a valve in claim 1 not expressly disclosed by Garrison is that the valve be “made of fixed pericardial tissue.” Patent Owner concedes that “Nguyen simply discloses that pericardium is fixed to make it more durable than it would be without fixation.” Sur-reply 9 (emphasis omitted). Garrison, however, does not expressly disclose the use of “fixed” tissue, and Patent Owner’s arguments suggest that a person of ordinary skill in the art would have understood from Nguyen that fixed tissue is more durable and would have had reason to apply that teaching to the valve material of Garrison. For the reasons provided above, we find use of fixed pericardial tissue in a tissue valve was well-known and obvious over Garrison, alone. However, to the extent an express disclosure of the use of fixed pericardial tissue in a tissue valve is needed, that is precisely what Nguyen provides. Nguyen expressly

equates the use of a porcine valve and the use of pericardial tissue, stating under the heading “Background of the Invention” that “[b]io-prosthetic valves may be formed from an intact, multi-leaflet porcine (pig) heart valve, or by shaping a plurality of individual leaflets out of bovine pericardial tissue and combining the leaflets to form the valve.” Ex. 1020, 1:28–31.

We further credit the testimony of Dr. Drasler in this regard, who explains as follows:

A person of ordinary skill in the art would have been motivated to apply Nguyen’s teachings of leaflets made of pericardial tissue to Garrison’s leaflets to achieve the predictable and beneficial result of using a material that [is] durable, biocompatible, and well known to have minimal antigenicity and be well suited for use in replacement heart valve.

Ex. 1002 ¶ 153 (citing Ex. 1020, 1:28–39, 1:51–54). In particular, Petitioner need not show that fixed pericardial tissue is more durable than the example of a porcine valve provided in Garrison. Petitioner has provided substantial evidence of why a person of ordinary skill in the art would have understood and had reason to use fixed pericardial tissue to form the valve taught by Garrison because Nguyen expressly taught the choice of fixed pericardial tissue was known to provide a durable material for the leaflets of a tissue valve.

Based upon consideration of the entire record, and for the reasons discussed above, we determine Petitioner has shown by a preponderance of the evidence that Garrison in light of Leonhardt and Nguyen teaches each limitation of the Challenged Claims and has also shown that an ordinarily skilled artisan would have had a reason to modify Garrison in light of Leonhardt and Nguyen, and would have had a reasonable expectation of success when doing so. On the whole, we find that the information provided

by Petitioner and Patent Owner in consideration of the *Graham* factors collectively demonstrates that Petitioner has shown by a preponderance of the evidence that the Challenged Claims are unpatentable under 35 U.S.C. § 103(a) as obvious over Garrison, Leonhardt, and Nguyen.

H. The Andersen/Limon Grounds

Petitioner also contends that the Challenged Claims are unpatentable as obvious over the Andersen/Limon Grounds. Pet. 52–78. In brief summary, Petitioner contends that Andersen teaches a valve prosthesis that uses a self-expandable stent corresponding to the recited “prosthetic heart valve,” but does not teach a delivery system. *Id.* at 52–53 (citing, e.g., Ex. 1013, 1:21–33, 2:27–33, 2:44–58, 4:36–41; 6:62–63; Fig. 12). According to Petitioner, “Andersen also teaches that ‘any prior art technique’ can be used during implantation to ‘supervise an accurate introduction and positioning of the valve prosthesis,’ including the use of ‘guide wires’ and a ‘catheter.’” *Id.* at 53 (citing Ex. 1013, 4:36–41; Ex. 1002 ¶¶ 155–157). Petitioner relies on Limon as teaching the recited “delivery system.” *Id.* at 54–57 (citing, e.g., Ex. 1008, 2:32–40, 5:27–54, Figs. 8, 9). Limon, however, has a priority date after Andersen. Ex. 1008, code (22); Ex. 1013, code (63). Further, Patent Owner disputes, among other things, whether Petitioner has shown a sufficient rationale for combining Andersen and Limon with a reasonable expectation of success. *See, e.g.*, Resp. 48–58.

We determined, as discussed above, that the Challenged Claims were shown to be unpatentable by a preponderance of the evidence under each of the Garrison Grounds. *See supra* Sections II.E–G. As a result, we do not reach the merits of the Andersen/Limon Grounds and make no determination

of whether Petitioner has shown the unpatentability of any of the Challenged Claims under the Andersen/Limon Grounds.

III. CONSTITUTIONAL CHALLENGE

Patent Owner states that it “preserves its right to argue that a finding of unpatentability by unconstitutionally appointed APJs violates the APA and the Due Process Clause and constitutes an unconstitutional taking.” Resp. 68. We decline to address Patent Owner’s constitutional challenge, except to note that the constitutionality of the appointments of the Administrative Patent Judges was addressed by the United States Supreme Court in *United States v. Arthrex, Inc.*, 141 S. Ct. 1970 (2021).

IV. CONCLUSION

The outcome for the Challenged Claims in this proceeding is set forth in summary as follows:

Claim(s)	35 U.S.C. §	Reference(s)/Basis¹³	Claim(s) Shown Unpatentable	Claim(s) Not Shown Unpatentable
1–5	103(a)	Garrison	1–5	
1–5	103(a)	Garrison, Leonhardt	1–5	
1–5	103(a)	Garrison, Nguyen	1–5	
1–5	103(a)	Garrison, Leonhardt, Nguyen	1–5	
1–3, 5	103(a)	Andersen, Limon, Gabbay		
1–3, 5	103(a)	Andersen, Limon, Phelps		
1–3, 5	103(a)	Andersen, Limon, Phelps, Nguyen		
4	103(a)	Andersen, Limon, Gabbay, Garrison		
4	103(a)	Andersen, Limon, Phelps, Garrison		
4	103(a)	Andersen, Limon, Phelps, Nguyen, Garrison		
Overall Outcome			1–5	

¹³ As explained above (*see supra* Section II.H), because we determined all Challenged Claims were shown to be unpatentable over the Garrison Grounds, we do not reach Petitioner’s contentions under the Andersen/Limon Grounds.

V. ORDER¹⁴

Upon consideration of the record before us, it is:

ORDERED that claims 1–5 of U.S. Patent No. 9,125,739 B2 have been proven by a preponderance of the evidence to be unpatentable;

FURTHER ORDERED that, pursuant to 35 U.S.C. § 318(b), upon expiration of the time for appeal of this Decision, or the termination of any such appeal, a certificate shall issue canceling claims 1–5; and

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

¹⁴ Should Patent Owner wish to pursue amendment of a Challenged Claim in a reissue or reexamination proceeding subsequent to the issuance of this decision, we draw Patent Owner's attention to the April 2019 *Notice Regarding Options for Amendments by Patent Owner Through Reissue or Reexamination During a Pending AIA Trial Proceeding*. See 84 Fed. Reg. 16,654 (Apr. 22, 2019). If Patent Owner chooses to file a reissue application or a request for reexamination of the challenged patent, we remind Patent Owner of its continuing obligation to notify the Board of any such related matters in updated mandatory notices. See 37 C.F.R. § 42.8(a)(3), (b)(2).

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