

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

EDWARDS LIFESCIENCES CORPORATION AND
EDWARDS LIFESCIENCES LLC,
Petitioner,

v.

COLIBRI HEART VALVE LLC,
Patent Owner.

IPR2020-01649
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)

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 Edwards Lifesciences Corporation and Edwards Lifesciences LLC (“Petitioner”)¹ 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

Petitioner filed a Petition pursuant to 35 U.S.C. §§ 311–319 requesting an *inter partes* review of the Challenged Claims. Paper 2 (“Pet.”). We instituted an *inter partes* review of the Challenged Claims on all grounds of unpatentability asserted in the Petition. Paper 8 (“Inst. Dec.”). Colibri Heart Valve LLC (“Patent Owner”)² 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. 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).

¹ Petitioner identifies no additional real parties in interest. Pet. 24.

² Patent Owner identifies no additional real parties in interest. Paper 4, 1.

B. Related Matters

The '739 patent is also challenged in *Medtronic CoreValve LLC, Edwards Lifesciences Corp., and Edwards Lifesciences LLC v. Colibri Heart Valve LLC*, IPR2020-01454 (filed September 2, 2020) (“the 01454-IPR”), 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”) to which Petitioner is not a party. Pet. 24–25; 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*, IPR2020-01453, Paper 11 (PTAB Mar. 5, 2021).

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 (“the '650 Application”), 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.

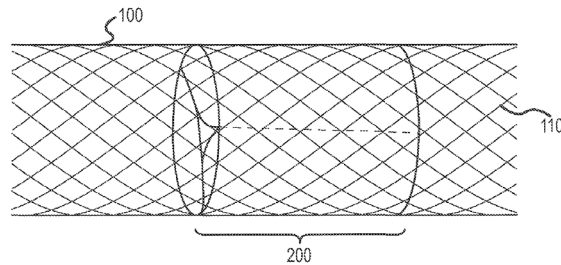


FIG.5

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.

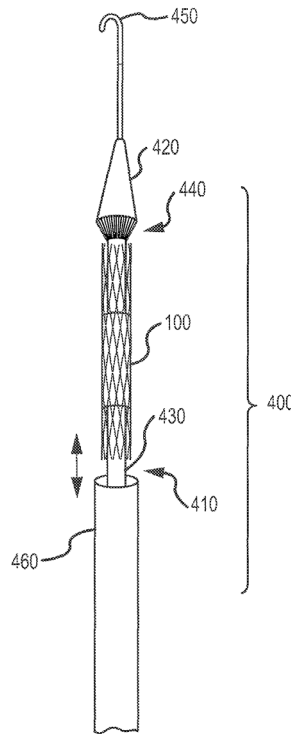


FIG.8

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 Steven L. Goldberg, M.D., 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. Goldberg and Dr. Dasi.

Dr. Goldberg indicates he received a Bachelor of Arts in Mathematics in 1980 and an M.D. in 1984 from the University of Kansas. Ex. 1020 ¶ 7. He was a Fellow in Cardiology at the University of California, Irvine from July 1990 through June 1993; an Assistant Professor of Medicine at UCLA from October 1993 through June 2000; and at the University of Washington Medical Center he was a practicing Interventional Cardiologist, an Associate Professor of Medicine from 2000 to 2006, a Clinical Associate Professor of Medicine from 2006 to 2014, and the director of the University of Washington Medical Center's Catheterization Laboratory from 2004 through 2014. *Id.* ¶¶ 10, 13, 14. Dr. Goldberg states he is the Medical Director for Structural Heart Disease at the Tyler Heart Institute,

Community Hospital of the Monterey Peninsula, and the Chief Medical Officer of a “medical device company that develops novel tools for the treatment of heart failure and related conditions.” *Id.* ¶¶ 4, 5. Dr. Goldberg also states that he has “implanted over 10,000 stents and performed hundreds of valvuloplasties of all heart valves,” “was a clinical study proctor for some of the first-ever-FDA approved stents,” and has “implanted about 70 transcatheter heart valves in patients.” *Id.* ¶¶ 18, 22.

Patent Owner argues that “Dr. Goldberg fell into the trap of opining as one of extraordinary skill in the art,” because at his deposition “he testified that in forming his opinions, he applied all of his experience up until January 4, 2002.” Resp. 3 (citing Ex. 2020, 20:5–14). According to Patent Owner the “agreed upon definition of a person of ordinary skill required “two years of experience,” and in 2002 Dr. Goldberg had “been practicing in the relevant field for approximately 17 years.” *Id.* We find Patent Owner’s argument unpersuasive, because it misrepresents Dr. Goldberg’s testimony, as follows:

Q. Did you apply all of the qualifications and experience that you set forth in your declaration up until January 4th, 2002, in reaching the opinions you set forth in your declaration, other than the Paniagua opinions?

A. The phrasing of the question is slightly confusing, but I believe that what you're asking is, did I consider the perspective of somebody whose knowledge -- a person skilled in the art’s knowledge was January 4th, 2002, and before. And hopefully, I answered your question correctly, but if not, it was due to my misunderstanding.

Q. (By Ms. Spires) No problem. I do appreciate the clarification. So I think part of the awkward wording is because of these two sections. So I’ll say, right now, I'm going to be putting aside the Paniagua grounds that you used the 2014 date for. So for all other grounds, did you apply all of your

own qualifications and experience up until January 4th, 2002, in reaching the opinions you put -- set forth in your declaration?

A. If I understand you correctly, yes. Yes. You don't phrase it in a way that is intuitively clear to a layperson, and -- but that's why I'm hedging just a little bit. But I believe we're on the same page and that I did apply that date as the date that I'm using as the reference.

Q. And the date that you're talking about, the January 4th, 2002, date, what I'm trying to find out is if you applied all of your own qualifications and experience that you've listed in your declaration up until that date when --

Q. (By Ms. Spires) -- reaching your opinions.

A. Yes.

Ex. 2020, 18:20–20:14 (objections to form omitted). We find no clear inconsistency between Dr. Goldberg's testimony and his declaration, which expressly states as follows:

I am informed that the scope and content of the prior art must be determined, as well as the level of ordinary skill in the art. I am further informed that a patent claim was obvious at the time of the invention 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 to a person having ordinary skill in the art. I am further informed that the focus when making a determination of obviousness should be on what a hypothetical person of ordinary skill in the pertinent art would have known at the time of the invention, and on what such a person would have reasonably expected to have been able to do in view of that knowledge.

Ex. 1020 ¶ 90. Dr. Goldberg 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 everything he knew in 2002. To the contrary, Dr. Goldberg expressly explained that his opinion was based on what "a person of

ordinary skill in the art” would have recognized, and further articulated what the qualifications he considered a person of ordinary skill in the art would have had at the relevant time. *See, e.g., id.*, ¶¶ 26, 27, 41, 42, 47. Patent Owner disregards numerous other instances during the deposition when Dr. Goldberg was asked and 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. *See, e.g.,* Ex. 2020, 24:5–10, 34:14–35:7, 36:5–37:6. Lastly, Patent Owner identifies an agreed-upon 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. Goldberg’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. 3–4; Reply 25–26. 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. Goldberg’s testimony in this case. As Dr. Goldberg’s qualifications are otherwise undisputed, we also determine that Dr. Goldberg is qualified to opine on the issues in this proceeding from the perspective of

a person of ordinary skill in the art. Ex. 1020, 102–146 (Dr. Goldberg’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 Testimony³	Date	Ex. No.
U.S. Patent No. 5,855,601 (“Bessler”)	Jan. 5, 1999	1006
U.S. Patent No. 5,332,402 (“Teitelbaum”)	July 26, 1994	1007
U.S. Patent No. 5,957,949 (“Leonhardt”)	Sept. 28, 1999	1012
U.S. Patent App. No. 2005/0113910 A1 (“Paniagua”)	May 26, 2005	1015
U.S. Patent App. No. 2001/0044633 A1 (“Klint”)	Nov. 22, 2001	1019
U.S. Patent App. No. 2002/0032481 A1 (“Gabbay”)	Mar. 14, 2002	1009
Declaration of Steven L. Goldberg, M.D.	Sept. 18, 2020	1020
Reply Declaration of Steven L. Goldberg, M.D.	Sept. 10, 2021	1036
Deposition Transcript of Dr. Steven L. Goldberg	May 28, 2021	2020
Declaration of Dr. Lakshmi Prasad Dasi	June 11, 2021	2019
Deposition Transcript of Dr. Lakshmi Prasad Dasi	Aug. 25, 2021	1039

F. Asserted Grounds of Unpatentability

Petitioner asserts that the Challenged Claims are unpatentable based on the following grounds (Pet. 26):

Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
1–5	103(a)	Bessler, Teitelbaum
1–5	103(a)	Bessler, Leonhardt
1–5	103(a)	Bessler, Leonhardt, Klint
1–5	103(a)	Bessler, Teitelbaum, Klint
1–5	102(b)	Paniagua

³ 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.

II. ANALYSIS

A. Legal Standards of Anticipation and Obviousness

Petitioner contends under one ground that the Challenged Claims are anticipated. Pet. 26. A claim is anticipated if a single prior art reference either expressly or inherently discloses every limitation of the claim.

Orion IP, LLC v. Hyundai Motor Am., 605 F.3d 967, 975 (Fed. Cir. 2010).

“A single prior art reference may anticipate without disclosing a feature of the claimed invention if such feature is necessarily present, or inherent, in that reference.” *Allergan, Inc. v. Apotex Inc.*, 754 F.3d 952, 958 (Fed. Cir. 2014) (citing *Schering Corp. v. Geneva Pharm.*, 339 F.3d 1373, 1377 (Fed. Cir. 2003)).

Petitioner contends under four grounds that the Challenged Claims are unpatentable based on obviousness.⁴ Pet. 26. 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 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).

⁴ 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.

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 contends that a person of ordinary skill in the art at the time of the invention “would have been an interventional cardiologist with a working knowledge of heart valve designs, expandable stents, and intravascular delivery systems for stents.”⁵ Pet. 41–42 (citing Ex. 1020 ¶ 27). Petitioner further states that such a person of ordinary skill “would, where necessary, work as a team in combination with a medical device engineer.” *Id.*

Patent Owner proposes the same level of ordinary skill in the art that Petitioner agreed to in the -01454 IPR, which Patent Owner sets forth as follows:

A [person of ordinary skill in the art] as of January 4, 2002 ‘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.’

Resp. 2 (quoting IPR2020-01454, Paper 1, 23); Ex. 2019 ¶¶ 21, 22.

According to Patent Owner, Petitioner’s proposed definition does not allow for the “differentiation among those who possess ordinary skill in the art versus those who possess extraordinary skill in the art.” Resp. 2–3 (citing

⁵ Petitioner provides the same level of ordinary skill for both its anticipation ground based on Paniagua as for the Bessler Grounds; however, Petitioner identifies April 15, 2014, as the date of invention for anticipation based on Paniagua and January 4, 2002, for the Bessler Grounds, noting that a person of ordinary skill as of the latter date “would have had the additional knowledge of the important developments in the art in the intervening 12 years.” Pet. 41–42.

Envtl. Designs, Ltd. v. Union Oil Co. of Cal., 713 F.2d 693, 697 (Fed. Cir. 1983)).

Petitioner argues in its Reply that Patent Owner “identifies no issue that would be impacted by the choice of definition” of a person of ordinary skill. Reply 24. Petitioner also notes that Patent Owner’s proposed definition similarly “sets out the minimum requirements for a [person of ordinary skill in the art] with no upper limit on experience.” *Id.* at 25.

We adopt Patent Owner’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))). It is also identical to the definition Petitioner agreed to in the 01454-IPR, which applies in that proceeding as well. Our adoption of Patent Owner’s proposed definition does not reflect a view that adopting Petitioner’s competing definition of the level of ordinary skill in the art would have had any impact on the outcome of this proceeding. To the contrary, our conclusions would have been the same under either party’s definition.

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. The parties specifically address three claim terms as follows. Pet. 37–41; Resp. 12–19.

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”).

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. 12 (citing Ex. 2025, 46; Ex. 2026; Ex. 2019 ¶¶ 66, 67). We discern no dispute over the meaning of “flares at both ends in a trumpet-like configuration” that requires an express construction. *See* Reply 23–30. *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 it “provides sufficient structure . . . when read in light of the [S]pecification.” Pet. 41 (citing *Mass. Inst. of Tech. v. Abacus Software*, 462 F.3d 1344, 1356 (Fed. Cir. 2006)). Alternatively, if it is construed to be a means-plus-function limitation, Petitioner asserts “the [S]pecification provides adequate structure.” *Id.* (citing Ex. 1001, 5:1–5, 5:11–15, 6:55–57, 6:21–7:18, 8:26–9:25, 10:26–54, Figs. 1–3, 9). 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. 19 (citing Ex. 2025, 15; Ex. 2026; Ex. 2019 ¶¶ 78, 79). We discern no dispute over the meaning of “valve means” that requires an express construction. *See* Reply 23–30.

3. “a delivery system . . . wherein the prosthetic heart valve is collapsed onto the pusher member”

Claim 1 recites “a delivery system . . . wherein the prosthetic heart valve is collapsed onto the pusher member to reside in a collapsed configuration on the pusher member.” Ex. 1001, 14:17–24. Petitioner contends that “onto” means “in contact with,” such that claim 1 requires a prosthetic heart valve collapsed *in contact with* the pusher member. Pet. 37–41. Patent Owner disputes Petitioner’s proposed construction and does not propose an alternative express construction. Resp. 12–19.

Petitioner reasons that the portion of the Specification of the ’739 patent that discusses the “pusher member” “was copied nearly word-for-

word from Bessler,” and that “the ‘pusher member’ and the meaning of mounting the replacement heart valve device ‘onto’ the ‘pusher member’ must be what Bessler teaches.” Pet. 37–38. Bessler is cited on the face of the ’739 patent. Ex. 1001, code (56). Petitioner does not suggest that the term “onto” appears anywhere in Bessler.

To purportedly support its argument that Bessler must define terms in the ’739 patent, Petitioner turns to extrinsic evidence from a district court proceeding in which Patent Owner allegedly made arguments concerning a different patent from the ’739 patent with the same specification to show that Patent Owner “argued that the only embodiment of a delivery system in the ’739 Patent that describes using a pusher member to push out a prosthetic device is the one that was copied from Bessler.” Pet. 38. Petitioner then turns to a figure from Bessler, which does not appear in the ’739 patent, to allegedly show that Bessler teaches a replacement heart valve “in contact with” a pusher member. *Id.* at 38–39 (citing Ex. 1006, Fig. 14).

Petitioner’s reasoning then turns to the prosecution history, with Petitioner arguing that Patent Owner did not “correct” the Examiner in regard to statements by the Examiner concerning Gabbay that made clear that “‘Gabbay . . . does not disclose the valve to be collapsed onto the pusher member’ because ‘Gabbay’s pusher member 210 or 716 is a plunger member with lumen, ending proximally to the valve, which pushes out the valve from behind.’” *Id.* at 39 (quoting Ex. 1002, 238) (alteration in original). Petitioner then accuses Patent Owner of embracing “the Examiner’s error” by failing to explain “to the Examiner that that the only description of a ‘pusher member’ in the specification describes the ‘pusher member’ as extending to a ‘hollow section at the distal end [] of the catheter’

where the replacement heart valve device is carried.” *Id.* at 40 (citing Ex. 1001, 11:44–51) (alteration in original).

According to Petitioner, “the sole written description of a ‘pusher member’ in the ’739 [p]atent *requires*” that “the pusher member ‘terminates proximal’ to the replacement heart valve device.” *Id.* Petitioner relegates any discussion of Figure 8 of the ’739 patent, which illustrates a prosthetic heart valve collapsed onto a pusher member, as claimed, to a footnote. *Id.* at 40 n.8. Petitioner states as follows:

Figure 8 of the ’739 [p]atent is not to the contrary. First, the description in the specification is inconsistent with what is illustrated in Figure 8, as a [person of ordinary skill in the art] would readily recognize. EX1020, ¶¶81–87. Additionally, to the extent Figure 8 is viewed in light of the specification, it identifies the “pusher member” as element 420, which is pictured as terminating adjacent to the stent 100. EX1001, Fig. 8; EX1020, ¶86, n.2.

Id. Dr. Goldberg testifies to the same thing, stating “[t]o the extent that Figure 8 in the ’739 [p]atent is given any consideration, I note that it depicts the purported ‘pusher member 420’ as adjacent to the prosthetic heart valve device and not as passing through and surrounded by the interior of the prosthetic heart valve device.” *See* Ex. 1001, Fig. 8; Ex. 1020 ¶¶ 86 n.2, 87.

Petitioner’s argument and Dr. Goldberg’s testimony in this regard are contrary to the express disclosure of the ’739 patent. The ’739 patent states that “[t]he 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.*” Ex. 1001, 11:48–51 (emphasis added). Petitioner’s argument, as supported by Dr. Goldberg, that pusher member 420 terminates adjacent to stent 100 and does not pass through the prosthetic heart valve device misrepresents what is illustrated

and expressly disclosed in writing in the '739 patent. Thus, we do not find Petitioner's argument or Dr. Goldberg's testimony adequately supported.

Patent Owner persuasively explains as follows:

Petitioners' argument cannot be squared with "the well understood notion that claims of unrelated patents must be construed separately." *e. Digital Corp. v. Futurewei Techs., Inc.*, 772 F.3d 723, 727 (Fed. Cir. 2014). *See also Texas Digital Sys. Inc. v. Telegenix, Inc.*, 308 F.3d 1193, 1211 (Fed. Cir. 2002) (holding that a common inventor's representation of "matrix displays and seven-segment displays as two separate embodiments of the same invention" was irrelevant and "sheds no light" on whether "the claims in an unrelated patent are broad enough to encompass both a matrix and the familiar seven-segment pattern."); *Goldenberg v. Cytogen, Inc.*, 373 F.3d 1158, 1167 (Fed. Cir. 2004) (noting that "this court's precedent takes a narrow view on when a related patent or its prosecution history is available to construe the claims of a patent at issue and draws a distinct line between patents that have a familial relationship and those that do not."); *Pfizer, Inc. v. Ranbaxy Labs. Ltd.*, 457 F.3d 1284, 1290 (Fed. Cir. 2006) (holding that statements made during prosecution of the later, unrelated '995 patent cannot be used to interpret claims of the '893 patent).

Resp. 17–18. As Patent Owner explains, notwithstanding a similarity in language, the '739 patent and Bessler are describing different figures with Bessler illustrating a pusher member in contact with a prosthetic heart valve, "whereas the '739 patent is disclosing a prosthetic heart valve that is collapsed *around* its pusher member." *Id.* at 13. As Patent Owner explains, statements in the prosecution history of the '739 patent (which Petitioner addressed and dismisses as associated with some sort of Examiner error (Pet. 40)) make clear that the purported invention was distinguished over prior art that merely showed a pusher member in contact with a prosthetic heart valve. *Id.* at 15–16 (citing Ex. 1002, 238, 319).

Patent Owner concludes as follows:

Thus, in light of Applicants’ repeated statements during prosecution that the prosthetic heart valve cannot be collapsed onto a pusher member that terminates proximally to the valve, Petitioners’ proposed construction must fail. Petitioners’ construction of “collapsed onto” to mean “collapsed in contact with” specifically includes “collapsed onto” a pusher member that terminates proximally to the valve as in Bessler, which the prosecution history makes clear is not the meaning of “collapsed onto.”

Id. at 17 (citing Ex. 2019 ¶¶ 75–77).

In its Reply, Petitioner argues that Figure 8 of the ’739 patent is “inconsistent with the [S]pecification.” Reply 19. We disagree because Figure 8 *is* part of the Specification. Petitioner further argues that Figure 8 mislabels the distal end as the “proximal end” of the catheter, and, therefore, the entire figure should be “disregarded” because of such “obvious errors.” *Id.* at 21–23.

Petitioner has shown no sufficient basis to “disregard” Figure 8, much less that Figure 8 is determinative of whether “onto” means “in contact with,” as Petitioner alleges. See Sur-reply 12–15. Likewise, Petitioner’s argument that Patent Owner “imposes an unsupported temporal limitation on ‘collapsed onto’” when Patent Owner addressed Klint provides no support for Petitioner’s proposed construction of “onto.” Reply 22–23. Consistent with our Decision on Institution, we determine on the full record that Petitioner fails to show sufficiently that “onto” means “in contact with.” See Inst. Dec. 23–27. Accordingly, a “delivery system . . . wherein the prosthetic heart valve is collapsed onto the pusher member” does not encompass a delivery system with a prosthetic heart valve only shown to be “in contact with” a pusher member. We find no further express construction

of “a delivery system . . . wherein the prosthetic heart valve is collapsed onto the pusher member” is necessary for purposes of this Decision.

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.

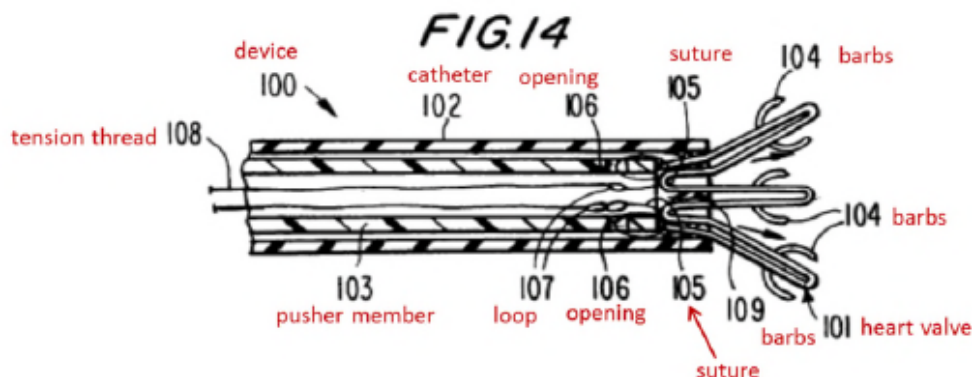
D. *Scope and Content of the Asserted Art Under Bessler Based Grounds*

Petitioner contends the Challenged Claims would have been obvious over Bessler in various combinations with Teitelbaum, Leonhardt, and Klint. Pet. 26. Each of these references is summarized in relevant part below.

1. *Summary of Bessler*

Bessler, titled “Artificial Heart Valve and Method and Device for Implanting the Same,” teaches a heart valve comprised of a self-expanding stent member and valve means that may be inserted percutaneously at the site of the removed heart valve “where it is released in a controlled fashion from the distal end of a catheter.” Ex. 1006, code (54), 2:55–67.

Figure 14 of Bessler, as annotated by Petitioner, is reproduced below.



Pet. 38–39. Figure 14 illustrates a cross-sectional view of the distal end of device 100 for the percutaneous and transluminal implantation of a heart valve showing heart valve 101 in a partially ejected state. Ex. 1006, 3:28–

30, 3:33–35. According to Petitioner, heart valve 101 “is just distal to, and is *in contact with*,” pusher member 103. Pet. 38. In regard to Figure 14, Bessler explains as follows:

[T]he catheter 102 has been brought to the appropriate site and the guide wire removed proximally. The pusher member 103 has been moved forward longitudinally of the catheter 102 to eject approximately one-half of the heart valve 101 from the distal end of the catheter 102. As seen in the drawing the distal end of the valve 101 is expanded and a slight pull of the entire unit will set the first circle of barbs 104 in the vessel wall. The heart valve 101 is held in place within the delivery catheter by a pair of threads or sutures 105. The sutures are looped through an opening 106 in the pusher member 103 and then passed about a portion of the heart valve 101 as shown. The other end of the suture 105 contains a loop 107. A tension thread 108 is passed through the suture loops and down through the center of the pusher member 103 to the proximal end of the catheter 102.

Ex. 1006, 7:46–61.

2. *Summary of Teitelbaum*

Teitelbaum, titled “Percutaneously-Inserted Cardiac Valve,” teaches an expandable replacement cardiac valve “maintained in a collapsed form by cold temperature.” Ex. 1007, codes (54), (57). In one design, the valve includes “a meshwork of nitinol wire,” where “[a]way from its central portion, the tubular structure flares markedly at both ends in a trumpet-like configuration.” *Id.* at 2:20–27. According to Teitelbaum, the “flared ends of the stent maintain the position of this component across the native valve following deployment.” *Id.* at 2:34–36. According to Teitelbaum, “[o]nce the stent has been pushed to the distal end of the sheath where it bridges the site of the dilated valve, the pusher will be held steady while the sheath is withdrawn, allowing the stent to come into contact with body temperature.” *Id.* at 3:54–59.

3. 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. 1012, codes (54), (57).

Figures 2 and 4 of Leonhardt are reproduced below.

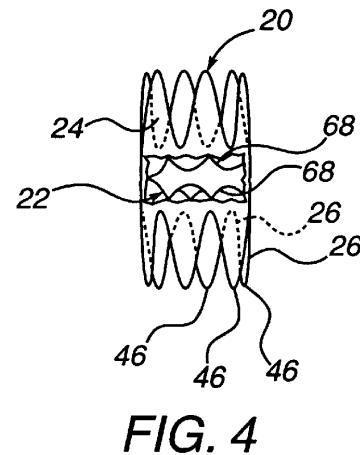
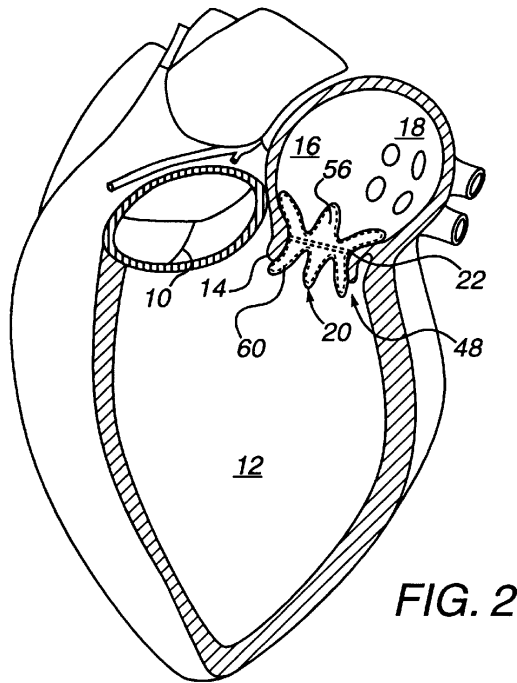


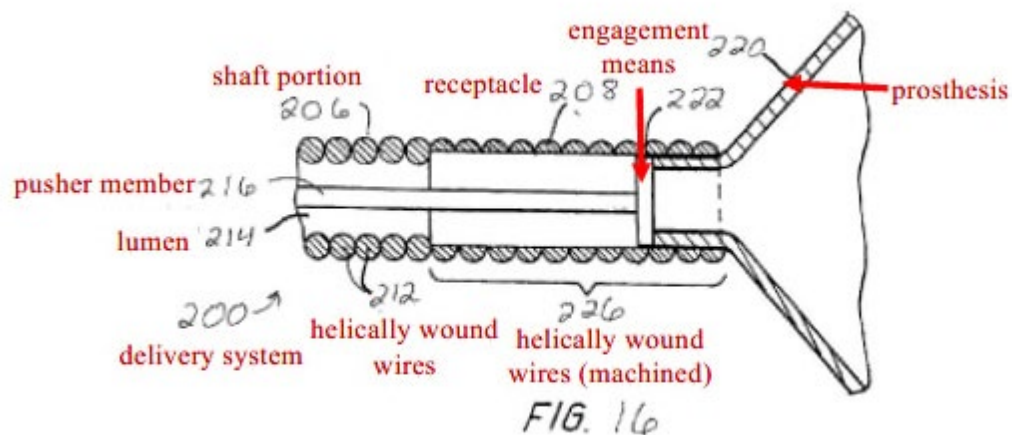
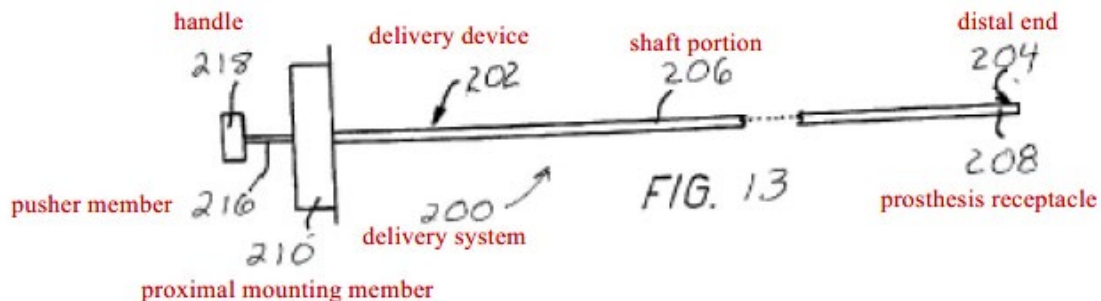
Figure 2 illustrates a “valve stent fully deployed within the mitral valve,” and Figure 4 illustrates a sectional view of a “biological valve within the stent.” *Id.* at 3:57–58, 3:61–62. As shown in Figure 4, valve stent 20 includes stent 26, biological valve 22, and graft material 24. *Id.* at 4:15–17. 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.

4. Summary of Klint

Klint, titled “Endovascular Medical Device with Plurality of Wires,” describes a “medical device for passage along the vasculature of a patient,” which “may be a catheter or may be one or more components of a delivery system for endovascular devices, such as a central member within a catheter, for example, a pusher or delivery device for an embolization coil.”

Ex. 1019, code (54), ¶ 15.

Figures 13 and 16 of Klint are reproduced below, with annotations provided by Petitioner.



Pet. 67–68. Figure 13 illustrates delivery system 200 for delivery of a prosthesis such as a stent and Figure 16 illustrates an enlarged partial view of an embodiment of the delivery system of Figure 13. *Id.* ¶¶ 36, 37.

Delivery system 200 includes “delivery device 202 having a distal end 204 and a shaft portion 206 extending between a prosthesis receptacle 208 at the distal end and a proximal mounting member 210 fixedly mounted to the shaft portion.” *Id.* ¶ 92. Delivery system 200 also includes “pusher member 216 which can be inserted through the lumen 214,” and handle or pin vise 218 “mounted on the pusher member for pushing it forwardly in the distal direction when a prosthesis 220 located in receptacle 208 is to be released from the introducer device by being pushed out of receptacle 208.” *Id.* ¶ 93. “At the distal end of the pusher member 216 an engagement means 222 can act on the prosthesis 220.” *Id.* ¶ 94. Klint further states as follows:

The engagement means can be for example a plate of a dimension fitting into receptacle 208 and abutting the proximal end of the prosthesis so that the plate pushes the prosthesis out of the receptacle when the pusher member is pushed forwardly. The engagement means can also be designed as an elongate member that extends coaxially inside the radially compressed prosthesis and engages the prosthesis at several locations along the length thereof so that the prostheses is partly pulled, partly pushed out of the receptacle. These engagement points or areas can be effected by radial projections, hooks, ridges, or another kind of engagement means such as a high friction material. This can be an advantage if the prosthesis has an extensive length, and in particular if it has a construction having a tendency to buckle when pushed upon.

Id.

E. Alleged Obviousness over Bessler and Teitelbaum

Petitioner contends the Challenged Claims would have been obvious over Bessler in combination with Teitelbaum. Pet. 47–66. Petitioner argues that the Specification of the ’739 patent “copies verbatim (or nearly so)” substantial portions of Bessler and that Bessler teaches “nearly all features”

of the Challenged Claims.” Pet. 4–15. As to the stent member “that flares at both ends in a trumpet-like configuration,” Petitioner argues that it is “[o]ne of the few elements of the claims of the ’739 [p]atent that was not copied nearly word-for-word from Bessler,” but was instead “copied verbatim (or nearly so) from Teitelbaum.” *Id.* at 15–16 (comparing, e.g., Ex. 1001, 7:59–67 to Ex. 1007, 5:52–63). Because it is determinative as to all Challenged Claims, we focus our discussion on the requirement of claim 1 of the ’739 patent, which recites that “the prosthetic heart valve is collapsed onto the pusher member.”

Petitioner relies only on Bessler as teaching the “collapsed onto the pusher member” limitation of claim 1 and asserts that because the ’739 patent allegedly “copied its only disclosure of a ‘pusher member’ from Bessler,” “whatever the ’739 [p]atent is argued to describe as the pusher member, Bessler must disclose.” Pet. 60–61 (citing Ex. 1001, 11:40–12:5; Ex. 1006, 4:53–5:14, 5:46–51; Ex. 1020 ¶¶ 142–143). Neither Petitioner nor Dr. Goldberg otherwise explains how Bessler teaches this limitation. Merely asserting that portions of the Specification of the ’739 patent were copied from Bessler is insufficient to show how a claimed feature not described in Bessler was taught by Bessler. Moreover, Petitioner neglects to sufficiently address in its arguments the entirety of the Specification of the ’739 patent, including Figure 8, which was not copied from Bessler, in discussing whether Bessler teaches the recited feature.

Further, to the extent Petitioner’s argument applies Petitioner’s proposed construction of “onto” as meaning “in contact with,” it is a construction we reject as explained above. *See supra* Section II.C.1; *see also* Pet. 61 (relying on other art “[t]o the extent that the term ‘onto’ in the phrase . . . is construed narrowly”). In this regard, Patent Owner shows that,

as illustrated in Figure 14 of Bessler, the pusher member and heart valve device are in a “side-by-side arrangement . . . rather than the collapsed-onto arrangement.” Resp. 33. Petitioner does not show that Bessler teaches any more than a delivery system with a prosthetic heart valve “in contact with” a pusher member. Pet. 60–61; Reply 8–15, 19–23. Because Petitioner has not shown by a preponderance of the evidence that the combination of Bessler and Teitelbaum teaches or suggests a “prosthetic heart valve is collapsed onto the pusher member,” as required by each Challenged Claim, Petitioner has not shown any Challenged Claim would have been obvious over Bessler and Teitelbaum. *Id.*

F. Alleged Obviousness over Bessler and Leonhardt

Petitioner contends the Challenged Claims would have been obvious over Bessler in combination with Leonhardt. Pet. 47–66. Petitioner relies on Leonhardt as teaching “the prosthetic heart valve is collapsed onto the pusher member,” which is the issue we focus our discussion on, because it is determinative as to all Challenged Claims.

Petitioner argues as follows:

To the extent that the term “onto” in the phrase “wherein the prosthetic heart valve is collapsed onto the pusher member” is construed narrowly such that it requires the pusher member to pass through the interior of the prosthetic valve (contrary to the only use of “pusher member” described in the specification (EX1001 at 11:40–12:5)), Leonhardt has a delivery system with a “push rod” with an inner passage through which an “inner catheter” extends. EX1012 at 6:45–49; EX1020, ¶144. That “inner catheter” “pass[es] through valve 22 prior to and during deployment.” EX1012 at 7:15–17; *see also id.* at 7:21–29, 8:23–31; EX1020, ¶145. Leonhardt further describes deploying the valve by “withdrawing outer sheath 106.” EX1012 at 10:53–11:22; EX1020, ¶145.

Pet. 61. Petitioner’s undeveloped argument appears to presume that “a delivery system . . . wherein the prosthetic heart valve is collapsed onto the pusher member to reside in a collapsed configuration on the pusher member” requires no more than that some part of the delivery system passes through the interior of the valve. *See id.* Petitioner’s argument fails to reflect that it is Petitioner’s burden to show how the Challenged Claims are unpatentable over the asserted art. Petitioner makes no showing supporting (and, to the contrary, suggests it disagrees with) a construction of “onto” as requiring “to pass through the interior of.” *See id.* Petitioner provides no evidence to support such a construction upon which our Decision could be based. *See, e.g.,* Ex. 1020 ¶ 144 (Dr. Goldberg offering no support for such a construction).

Moreover, Petitioner is not precise in identifying what features of Leonhardt it relies on as corresponding to a “pusher member.” Specifically, Leonhardt describes push rod 112 as “a metallic compression spring” that has the “ability to act as a push rod for exerting force against valve stent 20 during deployment.” Ex. 1012, 8:23–27. Petitioner, however, does *not* rely on push rod 112 as corresponding to the recited “pusher member” because it does not “pass through the interior of the prosthetic valve,” as Petitioner purports to define the limitation at issue. Instead, Petitioner argues that an “inner catheter” extends through push rod 112 and through valve 22, and asserts that it is this “inner catheter” that corresponds to a pusher member for no apparent reason other than that it would meet the unsupported definition of “onto” as requiring “to pass through the interior of” that Petitioner proposes, but argues against. This “inner catheter” that Petitioner refers to appears to be inner catheter 110, which Leonhardt describes as “independently slidable” relative to push rod 112, and intended as a means

for transporting fluid to, for example, fill or empty a balloon. *Id.* at 7:25–60, 8:29–31. Patent Owner argues, and we agree, that Petitioner has “failed to identify any role that Leonhardt’s inner catheter 110 plays in causing the replacement heart valve device to be ‘pushed out of the catheter,’ as the ’739 patent describes is a function of the pusher member.” Resp. 35 (citing, e.g., Ex. 2019 ¶ 152; Ex. 1001, 11:48–54).

Petitioner further argues that “the arrangement of Leonhardt’s delivery system parallels that depicted in Figure 8 of the ’739 [p]atent.” Pet. 61–62 (citing Ex. 1020 ¶ 145). Petitioner then reproduces in the Petition Figure 5 of Leonhardt and Figure 8 of the ’739 patent with no additional explanation. The portion of Dr. Goldberg’s declaration cited by Petitioner likewise provides no explanation and his unsupported, conclusory opinion that one figure “parallels” another is not persuasive. *See* Ex. 1020 ¶ 145. We agree with Patent Owner that “Leonhardt’s Figure 5 does not even include Leonhardt’s valve stent (20) or valve (22), much less disclose that Leonhardt’s ‘prosthetic heart valve is collapsed onto the pusher member’ as claim 1 recites.” Resp. 38–39 (citing Ex. 2019 ¶159; Ex. 1012, 7:11–12, Fig. 5).

In its Reply, Petitioner takes issue with Patent Owner’s arguments, but offers no persuasive support for the construction of “onto” that it applies or its interpretation of Leonhardt. Reply 12–15. Instead Petitioner argues, improperly for the first time, various similarities between Leonhardt Figure 5 and Figure 8 of the ’739 patent that purportedly show each “discloses the same elements that *Dr. Dasi* identifies as the pusher member in Figure 8 of the ’739” patent. *Id.* (emphases added). Again, Petitioner’s argument fails to reflect that it is Petitioner’s burden to show (not Dr. Dasi’s to disprove) how the Challenged Claims are unpatentable over the asserted

art, which Petitioner has failed to do. Petitioner’s attempt in its Reply to rely on Dr. Dasi’s testimony to show that “the frictional force that is part of the pushing force for deployment can be provided by the portion of the catheter tube” has no merit. *Id.* at 14–15 (citing Ex. 1039, 66:20–67:14 (discussing how the invention of the ’739 patent operates, not how Leonhardt operates). Petitioner provides no evidence of a “frictional force” associated with Leonhardt’s valve and inner catheter 110. Patent Owner argues in its Sur-reply, and we agree, as follows:

[A]lthough Petitioner alleges that “the frictional force that is part of the pushing force for deployment can be provided by the portion of the catheter tube on which the prosthesis is based,” Petitioner has never alleged or provided any evidence of such a frictional force between Leonhardt’s inner catheter—used only as a conduit for transporting fluid—and prosthetic heart valve, nor does Petitioner’s citation for this proposition support its claim. (Ex. 1039, 65:22–67:14 (discussing “the friction between the pusher member and the stent” in the ’739, not in Leonhardt).

Sur-reply 25. Because Petitioner has not shown by a preponderance of the evidence that the combination of Bessler and Leonhardt teaches or suggests a “prosthetic heart valve is collapsed onto the pusher member,” as required by each Challenged Claim, Petitioner has not shown any Challenged Claim would have been obvious over Bessler and Leonhardt.

G. Alleged Obviousness over Bessler, Leonhardt, and Klint

Petitioner contends the Challenged Claims would have been obvious over Bessler in combination with Leonhardt and Klint. Pet. 47–70; Reply 1–17. Petitioner’s contentions are supported by Dr. Goldberg. Ex. 1020 ¶¶ 119–162. As to the stent member “that flares at both ends in a trumpet-like configuration,” Petitioner relies on Leonhardt. Pet. 52–53. Petitioner further relies on Klint as teaching “the prosthetic heart valve is collapsed

onto the pusher member.” *Id.* at 66–68. Patent Owner disputes Petitioner’s contentions primarily with regard to the teachings of Klint and the reasons supporting the asserted combination of Bessler, Leonhardt, and Klint. Resp. 40–66; Sur-reply 4–25. Patent Owner’s arguments are supported by Dr. Dasi. Ex. 2019 ¶¶ 102–190.

Below we first explain our determination, based on our review of the entire record developed at trial, that Petitioner has shown, by a preponderance of the evidence, that Bessler in combination with Leonhardt and Klint 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 Bessler in light of the teachings of Leonhardt and Klint, as Petitioner asserts, and would have had a reasonable expectation of success. 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 the combination of Bessler, Leonhardt, and Klint.

1. Differences Between the Subject Matter of Independent Claim 1 and the Combination of Bessler, Leonhardt, and Klint

The combination of Bessler, Leonhardt, and Klint teaches each limitation of claim 1, as shown by Petitioner, for the reasons below based on the supporting cited evidence of record. *See* Pet. 48–64. 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. 40–65; Sur-reply 10–25.

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, Bessler teaches, as shown by Petitioner, “artificial heart valves,” including a delivery system with guidewire 94. Pet. 48–49 (citing Ex. 1006, 1:7–11, 5:13–14, 7:35–38; Ex. 1020 ¶ 121).

a prosthetic heart valve including:

a stent member having an inner channel, the stent member collapsible, expandable and configured for transluminal percutaneous delivery,

Bessler teaches, as shown by Petitioner, a prosthetic heart valve that is collapsible and expandable and that “may be implanted percutaneously and transluminally.” Pet. 48–49 (citing Ex. 1006, 2:57–62, 3:52–55, 4:21–26, 5:44–51, 5:58–60; Ex. 1020 ¶ 122).

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

Petitioner recognizes that Bessler does not teach a stent member “that flares at both ends in a trumpet-like configuration.” *Id.* at 49. Instead, Petitioner shows, and Patent Owner does not dispute, that Leonhardt teaches 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

⁶ We separately address Patent Owner’s arguments directed to Petitioner’s reasons supporting the combination of Bessler, Leonhardt, and Klint after addressing how the prior art teaches each limitation. *See infra* Section II.G.6.

ends in a trumpet-like configuration.” *Id.* at 51–52 (citing Ex. 1012, 4:60–65, 5:2–5, 6:10–11, 6:19–22, Fig. 2; Ex. 1020 ¶ 125); *see generally* Resp.

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;

Bessler teaches, as shown by Petitioner, the recited valve means, including the recited leaflets. Pet. 54–56 (citing, e.g., Ex. 1006, 3:65–4:1, 4:9–11, 5:21–24, 6:20–24, Figs. 2, 3; Ex. 1020 ¶¶ 128–133, 135, 136). Specifically, Bessler states that “[t]he flexible valve means preferably comprises porcine pericardium configured with three leaflets.” Ex. 1006, 4:9–11; *see also id.* at 5:21–24 (stating that “[t]he center portion 23 of valve member 22 is generally arcuate in shape and comprises three leaflets 24 as shown, although it is understood that there could be from 2 to 4 leaflets”). Dr. Goldberg explains, and Patent Owner does not dispute, that the “generally arcuate center portion” is “the valve” and, as shown in Figures 2 and 3 of Bessler, “resides entirely within the inner channel of the stent member.” Ex. 1020 ¶¶ 128, 131. We also find persuasive Petitioner’s explanation that neither the ’739 patent nor Bessler “explicitly recite[s]” the negative limitation of “no reinforcing member,” but that a person of ordinary skill in the art would have understood that the absence of any mention in Bessler of such reinforcing members shows that there are no reinforcing members. Pet. 56 (citing Ex. 1006, 3:55–4:3, 5:15–24, 5:28–35, 5:36–38, Figs. 2–4; Ex. 1020 ¶¶ 135, 136). 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 Bessler teaches the “valve means” limitation of 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,

Petitioner contends that the '739 patent “copies its disclosure of the delivery system including a pusher member almost word-for-word from Bessler.” Pet. 57. As shown by Petitioner, Bessler teaches “[t]he system for implanting the above described artificial heart valve percutaneously and transluminally includes a flexible catheter,” and the “catheter has a pusher member disposed within the catheter lumen.” *Id.* (quoting Ex. 1006, 4:53–63; Ex. 1020 ¶ 137). Petitioner also shows that the pusher member taught by Bessler includes a guidewire lumen. *Id.* at 58 (citing Ex. 1006, 7:35–38 (“[a] guidewire 94 having a blunt end 95 is disposed through a lumen 97 of the pusher member 93 and is used to guide the distal end of the catheter 91 to the desired site”)). Petitioner further shows that “Bessler’s pusher member is disposed within a lumen of the moveable sheath (what Bessler refers to as a ‘catheter’).” *Id.* at 59 (citing Ex. 1006, 4:60–63 (“The catheter has a pusher member disposed within the catheter lumen and extending from the proximal end of the catheter to the hollow section at the distal end of the catheter.”)). Patent Owner does not dispute Petitioner’s contentions based on Bessler in regard to these recited features. 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 Bessler teaches the “delivery system . . . 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,

Klint teaches, as shown by Petitioner, a delivery system for a valve member that provides for the engagement of the pusher member with the prosthesis such that the prosthesis “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.”⁷ Pet. 67–68 (citing Ex. 1019 ¶¶ 21, 91–103, Figs. 13, 16; Ex. 1020 ¶¶ 157–160). Specifically, Klint teaches engagement means 222 at the end of pusher member 216 and expressly states that engagement means 222 may abut the proximal end of the prosthesis or may “also be designed as an elongate member that extends coaxially inside the radially compressed prosthesis and *engages the prosthesis* at several locations along the length thereof so that the prostheses is partly pulled, partly pushed out of the receptacle.” Ex. 1019 ¶ 94 (emphasis added).

Patent Owner advances several arguments asserting Klint does not disclose a prosthetic heart valve collapsed onto the pusher member, each of which is not persuasive for the reasons that follow. Resp. 40–45; Sur-reply 19–22. First, Patent Owner argues that Petitioner fails to “explain why, if at all,” a person of ordinary skill in the art would have considered “a pusher member that ‘passes through’ the collapsed prosthesis to be the same as having” the prosthesis collapsed onto the pusher member.” Resp. 43. Although Petitioner describes Klint as teaching “delivery systems

⁷ Petitioner’s contentions based on Klint are not premised on Petitioner’s proposed construction of “onto” as meaning “in contact with,” which is a construction we reject, as explained above. *See supra* section II.C.1.

where the pusher member passes through the collapsed prosthesis,” Petitioner cites the disclosure in Klint that expressly states the pusher member does not merely “pass through” the collapses prosthesis, but “engages the prosthesis . . . so that the prosthesis is partly pulled, partly pushed out of the receptacle.” Pet. 68 (citing Ex. 1019 ¶ 94). Petitioner’s argument is not persuasive because it is inconsistent with Klint. *See* Reply 9.

Second, Patent Owner argues that a person of ordinary skill in the art “would not view an already collapsed heart valve that then has a pusher member[] passed through it to be ‘collapsed onto’ the pusher member.” Resp. 43 (citing Ex. 2019 ¶¶ 173–176). Patent Owner directs us to nothing in Klint that supports its argument that the pusher member of Klint is passed through “an already collapsed heart valve.” Instead Petitioner relies on Dr. Dasi’s unsupported testimony, which we find inconsistent with Klint. *See* Ex. 2019 ¶ 175. Dr. Dasi includes “an example” of a pusher member that is “pushed into the prosthesis receptacle” after it “is in position for delivery.” *Id.* We give little weight to Dr. Dasi’s depiction because it is his own, unsupported creation and is inconsistent with Klint. Specifically, Klint states that the prosthesis may “be designed as an elongate member that extends coaxially inside the radially compressed prosthesis and *engages the prosthesis* at several locations along the length thereof so that the prostheses is partly pulled, partly pushed out of the receptacle.” Ex. 1019 ¶ 94. Dr. Dasi offers no explanation or support for the proposition that a pusher member being inserted into the prosthesis only after it is “in position for delivery” would engage the prosthesis at several locations and both pull and push the prosthesis out of the receptacle, as expressly taught by Klint. *Id.*

Relatedly, Patent Owner further argues that “instead of being ‘collapsed on the pusher member,’ a [person of ordinary skill in the art] would therefore understand that the valve device is next to the pusher member while the valve device is collapsed at the distal end of the delivery device in the prosthesis recepta[c]le,” and that “once the device of Klint’s second embodiment is in position for delivery, a [person of ordinary skill in the art] would understand that the elongate engagement member is pushed into the prosthesis recepta[c]le to engage the prosthesis ‘at several locations along the length thereof’ from the inside and push it out.” Resp. 44–45 (emphasis omitted). Patent Owner’s argument is fundamentally flawed because the Challenged Claims are directed to a device, not a method, and *when* the “prosthetic heart valve is collapsed onto the pusher member” is irrelevant. Thus, even if Klint were to be understood as teaching a pusher member that isn’t “pushed into the prosthesis” until the prosthesis is in position for delivery, that does not suggest that Klint fails to disclose the recited heart valve that “is collapsed onto the pusher member.” We further agree with Petitioner’s argument in its Reply that “Dr. Dasi’s own mock-up” shows a prosthesis collapsed onto a pusher member. In this regard we credit the testimony of Dr. Goldberg, because it is supported by Klint, as follows:

There is no limitation in Klint requiring that the elongate member does not engage with the prosthesis until “that prosthesis is already in place and ready to be released from its receptacle” (Exhibit 2019 at ¶ 176). Thus, a [person of ordinary skill in the art] would interpret Klint to include embodiments where the prosthesis was pre-loaded onto the pusher member before delivery to the implantation site. Under either scenario (i.e., pre-loaded or, as Dr. Dasi suggests, loaded during the course of the procedure), the prosthesis is “collapsed onto the pusher member to reside in a collapsed configuration on the pusher member” as

the prosthesis will be in a collapsed state on the pusher member prior to its deployment in a patient.

Ex. 1036 ¶ 10. We note Dr. Goldberg’s testimony above does not contradict the deposition testimony Petitioner directs us to in which Dr. Goldberg did not recall whether in Klint “it’s distinguished as to how those pieces [i.e., the elongate member and the prosthesis] are incorporated together.” Resp. 43–44 (quoting Ex. 2020, 66:18–67:2); *see also* Ex. 2020, 66:5–17 (Dr. Goldberg testifying that Klint does not require the elongate member to be pushed into the prosthesis receptacle because the prosthesis may be “just collapsed down over the catheter”).

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 Klint teaches that “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” limitation of claim 1.

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.

Bessler teaches, as shown by Petitioner, a distal end of the prosthetic heart valve located at a distal end of the moveable sheath. Pet. 63 (citing 4:63–66, 7:30–33, 7:48–53, Fig. 14; Ex. 1020 ¶ 148). Bessler also teaches, as shown by Petitioner, valve means that reside within the inner channel of the stent member in both collapsed and deployed configurations, as illustrated in Figures 4 and 5 of Bessler. Pet. 63–64 (citing Ex. 1006, 3:65–

4:1, 4:4–9, 5:15–23, Figs. 2–5; Ex. 1020 ¶¶ 130–133). Patent Owner does not dispute Petitioner’s contentions based on Bessler in regard to these recited features. 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 Bessler teaches these limitations of claim 1.

2. Differences Between the Subject Matter of Dependent Claim 2 and the Combination of Bessler, Leonhardt, and Klint

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 Bessler teaches a self-expanding stent member. Pet. 64 (citing Ex. 1006, 2:60–62; Ex. 1020 ¶ 151); *see generally* Resp. Specifically, Bessler teaches a stent member that is “self-expanding.” Ex. 1006, 2:60–63, 3:52–55. Based on the cited evidence of record, which we adopt as our own findings, Petitioner has shown that Bessler teaches the additional limitations of claim 2.

3. Differences Between the Subject Matter of Dependent Claim 3 and the Combination of Bessler, Leonhardt, and Klint

Claim 3 requires that “the stent member comprises nitinol.” Ex. 1001, 14:31–32. Petitioner shows, and Patent Owner does not dispute, that Bessler teaches a stent member that may be made from nitinol. Pet. 64 (citing Ex. 1006, 6:3–7; Ex. 1020 ¶ 152); *see generally* Resp. Specifically, Bessler states that “[t]he stent members of the artificial heart valves of the present invention may be made from . . . nitinol.” Ex. 1006, 6:3–7. Based on the cited evidence of record, which we adopt as our own findings, Petitioner has shown that Bessler teaches the additional limitations of claim 3.

4. *Differences Between the Subject Matter of Dependent Claim 4 and the Combination of Bessler, Leonhardt, and Klint*

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. Petitioner shows, and Patent Owner does not dispute, that Bessler teaches a stent member with barbs that are “disposed in two spaced-apart, circular configurations with the barbs in one circle extending in an upstream direction and the barbs in the other circle extending in a downstream direction.” Pet. 65–66 (quoting Ex. 1006, 4:14–18); *see generally* Resp. Based on the cited evidence of record, which we adopt as our own findings, Petitioner has shown that Bessler teaches the additional limitations of claim 4.

5. *Differences Between the Subject Matter of Dependent Claim 5 and the Combination of Bessler, Leonhardt, and Klint*

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.

Petitioner shows, and Patent Owner does not dispute, that Bessler teaches such a controlled release delivery system, noting that the '739 patent description “was copied nearly word-for-word from Bessler’s description.” Pet. 66 (citing Ex. 1006, 4:63–5:3, 7:38–42, 7:53–67, Figs. 14, 15). Dr. Dasi likewise acknowledges that “Bessler discusses a restraining method that would keep a valve device from popping out and hold it for controlled release using sutures and threads.” Ex. 2019 ¶ 188. Based on the cited evidence of record, which we adopt as our own findings, Petitioner has shown that Bessler teaches the additional limitations of claim 5.⁸

6. Reasons Supporting Obviousness Over Bessler, Leonhardt, and Klint

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 by the combination of Bessler, Leonhardt, and Klint, in light of the knowledge of a person of ordinary skill in the art. We further find that, to the extent a feature of Bessler 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 in light of the teachings of

⁸ Although Patent Owner argues that “a device made from the combination of Bessler and Klint would not have any mechanism for controlled release,” Patent Owner does not dispute that Bessler expressly teaches a controlled release mechanism, as shown by Petitioner, and instead argues Petitioner does not explain how the asserted art would have been combined. Resp. 65–66; Sur-reply 4–7. We address Patent Owner’s arguments below in regard to reasons supporting obviousness. *See infra* Section II.G.6.c.

Leonhardt and Klint. We focus our discussion below on the issues in dispute, addressing in particular the limitations regarding a “trumpet-like configuration,” a “delivery system,” “controlled release,” and, lastly, whether Petitioner’s reliance on Bessler was improper.

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

Petitioner provides persuasive reasons a person of ordinary skill in the art would have had reason to combine Bessler’s valve structure with the flared stent structure of Leonhardt with a reasonable expectation of success. Specifically, Petitioner reasons as follows:

Bessler describes a goal of its invention as “anchor[ing] the expanded stent member at a desired site.” EX1006 at 2:62–63. A [person of ordinary skill in the art] thus would have been motivated to combine Bessler’s valve structure with the flared stent structure of Leonhardt because Leonhardt teaches that the advantage of its flared stent structure is that the “flair[s] ... conform and seal to the tissue” (EX1012 at 6:21–22; *see also id.* at 4:60–65, 5:2–5). Thus, Bessler and Leonhardt both recognize improved anchoring and sealing as desired results. A [person of ordinary skill in the art] would have been motivated to combine Bessler with Leonhardt’s flared stent to achieve improved embedding and anchoring of the stent and would have found this slight modification of the stent member to change the shape at the ends to be a routine modification that would clearly work and yield predictable results. EX1020, ¶¶126–27.

Pet. 53 (citing Ex. 1020 ¶¶ 126–127). Petitioner further reasons that numerous other references in addition to Leonhardt “taught the use and advantages of a flared stent structure . . . each of which provide further motivation to combine the teachings of Bessler and Leonhardt.” *Id.* (citing Ex. 1007; Ex. 1009; Ex. 1010; Ex. 1011; Ex. 1016, 7; Ex. 1017; Ex. 1018, 167, 169).

Patent Owner argues that a person of ordinary skill in the art “would not have wanted to use a valve device that modified Bessler’s unusual single-wired stent into a flared shape—such as that of . . . Leonhardt—due to concerns that a flared shape would increase paravalvular leakage.” Resp. 51 (citing, e.g., Ex. 2019 ¶¶ 105–109, 124, 131); *see also id.* at 52 (arguing Bessler’s stent has an “increased susceptibility to bending inwards like a cantilever”); *id.* at 62 (arguing “Leonhardt’s fingers leave significant space between the portions of the stent that can contact native tissue,” which would purportedly allow blood to leak). Patent Owner’s argument is not persuasive because it is unsupported and contrary to the express disclosures of both Bessler and Leonhardt.

Patent Owner’s argument relies only on the opinion of Dr. Dasi, which is unsupported and speculative. *See* Ex. 2019 ¶¶ 105–109, 124, 131. The notion that a flared stent is more likely to leak is supported by no more than Dr. Dasi stating that “[a]dding a flared shape to Bessler’s sine-wave or zig-zag conformation would result in the bends of the wire being further apart from each other relative to a non-flared configuration, giving more space for blood to leak through as the blood pressure pushes the valve’s tissue inward away from the vessel wall.” *Id.* ¶ 124. Dr. Dasi does not state more blood would necessarily leak through, does not explain why “more space” in the stent equates to greater blood leakage, and does not support his statements with any evidence. Moreover, as shown by Petitioner, Dr. Dasi did not appreciate that Bessler is not limited to a “sine-wave or zig-zag conformation.” Bessler expressly states in regard to “the stent members of the artificial heart valves of the present invention,” that “[t]he configuration may be the zig-zag configuration shown or a sine wave configuration, *mesh configuration* or a similar configuration which will allow the stent to be

readily collapsible and self-expandable.” Ex. 1006, 6:6:3–11. Dr. Dasi, however, testified that, to his “knowledge, there’s no mesh pattern stent disclosed in Bessler.” Ex. 1039, 35:8–36:6. Moreover, as shown by Petitioner, Leonhardt expressly teaches the very benefit Petitioner relies upon as a reason for the asserted combination, stating the stent “will flair sufficiently to conform and seal to the tissue,” negating Patent Owner’s suggestion that only hindsight motivated the asserted combination. Pet 53; Ex. 1012, 6:19–22; Resp. 53 (citing *Innogenetics, N.V. v. Abbott Labs*, 512 F.3d 1363, 1373–74 (Fed. Cir. 2008)).

Next, Patent Owner argues that a person of ordinary skill in the art “would not have been motivated to combine Bessler and Leonhardt as Bessler relates to aortic valve replacement devices . . . and Petitioners rely on an embodiment from Leonhardt that includes a device having fingers that Leonhardt suggests ‘will flair sufficiently to conform and seal to the tissue’ at the mitral annulus.” Resp. 59–63 (citing, e.g., Ex. 1006, 1:64–2:8; Ex. 2020, 26:2–9). Patent Owner directs us to no persuasive evidence that Bessler is limited to aortic valve replacement devices, only that Bessler discusses as background “seminal articles related to TAVR [transcatheter aortic valve replacement].” Resp. 59 (citing Ex. 1006, 1:64–2:8; Ex. 1012, 5:41–42, 6:19–22; Ex. 2020, 26:2–9 (Dr. Goldberg stating that Bessler is “focused on aortic valve,” but he is unable to recall “if there’s any language in the patent that might allow it to be used in other valves”). Leonhardt, however, expressly states that it is not limited to the mitral heart valve. *See* Ex. 1012, 3:59–60, 9:63–67; Fig. 3 (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”).

According to Patent Owner, “the anchoring needs in an aortic valve are vastly different from those in a mitral valve,” and “Leonhardt would need to be positioned in the aortic valve in a different manner than Leonhardt shows for the mitral position,” because in the aortic valve “the fingers” of Leonhardt “would push the native leaflets towards the coronary ostia.” Resp. 60–61. Patent Owner’s argument lacks merit as the Challenged Claims are directed to a device that is not limited to applications where the native leaflets remain in place. Moreover, “[t]he 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.* Dr. Goldberg explains that “transcatheter replacement valve technology—at any valve location—was in its infancy in January 2002,” a person of ordinary skill in the art “at that time was interested in and willing to consider using any potentially beneficial features or improvements in prosthetic valve devices,” and the teachings of Bessler and Leonhardt “were not narrowly confined to application in a particular heart valve.” Ex. 1036 ¶¶ 6, 7 (citing, e.g., Ex. 1006, 2:26–29, claim 1; Ex. 1012, 4:56–65, 9:64–67).

We have also considered Patent Owner’s argument that a person of ordinary skill in the art “would also be concerned the fingers from Leonhardt’s bottom ring will directly interfere below the aorta-mitral curtain with the mitral anterior leaflet and the ventricular wall,” and that “because Leonhardt’s device is constructed with only a single connecting bar through its central region, it would not be able to exert sufficient radial force at the annular level to seal to the calcified native aortic leaflets.” Resp. 61–62; *see*

also id. (arguing that Dr. Goldberg “failed to take into consideration the amount of radial force that Leonhardt’s valve device could apply”). Patent Owner’s argument again presumes that the native valve leaflets are necessarily left in place, however, as Petitioner accurately explains, “Bessler teaches that the diseased native valve leaflets may be excised prior to implantation of the prosthesis, thus alleviating any purported concern of blocking the coronaries with the native valve leaflets.” Reply 7 (citing Ex. 1006, 2:63–67, 4:27–52, 6:32–50, 7:1–25; Ex. 1039, 95:19–96:2).

Patent Owner additionally argues that “[t]o the extent Petitioners are suggesting combining Bessler and Leonhardt for use in the mitral position,” Petitioner fails to show a reasonable expectation of success. Resp. 62–63. As explained above, Petitioner has shown sufficiently reasons a person of ordinary skill in the art would have applied the teachings of an aortic prosthesis with teachings of a mitral valve, and vice-versa. *See* Reply 6. Further, according to Patent Owner, in 2002 “no transcatheter mitral valve replacement device was available, no device had been in clinical trials, none was FDA approved, and indeed, no in-man transcatheter mitral valve replacement had been reported.” *Id.* The issues Patent Owner raises are not persuasive because they are directed to regulatory approval and market availability, not to whether the Challenged Claims would have been obvious to a person of ordinary skill in the art.

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 stent taught by Bessler to include the “flared at both ends in a trumpet-like configuration” of Leonhardt’s stent with a reasonable expectation of success.

b. “collapsed onto” (claim 1)

Petitioner shows that Klint expressly provides the reason and motivation for combining its teaching of “engagement means” with a delivery system as taught by Bessler and Leonhardt. Pet. 69–70. Specifically, Klint expressly states that the “engagement means” that act on the prosthesis “can also be designed as an elongate member that extends coaxially inside the radially compressed prosthesis and engages the prosthesis at several locations,” which “can be an advantage if the prosthesis has an extensive length, and in particular if it has a construction having a tendency to buckle when pushed upon.” Ex. 1019 ¶ 94; Ex. 1020 ¶ 162. Petitioner further shows that a person of ordinary skill in the art would have had a reasonable expectation of success, because it would have been a “simple substitution of one known prior art delivery system element (a pusher member adjacent to the collapsed prosthesis [as taught by Bessler]) with another (a pusher member that extends through the interior of the collapsed prosthesis [as taught by Leonhardt]).” Pet. 69 (citing Ex. 1020 ¶161).

Petitioner’s reasoning is persuasive because it is expressly supported by Klint, which teaches both a pusher member that is adjacent the collapsed prosthesis and, as an alternative, a pusher member that “also” extends coaxially inside of, and engages with, the compressed prosthesis. Ex. 1019 ¶ 94. Additionally, Dr. Goldberg supports Petitioner’s assertion that a person of ordinary skill in the art would have recognized that “collapsing the prosthesis onto the pusher member increases the precision of placement when the apparatus is held steady and released . . . rather than pushed out of a catheter.” Ex. 1020 ¶ 161 (citing Ex. 1007, 3:54–61, 5:15–22).

Patent Owner's arguments in opposition are deficient because they are unsupported and contrary to the teachings of the asserted art. Resp. 45–51. According to Patent Owner, even though Klint is broadly directed to a delivery system “for use in the delivery of a prosthesis to a treatment site in the vasculature,” a person of ordinary skill in the art would not have applied Klint's teaching of an “engagement means” that acts on the prosthesis “as an elongate member that extends coaxially inside the radially compress prosthesis” because it “would have risked damaging the valve device's leaflets.” Resp. 45–50 (citing, e.g., Ex. 2019 ¶¶ 178–183). Dr. Dasi's testimony in support is unsupported and fails to address the express teachings of Klint. *See* Ex. 2019 ¶¶ 178–183. In particular, Klint states, with regard to how the engagement means extending coaxially inside the radially compressed prosthesis engage the prosthesis at several locations, that “[t]hese engagement points or areas can be [a]ffected by radial projections, hooks, ridges, or another kind of engagement means such as a high friction material.” Ex. 1019 ¶ 94. Dr. Dasi states that Petitioner does not “account in any way for the new forces and new engagement means (hooks, etc.) that are applied to the heart valve device—and specifically the leaflets—using Klint's” engagement means extending coaxially inside the prosthesis and did not “account for what a person of ordinary skill would have done to try to avoid damage to the leaflets.” Ex. 2019 ¶¶ 180–181. Dr. Dasi further states as follows:

[T]he pusher member's engagement means are specifically meant to push and pull on the interior of the prosthesis and leaflets, increasing the risk of damaging the leaflets. Hooks and the like that are engaged with the valve device would also not have been expected to disengage easily as the valve device expands, increasing the risk of damaging the leaflets further and increasing the possibility that the valve

device does not successfully disengage from the pusher member. A person of skill would have understood that hooks, ridges, and the like could cause tears or damage to the leaflets during deployment, which would defeat the purpose of implanting a replacement device.

Id. ¶ 182; *see also id.* ¶ 183 (stating that the if a flared shape were added to Bessler’s stent, “using Klint’s pusher member would increase the risk of damaging the leaflets”).

We give little weight to Dr. Dasi’s opinion because it cites no evidence in support of his views. As Petitioner notes, Dr. Dasi does not address Klint’s express disclosure that the engagement means are not limited to hooks or the like, but also includes “another kind of engagement means such as a high friction material.” Ex. 1019 ¶ 94. Dr. Dasi does not suggest a risk of damage from “high friction material,” and in fact agreed with regard to the operation of the device of the ’739 patent that it is a combination of “friction” between the valve prosthesis and the tube that it is collapsed on and “geometrical features” that deploy the stent as claimed. Ex. 1039, 66:10–67:16 (stating in regard to the ’739 patent that “not only is the friction between the pusher member and the stent important, but also the geometry of the pusher member on both ends of the stent” and that “it’s a combination of everything together helping push the valve stent out”). Dr. Dasi’s testimony supports that the deployment system taught in Klint using high-friction material at engagement points between the engagement means and the stent corresponds to the deployment system of the ’739 patent. We further find persuasive in this regard Dr. Goldberg’s explanation, because it is supported by Klint, as follows:

[Patent Owner]’s and Dr. Dasi’s primary concern regarding the use of Klint’s pusher member with a replacement heart valve device appears to be the potential for damage to the

valve leaflets from the use of “hooks, ridges, and the like” (Paper No. 14 at 48) to engage the prosthesis. Paper No. 14 at 46–50, 64–65; Exhibit 2019 at ¶¶ 140–42, 180–83. A [person of ordinary skill in the art], however, would have avoided the risk of damage to the valve leaflets from the use of hooks as an engagement means by either (or both): (1) using “another kind of engagement means such as a high friction material” (Exhibit 1019 at ¶ [0094]), or threads or sutures (*id.* ¶¶ [0110], [0113] (see below)), as expressly disclosed in Klint; or (2) not locating a potentially sharp engagement means, like a hook, in the area of the prosthetic device where there is valve tissue. For example, Bessler’s Figure 5 illustrates that the valve tissue is only located at one end of the heart valve device (the inflow end) [illustrations omitted]. The rest of the device is the metal of the stent. A [person of ordinary skill in the art] using hooks as an engagement means could simply locate the engagement means along portions of the outflow end of the device, away from the valve tissue. There is no teaching or requirement in Klint that the engagement means must be hooks, or that the engagement means must be located in the area of the valve tissue.

Ex. 1036 ¶ 12. For substantially the same reasons we find not persuasive Patent Owner’s argument that the asserted combination would not be beneficial in permitting an operator to hold the apparatus steady because a person of ordinary skill in the art purportedly “would not have expected hooks and the like that are engaged with the valve device to disengage easily as the valve device expands.” Resp. 50 (citing Ex. 2019 ¶ 182). As explained above, Klint is not limited to “hooks and the like,” and Patent Owner fails to persuasively show that the purported risk of damage from hooks and like also applies to Klint’s teaching of the use of high-friction material. Lastly, Patent Owner argues that because Petitioner asserts the combination of Bessler and Leonhardt would beneficially permit the operator to hold the apparatus steady, a person of ordinary skill in the art would have had no motivation to further combine the teachings of Klint to

accomplish the same goal. Resp. 50–51. Patent Owner’s argument is not persuasive because Patent Owner cites no authority for the proposition that various combinations of art cannot be motivated by the same goal, and provides no evidence that the addition of the teachings of Klint to the combination of Bessler and Leonhardt would not result in an operator being able to hold the apparatus steadier than a combination of Bessler and Leonhardt without the teachings of Klint.

c. “controlled release mechanism” (claim 5)

As explained above, there is no dispute that Bessler, without modification, teaches a controlled release mechanism as claimed. *See supra* Section II.G.5. Patent Owner argues as follows:

A [person of ordinary skill in the art] would understand that substituting Klint’s pusher member for Bessler’s pusher member would mean that Bessler’s “sutures [that] are looped through an opening 106 in the pusher member 103 and then passed about a portion of the heart valve 101” would also be removed, as Klint contains no indication that it has an opening in its pusher member for sutures to be looped through.” Resp. 65–66 (citing Ex. 1006, 7:43–61; Ex. 2019 ¶ 188); Sur-reply 4–7.

Resp. 65. According to Patent Owner, “Bessler’s threads or sutures are the portions of that device that allow for controlled release of the valve device,” and “without those threads and sutures, Bessler’s valve device is not restrained; it will simply pop out of the sheath during deployment.” *Id.* at 66 (citing Ex. 2019 ¶¶ 189–190). Petitioner proposes applying the teachings of Klint to Bessler, not bodily incorporating the pusher member of Klint directly into the delivery system of Bessler. Petitioner does not propose eliminating from the asserted combination Bessler’s teaching of a controlled release system and need not provide a reason why an existing feature of Bessler isn’t removed from the asserted combination.

Moreover, Patent Owner’s argument lacks merit because a showing of obviousness does not require bodily incorporation. *Keller*, 642 F.2d at 425. Petitioner applies the teachings of Klint to Bessler, not bodily incorporating the pusher member of Klint into the Bessler. Petitioner further explains that there is nothing that prevents Bessler from retaining the controlled release mechanism it teaches when the teachings of Klint are applied. Petitioner notes that Patent Owner’s “entire argument appears to be anchored to Klint not having holes in its pusher member,” but “there is no suggestion that Bessler’s pusher member and controlled release sutures could not be combined with Klint’s pusher member, or that the resulting system could not be adapted to include locations to secure the sutures taught by Bessler.” Reply 15–16.

We have further considered Patent Owner’s additional arguments in its Sur-reply and find them unconvincing. Sur-reply 4–7. Patent Owner argues that “the fact that Bessler/Klint does not teach away from this modification does not equate to a [person of ordinary skill in the art] being motivated to make this modification—something Petitioner has never alleged.” *Id.* at 6. Petitioner, however, does not propose a modification of the controlled release mechanism Bessler teaches.

d. Whether Petitioner’s Reliance on Bessler was Improper

Patent Owner argues that a person of ordinary skill in the art “would not have started with Bessler’s valve design” because such person “would have recognized that Bessler’s valve device design was inferior to the state of the art in January 2002.” Resp. 24–27 (citing Ex. 2019 ¶ 103). According to Patent Owner, Bessler’s “sine-wave or zig-zag configuration stent design” was not “desirable” compared to a “network pattern,” which was purportedly “the most common and preferred stent design at the time.”

Id. at 25. Petitioner shows that the factual basis of Patent Owner’s argument about Bessler is simply wrong. “Bessler is not limited to a sine-wave or zig-zag configuration,” and “as an alternative, expressly teaches a ‘mesh configuration or a similar configuration which will allow the stent to be readily collapsible and self-expandable.” Reply 2 (quoting Ex. 1006, 6:7–11). Petitioner further shows that Dr. Dasi “ignored this express teaching,” and testified that to his “knowledge, there’s no mesh pattern stent disclosed in Bessler.” *Id.* (quoting Ex. 1039, 35:15–36:6).

Patent Owner further faults Dr. Goldberg for failing to “consider the patterns of the stents he purports to combine when rendering his opinions.” Resp. 26–27 (quoting Ex. 2020, 52:2–13). Dr. Goldberg stated that he recognized what the prior art was “speaking about” with regard to patterns of the stent, but he did not focus on it because “that didn’t strike me as being germane to the purposes of this IPR.” *Id.* Dr. Goldberg was correct as “the patterns of the stents” is not a feature of any of the Challenged Claims.

Patent Owner further argues various reasons why Bessler’s stent design was inferior, including, for example, that a person of ordinary skill in the art would not have expected it “to supply the uniform radial force needed to force the native leaflets out of place.” Resp. 27–28. The Challenged Claims, however, do not require the stent provide any specific “radial force” and are not limited to applications where the native valve leaflets remain in place. Similarly, Patent Owner’s assertion that “Bessler’s stent shape would have been expected to result in substantial paravalvular leakage” is supported only by conclusory and unsupported testimony from Dr. Dasi, which we find not persuasive. *See id.* at 28–29. Nor is there any evidence of what would have constituted “substantial” leakage, or any requirement in the Challenged Claims tied specifically to a degree of leakage. More

fundamentally, all of Patent Owner's arguments in this regard are misdirected because Petitioner is not 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 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").

*7. Collective Consideration of the Graham Factors*⁹

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 the combination of Bessler, Leonhardt, and Klint teaches each limitation of the Challenged Claims and has also shown that an ordinarily skilled artisan would have had a reason to modify Bessler in light of Leonhardt and Klint, 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 Bessler, Leonhardt, and Klint.

⁹ The parties did not provide or discuss objective evidence of nonobviousness. *See generally* Pet.; Resp.

H. Alleged Obviousness over Bessler, Teitelbaum, and Klint

Petitioner contends the Challenged Claims would have been obvious over Bessler in combination with Teitelbaum and Klint. Pet. 47–70; Reply 1–17. According to Petitioner, the Specification of the ’739 patent “copies verbatim (or nearly so) over one hundred lines from Bessler . . . and Teitelbaum.” Pet. 4–11. Petitioner argues that Bessler teaches “nearly all features” of the Challenged Claims other than that the stent member “flares at both ends in a trumpet-like configuration.” *Id.* at 11–15. As to the stent member that “flares at both ends in a trumpet-like configuration,” Petitioner relies on Teitelbaum. *Id.* at 15–16. Petitioner also relies on Klint as teaching a delivery system for a prosthetic valve that is collapsed onto a pusher member, as recited by claim 1 of the ’739 patent. *Id.* at 66–68.

For the same reasons discussed above with regard to obviousness over the combination of Bessler, Leonhardt, and Klint, Petitioner has shown by a preponderance of the evidence that all of the features of the Challenged Claims, other than a stent member “that flares at both ends in a trumpet-like configuration” are taught by Bessler and Klint. *See supra* Section II.G.1 to II.G.5. As to the “trumpet-like configuration,” Petitioner shows that the ’739 patent copied its description nearly verbatim from Teitelbaum. *Id.* at 15–16 (comparing, e.g., Ex. 1001, 7:59–67 to Ex. 1007, 5:52–63). Specifically, Teitelbaum teaches stent member with a “tubular structure” that “[a]way from its central portion ... flares markedly at both ends in a trumpet-like configuration.” Ex. 1007, 2:21–29, 5:51–65, Fig. 2. Thus, there is no dispute that Teitelbaum teaches a stent member “that flares at both ends in a trumpet-like configuration,” as recited by claim 1.

In support of the asserted combination of Teitelbaum with Bessler and Klint, Petitioner provides the following reasoning, which we determine is persuasive:

Both Teitelbaum and Bessler recognize the desirability of “anchor[ing] the expanded stent member at a desired site” (EX1006 at 2:62–63). Bessler teaches the optional use of barbs to aid in achieving this goal (*id.*); Teitelbaum explains that the purpose of the flared stent is to “maintain the position of this component across the native valve following deployment” (EX1007 at 2:34–36, 5:63–65). Thus, a [person of ordinary skill in the art] would have been motivated to modify Bessler’s device by using a flared stent as taught by Teitelbaum in conjunction with, or as an alternative to, Bessler’s optional barbs in order to better anchor the device in place and improve sealing, reducing leakage of blood around the valve device (known as “paravalvular leakage”). EX1020, ¶124. A [person of ordinary skill in the art] would have found this slight modification of the stent member to change the shape at the ends to be a routine modification that would clearly work and yield predictable results. *Id.* In addition to Teitelbaum, other investigators had already taught the use and advantages of a flared stent structure, including Leonhardt (EX1012), Cribier (EX1017), the Wallstent (EX1016 at 7; EX1018 at 167, 169), Garrison (EX1010), Gabbay (EX1009), and Bailey (EX1011). Each of these prior art teachings provide further motivation to combine Bessler with Teitelbaum. Gabbay, for example, provides further confirmation that a person of ordinary skill in the art would have been motivated to combine the use of barbs with a trumpet-like stent structure for improved securement and engagement with the surrounding tissue. EX1009 at ¶[0048] (“[T]he spike portions 38’ and 40’ may extend radially outwardly from the stent in different directions. In addition, the inflow end 32’ also may flare outwardly for engagement with surrounding tissue when implanted.”). And Bailey notes that if the embodiment of Bessler without barbs is selected there is an increased risk of device migration, further bolstering the motivation to modify Bessler with a trumpet-like shape to secure the device in place. EX1011 at 4:17-18 (“the [Bessler] device is unstable and prone to

migration if barbs are omitted”). Thus, the use of a stent with a trumpet-like configuration, including its implementation and advantages, was well-known to a [person of ordinary skill in the art] by January 4, 2002. EX1020, ¶124.

Pet. 50–52.

Patent Owner’s arguments in opposition to the combination of Bessler, Teitelbaum, and Klint are substantially the same as the arguments Patent Owner raises with regard to the combination of Bessler, Leonhardt and Klint, addressed above. In fact, the parties address both of these grounds together in their briefing. Pet. 47–70; Resp. 24–66. Petitioner relies on Teitelbaum as disclosing a stent member with a “trumpet-like configuration” in place of Leonhardt’s teaching of the same feature, and asserts that substantially the same reasons support the combination of either Leonhardt or Teitelbaum with Bessler and Klint. Pet. 47–70.

Patent Owner’s arguments specific to Teitelbaum in opposition are not persuasive. Resp. 53–58. Patent Owner argues that Bessler and Teitelbaum would not be combined by a person of ordinary skill in the art because Bessler relates to aortic valve replacement devices and Teitelbaum relates to mitral valve replacement devices and that Petitioner has not shown that a person of ordinary skill in the art would “have had a reasonable expectation that this combination would have been successful.” Resp. 54–58 (citing, e.g., Ex. 2019 ¶¶ 118–124). Petitioner, however, shows that Bessler and Teitelbaum are not “limited to a prosthesis for a particular heart valve, which Dr. Dasi does not dispute.” Reply 6 (citing Ex. 1006, 2:26–29, claim 1; Ex. 1007, 4:38–44, claims 1, 5; Ex. 1039, 98:5–108:13; Ex. 1036 ¶ 7). For the same reasons detailed above, we are persuaded that a person of ordinary skill in the art would not have considered the teachings of Teitelbaum in combination with Bessler even if Teitelbaum were focused on

mitral valves. *See supra* Section II.6.a. Patent Owner’s additional arguments in opposition to the combination of Bessler, Teitelbaum, and Klint mirror the arguments it asserts in opposition to the combination of Bessler, Leonhardt and Klint. Resp. 24–66. Accordingly, we find Patent Owner’s arguments are not persuasive for the same reasons discussed above.

Based upon our consideration of the entire record, and for the reasons discussed above, we determine Petitioner has shown by a preponderance of the evidence that the combination of Bessler, Teitelbaum, and Klint teaches each limitation of the Challenged Claims and has also shown that an ordinarily skilled artisan would have had a reason to modify Bessler in light of Teitelbaum and Klint, 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 Bessler, Teitelbaum, and Klint.

I. Alleged Anticipation by Paniagua

Petitioner argues that the Challenged Claims are anticipated by Paniagua, that publication of the ’688 Application, which is the grandparent application to the application that issued as the ’739 patent. Pet. 42–47. In summary, Petitioner argues that “the [S]pecification of the ’739 [p]atent fails to provide written description support for a valve means with two to four individual leaflets made from multiple separate pieces of valve material as claimed in each of the claims,” that “[a]s a result, [Paniagua] is prior art under 35 U.S.C. §102(b),” and that “[b]ecause the specification of Paniagua

is identical to the '739 [p]atent's, it anticipates each and every limitation of Claims 1–5.” *Id.* at 42–43.

“Written description is a question of fact, judged from the perspective of one of ordinary skill in the art as of the relevant filing date.” *Immunex Corp. v. Sandoz Inc.*, 964 F.3d 1049, 1063 (Fed. Cir. 2020). In this regard, the Federal Circuit recently explained as follows:

Under our written-description case law, the “critical inquiry” is whether the relevant artisan reading the specification “would understand that the inventor was in possession of [the claimed invention] at the time of filing.” *Alcon Research Ltd. v. Barr Labs., Inc.*, 745 F.3d 1180, 1190–91 (Fed. Cir. 2014). “[T]he specification must describe an invention understandable to that skilled artisan and show that the inventor actually invented the invention claimed.” [*Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc)]. Actual reduction to practice is not a requirement. *Id.* at 1352; *Centocor Ortho Biotech, Inc. v. Abbott Labs.*, 636 F.3d 1341, 1353 (Fed. Cir. 2011); *Univ. of Rochester v. G.D. Searle & Co., Inc.*, 358 F.3d 916, 926 (Fed. Cir. 2004). Ascertaining the required possession starts with an accurate understanding of the claimed invention, *Amgen Inc. v. Sanofi*, 872 F.3d 1367, 1373 (Fed. Cir. 2017), and proceeds to an “objective inquiry into the four corners of the specification,” *Ariad*, 598 F.3d at 1351. “[A] patentee may rely on information that is well-known in the art” to the extent it informs how a relevant artisan would reasonably understand what is actually described in the specification. *Ajinomoto Co., Inc. v. ITC*, 932 F.3d 1342, 1359 (Fed. Cir. 2019) (quoting *Boston Scientific Corp. v. Johnson & Johnson*, 647 F.3d 1353, 1366 (Fed. Cir. 2011)) (internal quotation marks omitted); see also *Centrak, Inc. v. Sonitor Technologies, Inc.*, 915 F.3d 1360, 1369 (Fed. Cir. 2019).

BASF Plant Science LP v. Commonwealth Sci. and Indus. Research Organisation, No. 2020-1415, 2022 WL 776064, at *11 (Fed. Cir. Mar. 15, 2022).

Claim 1 of the '739 patent recites “a valve means including two to four individual leaflets made of fixed pericardial tissue.” Ex. 1001, 14:11–12. Petitioner argues that this claim language is “not limited to a single-piece valve design but broadly . . . cover[s] *both* valve means where the leaflets are made from a single piece of tissue material *and* valve means where the leaflets are constructed from multiple, separate pieces of tissue material.” Pet. 34. There is *no dispute* that Paniagua describes in writing valve means where the leaflets are constructed from multiple, separate pieces of tissue. Ex. 1015 ¶¶ 18–21; Ex. 1001 3:55–4:32.

Instead, Petitioner argues that the '739 patent “draws a real distinction between [transcatheter heart valves] where the valve leaflets are made from a single piece of tissue material and [transcatheter heart valves] where the leaflets are formed by cutting and suturing multiple separate pieces of tissue together.” *Id.* Because of this “real distinction” between one piece leaflets and multiple piece leaflets, Petitioner contends the '739 patent “claims a broader scope of invention than the '266 Application supports,” such that the '739 patent has priority only to the '650 Application, which included for the first time the claim language at issue. *Id.* at 34–37.

Patent Owner cites no legal authority in the Petition for the proposition that the scope of written description support for later filed claims turns on whether an application specification makes a “real distinction” from the prior art, as described in the application. Petitioner directs us in the Petition to *Dr. Reddy's Labs. S.A. v. Indivior UK Ltd.*, IPR2019-00329, Paper 49 at 82–86 (PTAB June 2, 2020) for the proposition that “challenged claims [were held] invalid as anticipated by earlier, related application publication with identical disclosure, which patent owner could not properly claim priority to because it did not provide written description support for

[the] full scope of [the] challenged claims.” Pet. 2. In the Institution Decision we explained, based on the record at that time, that Petitioner’s reliance on the Board’s nonprecedential decision in *Dr. Reddy’s* was misplaced, stating as follows:

In *Dr. Reddy’s* the Board found in regard to a composition claim that “the disputed ranges and ratios in [the challenged claims] place limits on the amount of polymer in the claimed films but that no such limits are disclosed in the [priority application] sufficient to provide written description support for those limitations.” IPR2019-00329, Paper 49 at 79. The claims at issue in this case are not composition claims with recited ranges and do not recite any limit on the number of pieces used to make the recited leaflets.

Moreover, turning to the Specification of the ’739 patent, which Petitioner concedes is the same as its parent and grandparent, we find ample written disclosure of one piece leaflets and multiple piece leaflets. *See, e.g.*, Ex. 1001, 3:36–4:32, 4:51–59; *see also* Prelim. Resp. 39–40 (describing how the ’739 patent discloses sewing valves to a stent). For example, the ’739 patent states “one prior replacement heart valve requires each sculpted leaflet to be trimmed in a way that forms an extended flap,” that the “tip of each pericardial tissue strand is sutured directly to a papillary muscle,” and that “[e]ach strand extends from the center of a leaflet in the valve, and each strand is sutured directly to either an anterior [or] posterior papillary muscle.” Ex. 1001, 3:55–64.

Inst. Dec. 42–43.

Following institution, Patent Owner argues that the Specification “describes prior art heart valves with leaflets made from multiple pieces of tissue material.” Resp. 20–21 (citing Ex. 1001, 3:41–44, 3:55–4:32, 4:51–57). According to Patent Owner, “[t]hese disclosures show that the inventors [had] possession of valve leaflets made from more than one sheet of tissue material.” *Id.* at 21 (citing Ex. 2019 ¶¶ 198–202). Patent Owner also reasons that although the ’739 patent describes a preferred embodiment

using a single piece of valve material to create the valve body and leaflets, the invention is not limited to a preferred embodiment. *Id.* (citing Ex. 1001, 9:8–11).

Additionally, Patent Owner argues that the claims of the '739 patent are directed to a product, not to a method of making that product or to a product-by-process, and that “all Applicants needed to provide was written description for the product—here the claimed valve—and enable it.” *Id.* at 22. According to Patent Owner, “the '739 patent’s term ‘leaflets’ is not limited as Petitioners allege because the scope of the claims—and the disclosure—includes leaflets in general, along with a host of other claim limitations relating to overall assembly.” *Id.* at 23.

Lastly, Patent Owner suggests that the issue Patent Owner raises is not a lack of written description, but disavowal, which Petitioner “do[es] not mention” and fails to show. *Id.* Patent Owner argues that “Petitioner[] do[es] not and cannot point to any language in the '739 [S]pecification rising to this level of explicit disclaimer.” *Id.*

In its Reply, according to Petitioner, “[t]he question here is not whether multi-piece leaflet valves were known in 2002, but whether the specification describes using valve leaflets made from multiple pieces in the *invention*. Reply 17. Petitioner identifies “[t]wo key portions” of the specification that it argues “make clear that it does not.” *Id.* We disagree.

First, Petitioner argues that the '739 patent “describes multipiece constructions as a shortcoming of the prior art.” Reply 17–18 (citing Ex. 1001, 4:45–59). The portion of the '739 patent cited by Petitioner does not support its assertion, but instead, states as follows:

A shortcoming of prior artificial tissue valves has been the inability to effectively simulate the exact anatomy of a native

heart valve. Although transplanted human or porcine aortic valves have the gross appearance of native aortic valves, the fixation process (freezing with liquid nitrogen, and chemical treatment, respectively) alters the histologic characteristics of the valve tissue. Porcine and bovine pericardial valves not only require chemical preparation (usually involving fixation with glutaraldehyde), but the leaflets must be sutured to cloth covered stents in order to hold the leaflets in position for proper opening and closing of the valve. Additionally, the leaflets of most such tissue valves are constructed by cutting or suturing the tissue material, resulting in leaflets that do not duplicate the form and function of a real valve and are more susceptible to failure.

Ex. 1001, 4:45–59. The excerpt of the '739 patent above does not expressly address “multipiece constructions” as Petitioner asserts. It identifies a shortcoming in the “inability to effectively simulate the exact anatomy of a native heart valve,” not in the use of “multipiece constructions.” Moreover, it discusses “transplanted human or porcine aortic valves,” and does not suggest that “human or porcine aortic valves” are only made of a “multipiece construction.” Lastly, it says leaflets are constructed by “cutting or suturing the tissue material,” but says nothing of whether the material is a single piece of material or is a “multipiece construction.” See Ex. 1001, 3:41–54.

Second, Petitioner argues that the '739 patent “describes the invention as *requiring* that the valve leaflets be formed from a single piece of material.” Reply 18 (citing Ex. 1001, 9:8–25) (emphasis added). The cited portion of the '739 patent does not support Petitioner’s assertion, but instead states as follows

Although a *preferred embodiment* of the invention comprises a single piece of valve material folded to create the valve body and a leaflet-forming portion that has no cuts or sutures, the inventors have discovered that as long as the leaflet portion of the valve itself is formed from a single piece of biocompatible valve

material, the other portions of the valve can be formed by suturing of one or more separate pieces of material without losing the novel and improved qualities of the present invention. This allows for the valve to be made even stronger, more durable and easier to make. This alternate embodiment comprises a leaflet forming layer made of a single piece of valve material attached to a separate piece forming the valve body having a folded cuff portion. The single piece leaflet forming layer is preferably cylindrical in shape and can be formed with or without folding. In this embodiment the single piece leaflet layer can itself be attached to the stent with or without a cylindrical cuff portion.

Ex. 1001, 9:8–24 (emphasis added). Thus, in a preferred embodiment “the novel and improved qualities of the present invention” are retained whether the “valve body and a leaflet-forming portion” are made of a single piece of material or if the “leaflet forming portion,” alone, is made of a single piece of material. *Id.* The claimed invention of the ’739 patent, however, is not limited to the “leaflet forming portion” of a valve, and the cited portion of the Specification reproduced above does not explicitly require every iteration of the invention claimed to include the “leaflet forming portion” of a valve to be made of a single piece of material.

Petitioner further directs us for the first time in its Reply to *Rivera v. ITC*, 857 F.3d 1315, 1321 (Fed. Cir. 2017). Reply 19. The cited portion of *Rivera* does not support Petitioner’s contentions. *Rivera* states that “the question is whether a pod adaptor assembly intended to allow compatibility between distinct brewing systems, also supports an undisclosed configuration that eliminates a fundamental component of one of those systems (i.e., the ‘pod’) through integration.” *Rivera*, 857 F.3d at 1321. In *Rivera*, the court explained “[t]here is no hint or discussion of a cartridge or pod adaptor assembly or receptacle that also serves as the ‘pod’ in the patent at issue, and that the appellee’s expert explained that the assemblies in the

patent at issue “would not function” “without a separate ‘pod’.” *Id.* at 1321.

The court concluded as follows:

Whatever a “pod” is, the specification indicates that it is distinct from the receptacle; for the integral filter cartridge to be supported by the written description definition of a “pod” it must act as both a “pod” and a receptacle. But nothing in the specification shows that the “pod” and the receptacle may be the same structure.

Id. (further noting that the patent owner’s expert agreed that the patent at issue was “silent” on the option of an integrated pod and receptacle); *see also id.* at 1322 (stating that “nothing” in the disclosure of the patent at issue “indicates the possibility of a cartridge with an integrated filter”). Petitioner fails to show that any of the relevant circumstances presented in *Rivera* are implicated in this proceeding. *See* Reply 19; *see also* Sur-reply 2–3 (arguing that “*Rivera* involved a single invention, and the evidence showed that this invention would not work with the element in question” (emphasis omitted)). Most notably, as discussed above, the Specification of the ’739 patent is not “silent” as to the use of multiple pieces of material for the valve leaflets; it is expressly described in the background of the invention.

Petitioner argues, and we agree, that “written description support is required for the full scope” of the Challenged Claims, however, there is no dispute that Paniagua discusses and describes a valve with valve leaflets made of multiple pieces of material. *See* Reply 18; Ex. 1015 ¶¶ 18–21. Further, the claims of the ’739 patent are not merely directed to a “leaflet-forming portion” of a valve means, as Petitioner recognizes. Reply 18. Claim 1 is directed to “an assembly,” comprising “a prosthetic heart valve,” “a stent member,” “a valve means,” and “a delivery system.” Ex. 1001,

14:2–29. Patent Owner argues that the ’739 patent “contains multiple components,” and further explains as follows.

[U]nlike in *Rivera*, Petitioner has provided no evidence that any of these inventive components—including those recited in the claims—*would not work* with the multiple piece leaflets that the patent discloses. Rather, the ’739’s Applicants invented, enabled, and described multiple components of a delivery system, each with its own advantages or purposes. And where an invention “possess[es] a number of advantages or purposes, [] there is no requirement that every claim directed to that invention be limited to encompass all of them.” *See Praxair, Inc. v. ATMI, Inc.*, 543 F.3d 1306, 1325 (Fed. Cir. 2008).

Sur-reply 3. Petitioner does not argue disavowal of any claimed feature and identifies no authority as a basis to disregard the written description of elements in the patent specification, even if those elements are arguably contrary to other unclaimed innovations also described in the patent.

Based on our full review of the record, we find that a preponderance of the evidence demonstrates that the ’739 patent is entitled to priority to the ’266 Application. The Specification of the ’739 patent provides a written description of one piece leaflets and multiple piece leaflets, as explained above, and the claims of the ’739 patent are not limited to a preferred embodiment that requires one-piece leaflets. Accordingly, Petitioner has not shown by a preponderance of the evidence that any of the Challenged Claims is anticipated by Paniagua.

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. 67. 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)/Basis	Claim(s) Shown Unpatentable	Claim(s) Not Shown Unpatentable
1–5	103(a)	Bessler, Teitelbaum		1–5
1–5	103(a)	Bessler, Leonhardt		1–5
1–5	103(a)	Bessler, Leonhardt, Klint	1–5	
1–5	103(a)	Bessler, Teitelbaum, Klint	1–5	
1–5	102(b)	Paniagua		1–5
Overall Outcome			1–5	

V. ORDER¹⁰

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.

¹⁰ 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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