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Paper 9
Date: August 16, 2021

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MEDTRONIC COREVALVE LLC and MEDTRONIC, INC.,
Petitioner,

v.

SPEYSIDE MEDICAL, LLC,
Patent Owner.

IPR2021-00239
Patent 8,377,118 B2

Before PATRICK R. SCANLON, JAMES J. MAYBERRY, and MICHELLE N. ANKENBRAND, *Administrative Patent Judges.*

SCANLON, *Administrative Patent Judge*.

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

I. INTRODUCTION

Medtronic CoreValve LLC and Medtronic, Inc. (collectively, "Petitioner") filed a Petition (Paper 2, "Pet.") requesting an *inter partes* review of claims 1, 2, 5, 7–11, 13, 14, and 18–23 of U.S. Patent No. 8,377,118 B2 (Ex. 1001, "the '118 patent"). Speyside Medical, LLC ("Patent Owner") filed a Preliminary Response (Paper 6, "Prelim. Resp."). With our authorization, Petitioner filed a Preliminary Reply (Paper 7, "Prelim. Reply") and Patent Owner filed a Preliminary Sur-reply (Paper 8, "Prelim. Sur-reply").

We have authority to determine whether to institute an *inter partes* review. *See* 35 U.S.C. § 314 (2018); 37 C.F.R. § 42.4(a) (2020). To institute an *inter partes* review, we must determine that the information presented in the Petition shows "a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314(a). For the reasons set forth below, we determine that the information presented in the Petition establishes a reasonable likelihood that Petitioner will prevail with respect to at least one challenged claim. Accordingly, an *inter partes* review of all of the claims and all of the grounds presented in the Petition is hereby instituted. *See SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1354, 1359–60 (2018); *see also PGS Geophysical AS v. Iancu*, 891 F.3d 1354, 1360 (Fed. Cir. 2018) (interpreting the statute to require "a simple yes-or-no institution choice respecting a petition, embracing all challenges included in the petition"); Patent Trial and Appeal Board Consolidated Trial Practice Guide 64 (Nov. 2019) ("The Board will not institute on fewer than all claims or all challenges in a petition."), *available at* https://www.uspto.gov/TrialPracticeGuideConsolidated ("TPG").

II. BACKGROUND

A. Real Parties in Interest

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

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

B. Related Matters

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

C. The '118 Patent

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

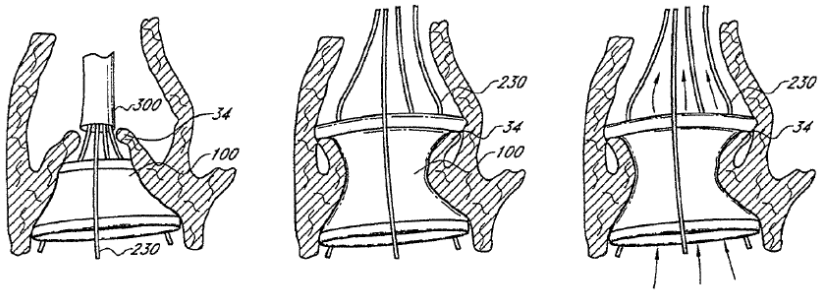


FIG. 47A FIG. 47B FIG. 47C

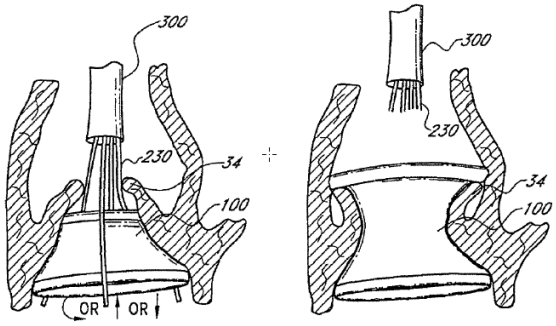


FIG. 47D FIG. 47E

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

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

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

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

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

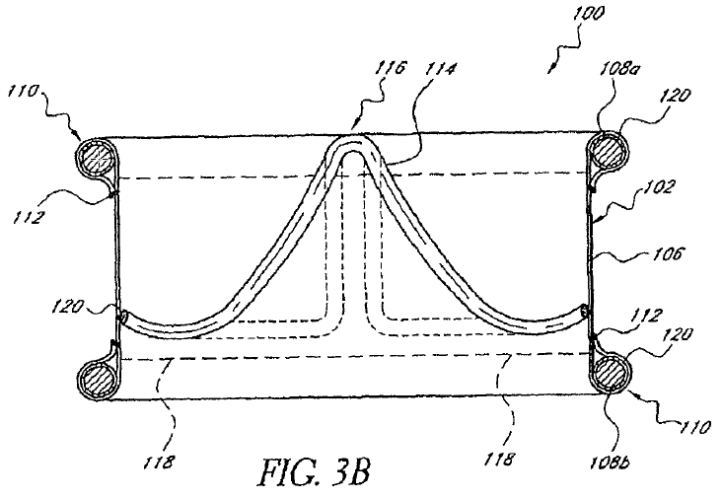


FIG. 3B

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

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

D. Illustrative Claim

Of the challenged claims, claim 1 is the sole independent claim. Claim 1 is reproduced below:

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

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

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

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

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

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

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

evaluating the position of the carrier element;

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

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

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

opposing sides of the native aortic heart valve in the second expanded configuration;

using the carrier element to exclude the native aortic heart valve in the second expanded configuration;

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

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

Ex. 1001, 79:24–67.

E. Asserted Grounds of Unpatentability

Petitioner contends that the challenged claims would have been unpatentable on the following grounds:[1]

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

Pet. 9. Petitioner supports its challenge with the Declaration of Dr. William J. Drasler (Ex. 1002).

[1] The Leahy-Smith America Invents Act ("AIA") included revisions to 35 U.S.C. § 103 that became effective on March 16, 2013. Pub. L. No. 112-29, §§ 3(c), 3(n)(1), 125 Stat. 284, 287, 293 (2011). Because the application from which the '118 patent issued has an effective filing date prior to March 16, 2013, we apply the pre-AIA version of § 103.
[2] Leonhardt et al., US 5,957,949, issued Sept. 28, 1999 (Ex. 1004).
[3] Gabbay, US 2002/0032481 A1, published Mar. 14, 2002 (Ex. 1046).
[4] Bailey, et al., US 2003/00233000 A1, published Jan. 30, 2003 (Ex. 1005).
[5] Moulopoulos, US 3,671,979, issued June 27, 1972 (Ex. 1019).

III. ANALYSIS

A. Level of Ordinary Skill in the Art

In determining whether an invention would have been obvious at the time it was made, 35 U.S.C. § 103 requires us to resolve the level of ordinary skill in the pertinent art at the time of the effective filing date of the claimed invention. *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966). The person of ordinary skill in the art is a hypothetical person who is presumed to have known the relevant art. *In re GPAC, Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995). Factors that may be considered in determining the level of ordinary skill in the art include, but are not limited to, the types of problems encountered in the art, the sophistication of the technology, and educational level of active workers in the field. *Id.* In a given case, one or more factors may predominate. *Id.*

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

For the purpose of its Preliminary Response, Patent Owner applies, and does not dispute, Petitioner's proposed level of ordinary skill in the art. Prelim. Resp. 19.

Based on our review of the record before us, we find that Petitioner's stated level of ordinary skill in the art is reasonable because it is consistent

with the evidence of record, including the asserted prior art. Accordingly, for the purpose of this Decision, we adopt Petitioner's definition.

B. Claim Construction

In *inter partes* reviews, the Board interprets claim language using the district-court-type standard, as described in *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (en banc). *See* 37 C.F.R. § 42.100(b) (2020). Under that standard, we generally give claim terms their ordinary and customary meaning, as would be understood by a person of ordinary skill in the art at the time of the invention, in light of the language of the claims, the specification, and the prosecution history. *See Phillips*, 415 F.3d at 1313–14. Although extrinsic evidence, when available, may also be useful when construing claim terms under this standard, extrinsic evidence should be considered in the context of the intrinsic evidence. *See id.* at 1317–19.

Petitioner argues that "[a]ll claim terms should be construed according to their plain and ordinary meaning as would have been understood by a [person having ordinary skill in the art] in view of the specification." Pet. 22 (citing Ex. 1002 ¶ 64). Regarding the limitation "a length of the carrier element in the moveable configuration being substantially equal to or less than a length of the carrier element in the first expanded configuration" of claim 1, Petitioner adds that the prior art discloses this limitation regardless of the exact metes and bounds of the term "substantially." *Id.* at 23 (citing Pet. 46–48; Ex. 1002 ¶¶ 66–67).

In response, Patent Owner argues that, for two claim terms, Petitioner's position is "contrary to the specification and prosecution history of the '118 Patent and/or inconsistent with positions [Petitioner] is advancing in corresponding district court litigation." Prelim. Resp. 19–20. For a third claim term, Patent Owner argues that Petitioner ignores its

district court position altogether. *Id.* at 20. We address these claim terms below.

1. "a length of the carrier element in the moveable configuration being substantially equal to or less than a length of the carrier element in the first expanded configuration" and "vicinity of the native aortic heart valve"

Patent Owner does not propose an express construction for either of these claim terms from claim 1. Prelim. Resp. 19–27. For both of these terms, however, Patent Owner argues that Petitioner fails to specify the metes and bounds of the terms or explain how the prior art falls within those metes and bounds. *Id.* at 20–21. Thus, according to Patent Owner, Petitioner fails to meet its burden under 37 C.F.R. § 42.104. *Id.* at 20, 22.

More specifically, Patent Owner argues that Petitioner's assertion regarding the term "substantially" suggests that the metes and bounds of this term "need to be defined in order to determine the scope of the claims, but [Petitioner] provides no such analysis or definition in the claim construction section of its Petition or in its analysis of the prior art." *Id.* at 49–50 (citing Pet. 23, 46–48). According to Patent Owner, Petitioner takes this approach because it "contends that the claim term is indefinite in the parallel district court action and wishes to avoid any admission that the scope of the claim term can be reasonably ascertained." *Id.* at 50 (citing Exs. 2001, 2002). Patent Owner argues that Petitioner's position in district court that the phrase "substantially" is indefinite does not absolve Petitioner of its obligation to identify how the claims should be construed in this proceeding. *Id.* at 50–51 (citing *CareFusion Corp. v. Baxter Int'l, Inc.*, IPR2016-01456, Paper 9 at 8–10, 18 (PTAB Feb. 6, 2017)). Patent Owner makes similar arguments with respect to the claim term "vicinity." *Id.* at 51–52 (citing *CareFusion*, Paper 9 at 8–10).

The petitioner in *CareFusion* argued that (1) certain claim limitations were means-plus-function terms under 35 U.S.C. § 112 ¶ 6, and (2) these means-plus-function terms were indefinite and thus not amenable to claim construction. *CareFusion*, Paper 9 at 7–8. The Board determined that the petitioner, in taking this position, had failed to identify the structure, material, or acts corresponding to the claimed function, and the assertion that the claim terms were indefinite did not excuse this failure to provide the required claim construction. *Id.* at 9. The present case can be distinguished from *CareFusion* because neither party is asserting that the claim terms in question are means-plus-function terms under 35 U.S.C. § 112 ¶ 6. As such, there is no indication that Petitioner fails to identify the specific portions of the specification that describe the structure, material, or acts corresponding to a claimed function, as required by 37 C.F.R. § 42.104(b)(3). Thus, for purposes of this Decision, we determine that Petitioner's position with respect to claim construction complies with 37 C.F.R. § 42.204(b)(3).

2. "opposing sides of the native aortic heart valve"

Petitioner does not propose an express construction for this limitation (Pet. 22–23), but does identify opposing portions of the lateral wall of a native heart valve in Leonhardt as "opposing sides" (*id.* at 38–39). Patent Owner argues that we should reject this "interpretation" of the claim term "opposing sides of the native aortic heart valve." Prelim. Resp. 22, 27 (citing *Phillips*, 415 F.3d at 1313; *Medrad, Inc. v. MRI Devices Corp.*, 401 F.3d 1313, 1319 (Fed. Cir. 2005)). Instead, Patent Owner argues that we should construe the "opposing sides" limitation to mean "the native heart valve's upstream and downstream sides." *Id.* at 22.

Patent Owner presents several arguments in support of this proposed construction. For example, Patent Owner argues that the Specification of the

'118 patent "explains that the disclosed replacement valve is deployed 'across the native valve annulus.'" Prelim. Resp. 24 (citing Ex. 1001, 73:42–49). Patent Owner further asserts that the Specification "explains that 'across the native valve annulus' means that the valve extends to either side of the valve annulus." *Id.* at 25 (citing Ex. 1001, 49:46–48). In addition, Patent Owner asserts that Figure 2A of the '118 patent shows a prosthetic valve carrier element extending across the native aortic valve, with the distal and proximal ends of the carrier element being positioned upstream and downstream of the valve. *Id.* at 26 (citing Ex. 1001, 11:16–26). Patent Owner also argues that applicant arguments made during the prosecution of the '118 patent "underscored that the step of positioning the replacement valve refers to its ***axial*** location relative to the native valve, ***not*** its lateral or outward expansion." *Id.* (citing Ex. 1003, 2072).

In view of our analysis below (*see infra* § III.E.3), we do not discern a need to construe this term explicitly because doing so would have no effect on the analysis. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (stating that "we need only construe terms 'that are in controversy, and only to the extent necessary to resolve the controversy'") (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999)).

We do give the parties notice, however, that claim construction, in general, is an issue to be addressed at trial and claim constructions expressly or implicitly addressed in this Decision are *preliminary* in nature. We will determine claim construction at the close of all the evidence and after any hearing. We thus invite the parties to brief further the proper construction of "opposing sides of the native aortic heart valve" during trial, if desired, and we will address the claim language on the complete trial record, including

any claim construction analysis for the term "opposing sides of the native aortic heart valve," to the extent included in the record.

C. Discretion Under 35 U.S.C. § 314(a) Due to Parallel Proceeding

Patent Owner argues that we should exercise discretion to deny institution under 35 U.S.C. § 314(a) in view of the parallel district court proceeding. Prelim. Resp. 53–58; *see also* Prelim. Sur-reply. Petitioner disagrees. Pet. 21; Prelim. Reply.

Institution of an *inter partes* review is discretionary. *See* 35 U.S.C. § 314(a) (authorizing institution of an *inter partes* review under particular circumstances, but not requiring institution under any circumstances); *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2140 (2016) ("[T]he agency's decision to deny a petition is a matter committed to the Patent Office's discretion."); *SAS*, 138 S. Ct. at 1356 ("[Section] 314(a) invests the Director with discretion on the question whether to institute review . . . ." (emphasis omitted)); *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d at 1356, 1367 (Fed. Cir. 2016) ("[T]he PTO is permitted, but never compelled, to institute an IPR proceeding.").

We consider an advanced state of a parallel district court proceeding as a "factor that weighs in favor of denying the Petition under § 314(a)." *NHK Spring Co. v. Intri-Plex Techs., Inc.*, IPR2018-00752, Paper 8 (PTAB Sept. 12, 2018) (precedential) ("*NHK*"). Specifically, we consider an early trial date as part of a "balanced assessment of all relevant circumstances of the case, including the merits." TPG 58. As part of this balanced assessment, we consider the following factors:

1. whether the court granted a stay or evidence exists that one may be granted if this proceeding is instituted;

2. proximity of the court's trial date to the Board's projected statutory deadline for a final written decision;

3. investment in the parallel proceeding by the court and the parties;

4. overlap between issues raised in the petition and in the parallel proceeding;

5. whether the petitioner and the defendant in the parallel proceeding are the same party; and

6. other circumstances that impact the Board's exercise of discretion, including the merits.

Apple Inc. v. Fintiv, Inc., IPR2020-00019, Paper 11 at 5–6 (PTAB Mar. 20, 2020) (precedential) ("*Fintiv*"). We address each factor below.

1. Factor 1: whether the court granted a stay or evidence exists that one may be granted if this proceeding is instituted

Petitioner states that it intends to seek a stay of the district court proceeding pending the outcome of this Petition and other related petitions. Pet. 21. Patent Owner argues that Petitioner has presented no evidence that a stay would be granted in the district court proceeding and judges in Delaware courts routinely deny motions to stay filed prior to the institution of an IPR. Prelim. Resp. 54–55. Petitioner responds that the district court has denied Petitioner's motion to stay without prejudice to refile following this Decision and that the district court is likely to stay if we institute some or all of the petitions challenging the patents asserted in the district court proceeding. Prelim. Reply 1.

The record indicates that no stay exists at present in the district court proceeding. We decline to speculate on the likelihood of a stay if Petitioner were to refile its motion in view of this Decision. Accordingly, this factor is neutral.

2. Factor 2: proximity of the court's trial date to the Board's projected statutory deadline for a final written decision

Petitioner argues that trial in the district court proceeding is scheduled for October 2022, and this date is about two months after the date that a Final Written Decision would issue for this proceeding. Pet. 21 (citing Ex. 1045); Prelim. Reply 1. Patent Owner asserts that Petitioner twice sought to delay the district court proceeding by moving to dismiss Patent Owner's Complaint and Amended Complaint, opposed a motion to file a second Amended Complaint, and objected to setting a case schedule until its motion to dismiss was resolved. Prelim. Resp. 55 (citing Ex. 2010; Ex. 2011; Ex. 2012; Ex. 2013); Prelim. Sur-reply 2.

The record at this stage indicates a trial date of October 11, 2022, for the district court proceeding, which would occur about two months after the statutory deadline for our final written decision. Ex. 1045, 14. Patent Owner's arguments that Petitioner's motions in the district court proceeding were designed to delay the district court proceeding in favor of this proceeding are conclusory and not persuasive. Therefore, this factor weighs against exercising our discretion to deny institution.

3. Factor 3: investment in the parallel proceeding by the court and the parties

Petitioner asserts that the district court "has not issued any substantive orders related to [the] '118 [patent]" and that although Patent Owner has served infringement contentions, Petitioner has not served invalidity contentions (as of the Petition's filing date), "depositions have not begun, and claim construction briefing has not begun." Pet. 21 (citing Ex. 1045).

Patent Owner argues that the parties have spent significant time and resources in the district court proceeding because Petitioner filed multiple

motions to dismiss, opposed Patent Owner's motion to file an Amended Complaint, and unsuccessfully sought to compel certain discovery that the district court found to be irrelevant. Prelim. Resp. 56. Patent Owner contends that the parties are in the midst of claim construction briefing and a *Markman* hearing is scheduled for August 11, 2021. *Id.* (citing Ex. 1042; Ex. 2018).[6] Patent Owner further asserts that the parties served initial discovery requests, produced hundreds of thousands of pages of documents in fact discovery, served initial infringement and invalidity contentions, and will complete expert discovery and dispositive motions by the deadline for a Final Written Decision. *Id.*

Petitioner responds that the parties will not have held the *Markman* hearing, served final invalidity contentions, or completed fact discovery by this Decision. Prelim. Reply 1 (citing Ex. 1045; Ex. 1062; Ex. 1064 (rescheduling *Markman* hearing to October 12, 2021)).

Patent Owner does not cite evidence to support its arguments regarding the stage of fact and expert discovery and initial infringement and invalidity contentions. Conversely, the record at this stage indicates that the court has rescheduled the *Markman* hearing to October 12, 2021, which will occur after this Decision. Ex. 1045; Ex. 1062; Ex. 1064. Further, the record does not indicate that the parties or district court have made more than minimal investments on invalidity issues at this time. Finally, Patent Owner's arguments about investments that will occur *after* this Decision, but prior to any Final Written Decision for this proceeding, are unpersuasive

[6] Patent Owner's citation to Exhibit 1042 appears to be a typographical error because there is no Exhibit 1042 in the record. It appears that the intended citation may be Exhibit 1045.

because we consider the investment "at the time of the institution decision" not at some later date. *Fintiv*, Paper 11, 9–10.

As a result, the parties and the district court have made relatively little investment in the district court proceeding at this time. Therefore, this factor weighs against exercising our discretion to deny institution.

4. Factor 4: overlap between issues raised in the petition and in the parallel proceeding

Petitioner contends that "[t]he same grounds, arguments and evidence could not be presented in litigation after the earlier-expected final written decision." Pet. 21. Patent Owner argues that Petitioner's initial invalidity contentions in the district court proceeding include the same prior art cited in the Petition. Prelim. Resp. 56 (citing Ex. 2014, 10–13; Ex. 2015). Patent Owner asserts that the Petition does not challenge any claims that are not asserted in the district court proceeding. *Id.* In addition, Patent Owner argues that "the Petition raises claim construction issues that are currently pending before the district court" and "[t]here also is a risk of the district court and the Board reaching different results for the terms 'vicinity' and 'length of the carrier element in a moveable configuration is substantially equal to or less than a length of the carrier element in the expanded configuration.'" *Id.* at 56–57 (citing Ex. 2001; Ex. 2003).

Petitioner responds that it "recently stipulated that if the Board institutes, Petitioners will not pursue the IPR grounds in the district court litigation." Prelim. Reply 1 (citing Ex. 1063). Patent Owner contends that Petitioner's stipulation is meaningless because it is not as broad as the scope of estoppel under 35 U.S.C. § 315 and it leaves the same concerns about duplicative proceedings and inconsistent rulings. Prelim. Sur-reply 1 (citing

Sand Revolution II, LLC v. Continental Intermodal Group – Trucking LLC, IPR2019-01393, Paper 24 at 12 (PTAB June 16, 2020) (informative)).

The record indicates that the references Petitioner asserts in its grounds here are also asserted in the district court proceeding. Ex. 2014, 10–13. Petitioner, however, stipulates in the district court proceeding that "[i]f the PTAB grants institution of IPR2021-00239, Medtronic will not pursue the same grounds against the patent at issue in that IPR in the corresponding district court litigation." Ex. 1063. Although Petitioner's stipulation is not as broad as the stipulation discussed in *Sotera Wireless, Inc. v. Masimo Corporation*, IPR2020-01019, Paper 12 (PTAB Dec. 1, 2020) (precedential), it "mitigates to some degree the concerns of duplicative efforts between the district court and the Board, as well as concerns of potentially conflicting decisions."[7] *See Sand Revolution II, LLC*, Paper 24 at 12.

Accordingly, we find this factor weighs marginally against exercising our discretion to deny institution.

5. Factor 5: whether the petitioner and the defendant in the parallel proceeding are the same party

Petitioner concedes that the parties for this proceeding and the district court proceeding are the same. Pet. 21. Because the statutory date for our final written decision falls before the October 2022 trial date in the district

[7] In any event, overlap between this proceeding and the district court proceeding may result in greater efficiency because the statutory date for our final written decision falls before the October 2022 trial date in the district court proceeding. Thus, Petitioner will be estopped from raising in the district court proceeding any prior art that it raised or reasonably could have raised in this IPR. 35 U.S.C. § 315(e)(2).

court proceeding, we find this factor weighs against exercising discretion to deny institution.

6. Factor 6: other circumstances that impact the Board's exercise of discretion, including the merits

Petitioner argues that the asserted grounds challenging the claims of the '118 patent are particularly strong. Pet. 21; Prelim. Reply 1–2. Patent Owner in turn argues that Petitioner fails to account for the Office previously analyzing the same or substantially the same prior art and finding that it did not teach all elements of the claims, which undercuts Petitioner's arguments that the asserted grounds are strong. Prelim. Sur-reply 1. Patent Owner also asserts that Petitioner's arguments in the Reply exceed the scope of our authorization because they include claim construction arguments. *Id.* at 2.

For the reasons discussed below regarding Petitioner's obviousness challenges, we find Petitioner's grounds to be strong. For example, the current record shows that Leonhardt and Gabbay disclose each limitation of challenged claim 1. *See infra* §§ III.E. Further, as we explain below, *see infra* § III.D, we do not exercise our discretion to deny institution under 35 U.S.C. § 325(d), so we are not persuaded that § 325(d) undercuts the strength of the merits.

Patent Owner's arguments regarding the scope of Petitioner's arguments in the Preliminary Reply are also unpersuasive. Our authorization to file the Preliminary Reply and the Preliminary Sur-reply stated that the briefs should address the *Fintiv* arguments raised in Patent Owner's Preliminary Response. Ex. 2021. Petitioner's arguments in the Preliminary Reply address *Fintiv* factor 6, which includes the merits of the grounds raised in the Petition. *Fintiv*, Paper 11 at 14. We do not view

Petitioner's reply arguments addressing this factor, which generally disagree with Patent Owner's position in the Preliminary Response regarding Petitioner's ground, as rearguing the merits of its challenges or bolstering its proposed grounds. Nor do we view Petitioner's reply arguments as directed to claim construction, as Patent Owner argues. Accordingly, this factor weighs against exercising our discretion to deny institution.

7. Conclusion

We have considered the circumstances and facts before us in view of the *Fintiv* factors. Because our analysis is fact-driven, no single factor is determinative of whether we exercise our discretion to deny institution under § 314(a). We take "a holistic view of whether efficiency and integrity of the system are best served by denying or instituting review" when evaluating these factors. *Fintiv*, Paper 11, 6. Evaluating all of the factors on this record, we determine that the circumstances presented here do not support exercising our discretion under § 314(a) to deny institution of *inter partes* review.

D. Discretion Under 35 U.S.C. § 325(d)

Petitioner argues that we should not exercise our discretion to deny institution under § 325(d) because the grounds raised in the Petition do not include the same or substantially the same prior art or arguments as were raised during prosecution of the '118 patent. Pet. 18–19. Further, Petitioner argues that, even if the art and arguments are substantially the same, the Examiner erred in a manner material to the patentability of the claims. *Id.* at 19. For this latter point, Petitioner contends:

> Despite properly rejecting the claims over **Leonhardt** alone (Ex. 1003, 2020-2031), the Office subsequently erred in a manner material to patentability . . . by failing to maintain the rejection after the Claims were amended to be limited to the

> "aortic valve" . . . . While the Examiner had previously relied on **Leonhardt's** teachings of the claimed method relative to the mitral valve, **Leonhardt** alternatively teaches that the same method could also be applied "in the…aortic valve." Leonhardt, 9:64-65. **Leonhardt** recognized the need for an artificial heart valve "which may be placed percutaneously at any point as well as directly over an existing vascular or cardiac valve." Leonhardt, 3:15-20.

Id. (third alteration in original). According to Petitioner, the Examiner was misled by the applicant's assertion that "Leonhardt does not disclose replacing the leaflet actuation of the native *aortic* heart valve." *Id.* (citing Ex. 1003, 2043). Petitioner also contends that the Examiner further erred by not identifying art similar to Gabbay. *Id.* at 20.

Patent Owner responds that the Petition relies on the same or substantially the same prior art or arguments previously presented to the Office. Prelim. Resp. 28–35. Specifically, Patent Owner asserts that Leonhardt was expressly considered during the prosecution of the '118 patent. *Id.* at 28. Patent Owner further asserts that Gabbay suffers from the same deficiencies as Leonhardt, and the arguments that the applicant relied on to distinguish Leonhardt during prosecution apply equally to distinguish Gabbay. *Id.* at 30–32 (citing Ex. 1046 ¶¶ 68–69, Fig. 19; Ex. 1003, 2072). Last, Patent Owner asserts that Bailey and Moulopoulos were previously presented to the Office via information disclosure statements. *Id.* at 33 (citing Ex. 1003, 1095, 1235).

Patent Owner further contends that Petitioner fails to demonstrate that the Office erred in a manner material to the patentability of the challenged claims. *Id.* at 33–35. According to Patent Owner, Petitioner's argument that the applicant misled the Examiner ignores both the prosecution history and Leonhardt's disclosure. *Id.* at 34. Patent Owner contends that, rather than

misleading the Examiner, the applicant explained why the Figure 3 embodiment of Leonhardt failed to meet the claim limitations—specifically, because Leonhardt's valve stent is positioned above the native aortic valve and not proximate opposing sides of the valve. *Id.* (citing Ex. 1003, 2072).

> To evaluate whether to exercise discretion under 35 U.S.C. § 325(d), the Board uses the following two-part framework: (1) whether the same or substantially the same art previously was presented to the Office or whether the same or substantially the same arguments previously were presented to the Office; and (2) if either condition of first part of the framework is satisfied, whether the petitioner has demonstrated that the Office erred in a manner material to the patentability of challenged claims.

Advanced Bionics, LLC v. MED-EL Elektromedizinische Geräte GmbH, IPR2019-01469, Paper 6 at 8 (PTAB Feb. 13, 2020) (precedential).

Here, some of the asserted references were previously presented to the Office. However, even assuming that overall the references asserted in the Petition are the same or substantially the same as those presented during prosecution, or that Petitioner's arguments are the same or substantially the same to those presented during prosecution, Petitioner demonstrates that the Office erred in a manner material to the patentability of the challenged claims. In particular, we determine that the Examiner erred in overlooking Leonhardt's disclosure regarding placement of a valve stent in a native aortic valve. Thus, we focus our discussion on the second part of the *Advanced Bionics* framework. Before doing so, we provide a brief summary of the '118 patent's prosecution history.

1. Relevant Prosecution History of the '118 Patent

The '118 patent issued from Application No. 11/579,723 ("the '723 application"). Ex. 1001, code (21). The '723 application included original claim 28, which issued as claim 1. *See* Ex. 1003, 2119 (mapping original

claim 28 to final claim 1). The Examiner rejected claim 28 (together with claims 29, 30, 32, 37, 38, 40–43, and 45–49) under 35 U.S.C. § 102(b) as anticipated by Leonhardt. *Id.* at 2023–26. The applicant subsequently submitted a Request for Continued Examination (RCE) together with an Amendment under 37 C.F.R. § 1.114. *Id.* at 2055–57, 2064–73.

Claim 28 was amended as follows, with strikethrough indicating a deletion and underlining indicating an addition:

> 28. (Currently Amended) A method for replacing a patient's native aortic heart valve in a heart, the method comprising:
>
> delivering an expandable carrier element and a replacement valve endovascularly to a vicinity of the native aortic heart valve while the heart is beating, the carrier element having proximal and distal ends, the replacement valve configured to allow the flow of blood through the replacement valve in a first direction and prevents the flow of blood through the replacement valve in a second direction;
>
> positioning the proximal and distal ends of the carrier element proximate opposing sides of the native aortic heart valve;
>
> expanding the carrier element from a collapsed delivery configuration to a first expanded configuration;
>
> using the carrier element to exclude the native aortic heart valve in the first expanded configuration,
>
> forming a seal between the carrier element and ~~respective~~ one or more native anatomical features in the first expanded configuration;
>
> using the replacement valve to replace ~~the function~~ leaflet actuation of the native aortic heart valve in the first expanded configuration;
>
> evaluating the position of the carrier element;
>
> at least partially collapsing the carrier element from the first expanded configuration to a moveable configuration;

> repositioning the carrier element in the moveable configuration in the vicinity of the native aortic heart valve;
>
> expanding the carrier element from the moveable configuration to a second expanded configuration to secure the carrier element in the vicinity of the native aortic heart valve, the proximal and distal ends of the carrier element being proximate opposing sides of the native aortic heart valve in the second expanded configuration;
>
> using the carrier element to exclude the native aortic heart valve in the second expanded configuration;
>
> forming a seal between the carrier element and ~~respective native~~ one or more anatomical features in the second expanded configuration; and
>
> using the replacement valve to replace ~~the function~~ leaflet actuation of the native aortic heart valve in the second expanded configuration.

Ex. 1003, 2065–66. Regarding amended claim 28, the applicant argued that "Leonhardt does not disclose replacing the leaflet actuation of the native *aortic* heart valve," and in Figure 3, "the valve stent is deployed *above* the native aortic heart valve and the proximal and distal ends of the carrier element and not positioned proximate opposing sides of the native aortic heart valve as claimed." *Id.* at 2072.

After this amendment, the Examiner rejected claim 28 on other grounds, but did not maintain the rejection based on Leonhardt. *Id.* at 2075–85.

2. Error Material to Patentability

In view of the above, we determine that the Examiner abandoned the rejection based on Leonhardt in response to the applicant amending claim 28 to recite a native *aortic* heart valve rather than a non-specific native heart valve and arguing that Leonhardt's valve stent is not deployed in a native

aortic heart valve as claimed. As Petitioner argues, however, Leonhardt does disclose deploying its valve stent in a native aortic valve. *See* Pet. 19. Specifically, Leonhardt discloses that the placement site of valve stent 20 can be "in the aorta *or aortic valve 10*" (Ex. 1004, 9:64–65 (emphasis added)). Thus, although much of Leonhardt's disclosure is focused on placing valve stent 20 in mitral valve 14 (*see, e.g.*, *id.* at 5:41–52, 10:22–30, Figs. 2, 9A–9D), Leonhardt also discloses placing valve stent 20 in native aortic valve 10. As such, we are persuaded that Petitioner demonstrates that the Office erred in a manner material to the patentability of the challenged claims by failing to consider Leonhardt's disclosure of an aortic valve deployment.

Accordingly, we do not exercise our discretion under § 325(d) to deny institution in this proceeding.

E. Asserted Obviousness Based on Leonhardt and Gabbay

Petitioner asserts that claims 1, 2, 5, 8–11, 13, 14, and 18–23 are unpatentable under 35 U.S.C. § 103(a) based on Leonhardt and Gabbay.[8] Pet. 24–66. Patent Owner provides arguments addressing this asserted ground of unpatentability. Prelim. Resp. 36–48. We first summarize the references and then address the parties' contentions.

1. Leonhardt

Leonhardt, titled "Percutaneous Placement Valve Stent," issued on September 28, 1999. Ex. 1004, codes (54), (45). Leonhardt is directed to "artificial valves . . . placed percutaneously by a catheter . . . [to] replace

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

existing valves such as are in the heart." *See id.* at 1:4–7. We reproduce Leonhardt's Figure 4, below.

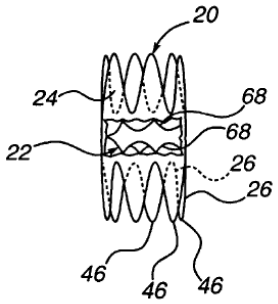


FIG. 4

Figure 4 depicts "a sectional view showing the biological valve within the stent." Ex. 1004, 3:61–62. "Valve stent 20 comprises a malleable graft material 24 enclosing deformable self-expanding stent 26 to which a biological valve 22 is attached. . . . The deployed valve stent 20 creates a patent one way fluid passageway." *Id.* at 5:45–51.

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

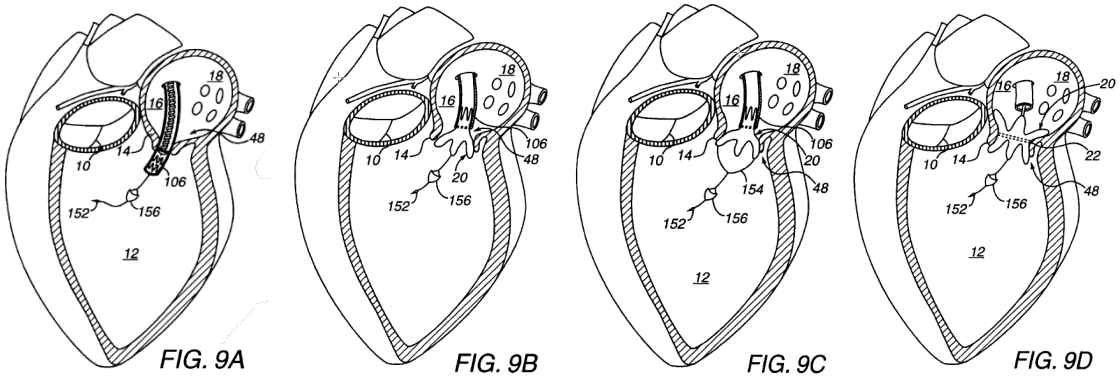


FIG. 9A FIG. 9B FIG. 9C FIG. 9D

Figures 9A–9D depict, as a series, "a method of deploying the valve stent in the mitral valve position." Ex. 1004, 4:8–10. Deployment catheter 100, with outer sheath 106, enters the body through a femoral artery (for replacing the aortic valve) and is moved to the heart. *Id.* at 9:50–10:11, Fig. 9A. Once in position, the distal end of valve stent 20 is deployed by withdrawing outer sheath 106 to allow distensible fingers 46 to self-expand.

Id. at 10:53–58, Fig. 9B. "Expansion balloon 154 is then inflated to a pressure sufficient to hold the distal end of valve stent 20 secure against the living tissue . . . [which] allows valve stent 20 to mold itself quickly into the living tissue at the placement site and achieve a patent seal." *Id.* at 11:3–9, Fig. 9C. As seen in Figure 9C, expansion balloon 154 occludes blood flow. *See also* Ex. 1001, 72:24–35 (discussing Leonhardt and stating that, at this stage of deployment, "the devices effectively block all aortic output"). Outer sheath 106 is further withdrawn to release the proximal end of valve stent 20. Ex. 1004, 11:13–15. Expansion balloon 154 is deflated, moved to the proximal end of stent 20, and re-inflated to seat the proximal end of the sent. *Id.* at 11:15–22.

"Tip balloon 152 or expansion balloon 154 may be advanced to either side of valve stent 20 and re[-]inflated to further mold valve stent 20 to the living tissue if necessary. This [step] should not be needed, however, because of the continuous outward force of super elastic stent 26." Ex. 1004, 11:32–36.

2. Gabbay

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

Prosthesis 10 may be compressed to a reduced cross-sectional dimension while being implanted. *Id.* ¶ 50. Once implanted, "the prosthesis may be permitted to return toward its original cross-sectional dimension so

as to engage a valve wall or other surrounding tissue at the desired position." *Id.* Figure 10 of Gabbay is reproduced below.

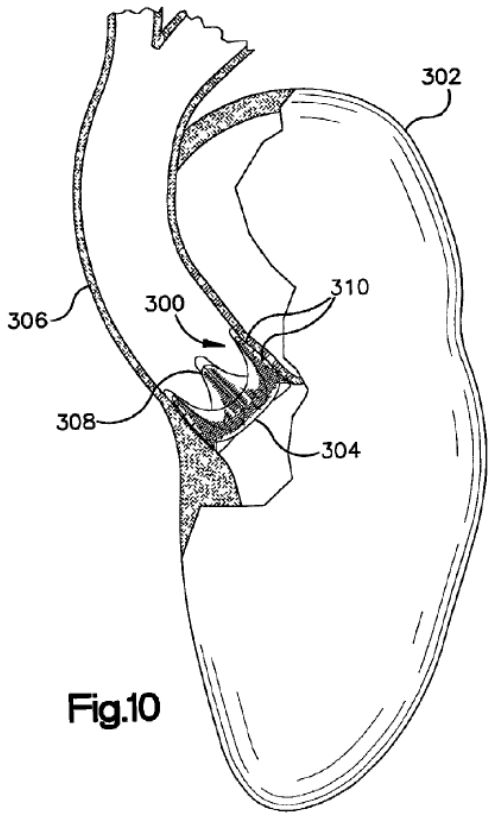


Figure 10 shows an example in which valvular prosthesis 300 is implanted in heart 302 in an aortic position. Ex. 1046 ¶ 68. Prior to valve implantation, the aortic valve, or at least calcified portions thereof, should be removed. *Id.* "An inflow end 304 of the prosthesis 300 is annularized with respect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

3. Independent Claim 1

Petitioner contends that the combination of Leonhardt and Gabbay discloses each limitation of independent claim 1. Pet. 34–51. To support its arguments, Petitioner identifies certain passages in the cited references and

explains the significance of each passage with respect to the corresponding claim limitation. *Id.* Petitioner also articulates reasons to combine the relied-upon aspects of Leonhardt and Gabbay. *Id.* at 31–34. Patent Owner argues that Leonhardt and Gabbay fail to disclose the claim 1 limitations "positioning the proximal and distal ends of the carrier element proximate opposing sides of the native aortic heart valve"[9] (Prelim. Resp. 36–42) and "using the carrier element to exclude the native aortic heart valve in the first expanded configuration"[10] (*id.* at 42–45). Patent Owner also argues that Petitioner fails to provide a non-hindsight motivation to combine Leonhardt and Gabbay. *Id.* at 45–47.

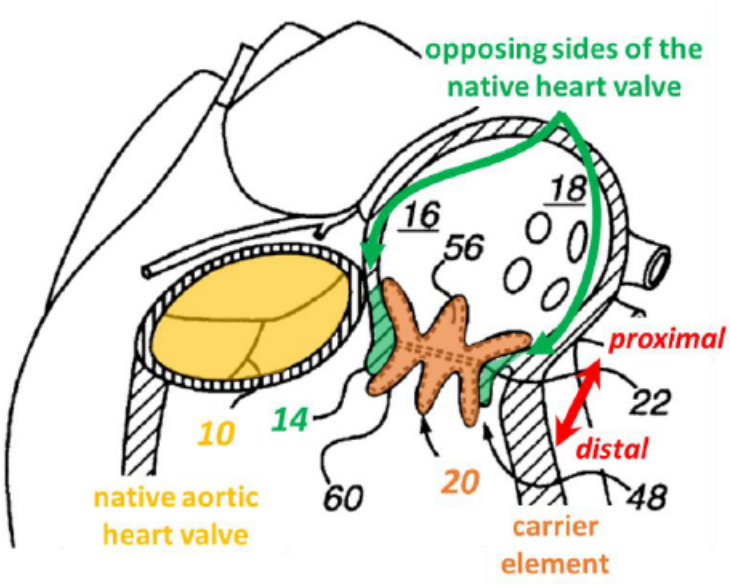
We have reviewed Petitioner's contentions with respect to the limitations of claim 1, and for the reasons discussed below, we determine that the Petition shows a reasonable likelihood that Petitioner would prevail in with respect to the contention that claim 1 would have been obvious based on Leonhardt and Gabbay. *See* Pet. 34–51. We address in turn below each of Patent Owner's arguments.

a) The "Opposing Sides" Limitation

In addressing this limitation, Petitioner argues that Leonhardt discloses placing valve stent 20 in the aortic valve. Pet. 38 (citing Ex. 1004, 9:64–65, 10:3–22, 10:53–55). According to Petitioner, one of ordinary skill in the art would have understood that placing valve stent 20 in the aortic valve would result in the stent's proximal and distal ends being placed proximate opposing sides of the aortic valve. *Id.* (citing Ex. 1002 ¶ 111).

[9] We refer to this limitation as "the 'opposing sides' limitation."
[10] We refer to this limitation as "the 'excluding' limitation."

Petitioner supports this assertion with an annotated, partial version of Leonhardt's Figure 2, which we reproduce below.



Id. at 39. For this annotated version of Figure 2, Petitioner added (1) green overlay to mitral valve 14, (2) green text with green arrows identifying portions of mitral valve 14 as "opposing sides of the native heart valve," (3) brown overlay to valve stent 20, with accompanying brown text identifying valve stent 20 as a "carrier element," (4) yellow overlay to aortic valve 10, with accompanying yellow text identifying aortic valve 10 as a "native aortic heart valve," and (5) red text with red arrows identifying proximal and distal locations relative to mitral valve 14 and valve stent 20. *Id.* Petitioner argues that annotated Figure 2 shows valve stent 20 positioned in the claimed configuration within the mitral valve, and the same configuration would apply when valve stent 20 is placed in the aortic valve. *Id.* at 38 (citing Ex. 1002 ¶ 111).

Alternatively, Petitioner argues that Leonhardt's valve stent 20, placed as shown in Figure 2, "is positioned as claimed even if 'opposing sides' are interpreted as the proximal and distal ends of the native valve on either side

of the annulus." *Id.* at 38 n.6 (citing Ex. 1001, 14:60–64, 49:46–48; Ex. 1002 ¶ 112).

Furthermore, Petitioner argues that, "[t]o the extent it is argued that further disclosure is required by Leonhardt" regarding the "opposing sides" limitation, Gabbay discloses the limitation. *Id.* at 40 (emphasis omitted). Specifically, Petitioner argues that, as shown in Figure 10, "**Gabbay** discloses implanting a 'valvular prosthesis 300…in the aortic position' to 'engage a valve wall'—meaning the stent's proximal/distal ends are positioned proximate opposing sides of the aortic valve." *Id.* (citing Ex. 1046 ¶¶ 50, 69) (alteration in original).

Patent Owner argues that Leonhardt and Gabbay fail to disclose the "opposing sides" limitation for three reasons. Prelim. Resp. 36–42. First, Patent Owner argues that we should reject Petitioner's arguments that Leonhardt and Gabbay each disclose the "opposing sides" limitation because these arguments "rely on an improper interpretation of the phrase 'opposing sides of the native aortic heart valve.'" *Id.* at 37 (citing Pet. 38–41). As discussed above, however, Petitioner argues, as an alternative to its assertion that opposing portions of the lateral wall of Leonhardt's native heart valve are "opposing sides," that Figure 2 of Leonhardt shows the proximal and distal ends of valve stent 20 positioned proximate the opposing proximal and distal ends of a native heart valve. Pet. 38 n.6. We agree with Petitioner that Figure 2 shows the proximal and distal ends of valve stent 20 (i.e., the carrier element) to be located proximate the opposing proximal and distal ends or sides of mitral valve 14. Thus, even under Patent Owner's proposed construction of "opposing sides," we are persuaded at this stage of the proceeding that Leonhardt discloses positioning the proximal and distal ends of a carrier element proximate opposing sides of a native heart valve.

Second, Patent Owner argues that we should reject Petitioner's alternative argument "because it is conclusory and relies on expert testimony that simply parrots the language of the Petition." Prelim. Resp. 38 (comparing Pet. 38 n.6 with Ex. 1002 ¶ 112; citing *TQ Delta, LLC v. Cisco Systems, Inc.*, 942 F.3d 1352, 1358–59 (Fed. Cir. 2019); 37 CFR § 42.65(a)). This argument is not persuasive because we disagree that either the Petition or Dr. Drasler's testimony on this point are conclusory. Rather, the Petition relies on object evidence in the form of Leonhardt's disclosure in Figure 2. Pet. 38 n.6. Dr. Drasler similarly relies on Figure 2 in testifying that Leonhardt discloses that valve stent 20 is positioned with one end above the valve annulus and the other end is below the annulus. Ex. 1002 ¶ 112.

Patent Owner further argues that Figures 2 and 9 of Leonhardt on which Petitioner and Dr. Drasler rely are "directed to replacement of the native ***mitral*** valve, not the ***aortic*** valve as claimed," and to the extent Petitioner contends that the same procedure would be used for both types of valves, this contention is also based on conclusory attorney argument and expert testimony. Prelim. Resp. 38 (citing Pet. 38–39; Ex. 1002 ¶ 121). In addition, referencing Figure 3, Patent Owner argues that Leonhardt discloses deploying its "prosthetic ***aortic*** valve ***above*** the native valve rather than proximate to its opposing sides." *Id.* at 39 (citing Ex. 1004, 3:59–61, Fig. 3). We are not persuaded by these arguments because, although Leonhardt discloses that the valve stent shown in Figure 3 is "fully deployed within the aorta above the aortic valve" (Ex. 1004, 3:60–61), Leonhardt also discloses that the placement site of valve stent 20 can be "in the aorta *or aortic valve 10*" (*id.* at 9:64–65 (emphasis added)). As such, we are persuaded at this stage of the proceeding that Leonhardt discloses deploying valve stent 20 in either the mitral valve or the aortic valve.

Third, Patent Owner argues that Petitioner fails to show that Gabbay discloses the "opposing sides" limitation. Prelim. Resp. 40. In particular, Patent Owner argues that Gabby discloses implanting prosthesis 300 in the aorta rather than the aortic valve. *Id.* at 41–42 (citing Ex. 1046 ¶¶ 68–69, Fig. 10). Although Patent Owner may be correct that Gabbay does not deploy its prosthesis in a native aortic valve,[11] we do not find this argument persuasive because, as discussed above, we are persuaded at this stage of the proceeding that Leonhardt discloses placing a replacement valve in a native aortic valve.

For these reasons, at this stage of the proceeding and on the current record, we determine that Petitioner has made a sufficient showing that the combination of Leonhardt and Gabbay discloses the "opposing sides" limitation.

b) The "Excluding" Limitation

For this limitation, Petitioner argues that Leonhardt discloses that valve stent 20 "'mold[s] itself quickly into the living tissue at the placement site' in the 'aortic valve' during deployment to 'conform and seal to the tissue' and thus exclude the aortic valve." Pet. 44 (quoting Ex. 1004, 11:5–9, 9:64–67, 6:16–22). Petitioner also argues that Leonhardt discloses that valve stent 20 "replaces the mitral valve by sealing 'with the tissue of mitral valve 14' to create 'a patent one way fluid passageway.'" *Id.* (quoting Ex. 1004, 5:41–52; citing *id.* at Fig. 2). In addition, Petitioner argues that, "[t]o the extent further disclosure of excluding the native aortic heart valve

[11] We note that Gabbay discloses that "[p]rior to implanting the prosthesis 300, the aortic valve or at least calcified portions thereof should be removed," and Figure 10 does not appear to show an aortic valve. Ex. 1046 ¶ 68, Fig. 10.

is required, Gabbay discloses using the carrier element to exclude the native aortic heart valve." *Id.* at 45 (emphasis omitted) (citing Ex. 1046, Fig. 10; Ex. 1002 ¶¶ 119–123).

Patent Owner again argues that Petitioner relies on Figures 2 and 9 of Leonhardt, which "are directed to the ***mitral*** valve, not the ***aortic*** valve as claimed," and to the extent Petitioner contends that the same procedure would be used for both types of valves, this contention is based on conclusory attorney argument and expert testimony. Prelim. Resp. 43 (citing Pet. 43–45; Ex. 1002 ¶¶ 119–121). For the reasons discussed above (*see supra* § III.E.3.a), we are not persuaded by this argument. Instead, we are persuaded at this stage of the proceeding that Leonhardt discloses deploying valve stent 20 in either the mitral valve or the aortic valve in a manner that excludes the native valve.

Patent Owner also argues that Petitioner fails to show that Gabbay discloses the "excluding" limitation. Prelim. Resp. 44. We do not find this argument persuasive, however, because, as discussed above, we are persuaded at this stage of the proceeding that Leonhardt discloses the "excluding" limitation.

For these reasons, at this stage of the proceeding and on the current record, we determine that Petitioner has made a sufficient showing that the combination of Leonhardt and Gabbay discloses the "excluding" limitation.

c) The Remaining Aspects of Petitioner's Contentions

Patent Owner does not offer any arguments specifically addressing the remaining limitations of claim 1. *See generally* Prelim. Resp. We have reviewed Petitioner's contentions with respect to the remaining limitations of claim 1 and determine that the Petition provides a sufficient showing, at

this stage of the proceeding, that the combination of Leonhardt and Gabbay satisfies each limitation. *See* Pet. 34–51.

d) Reasons to Combine

Petitioner argues that one of ordinary skill in the art "would have been motivated to apply **Gabbay's** teachings of excluding the aortic valve to **Leonhardt's** prosthesis placement to achieve the beneficial and predictable result of improved prosthesis placement and operation." Pet. 33 (citing Ex. 1004, 1:5–8, 9:63–67; Ex. 1046 ¶ 68; Ex. 1002 ¶ 96).

Patent Owner first argues that this reasoning is conclusory because "there is no teaching or suggestion in Leonhardt or otherwise, that the placement of its prosthetic valve relative to the native aortic valve is problematic." Prelim. Resp. 45 (citing Ex. 1004, 3:59–61, Fig. 3). This argument is not persuasive. That Leonhardt does not indicate that its disclosed placement of its valve stent is problematic is not surprising; nor does it mean that Petitioner's reasoning is conclusory. *See DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co.*, 464 F.3d 1356, 1361 (Fed. Cir. 2006) ("The motivation need not be found in the references sought to be combined, but may be found in any number of sources, including common knowledge, the prior art as a whole, or the nature of the problem itself.").

Furthermore, Dr. Drasler testifies that

> [p]lacement of Leonhardt's prosthesis at a location other than over and excluding the native aortic valve, e.g., further up the aorta without covering the aortic valve or at the aortic valve but without covering or sealing off the aortic valve, would result in sub-optimal performance and fail to fully correct the patient's failing native aortic valve.

Ex. 1002 ¶ 97. Although, as noted above, Leonhardt discloses that valve stent 20 can be in aortic valve 10 (Ex. 1004, 9:64–65), Leonhardt also discloses that the valve stent shown in Figure 3 is "fully deployed within the aorta above the aortic valve" (*id.* at 3:59–61). In fact, Patent Owner relies on the latter disclosure to argue that Leonhardt does not disclose deploying a prosthetic valve in the aortic valve. Prelim. Resp. 39 (citing Ex. 1004, 3:59–61, Fig. 3). At this stage of the proceeding, we credit Dr. Drasler's uncontroverted testimony that placing a prosthetic valve in the aortic valve, as opposed to above the aortic valve, would have been beneficial.

Second, Patent Owner argues that Petitioner's "statements concerning the alleged problems with Leonhardt's placement of the prosthetic valve 'further up the aorta' are improper hindsight." Prelim. Resp. 46 (citing Pet. 33). According to Patent Owner, Petitioner's statements "***[i]f*** the prosthesis was placed further up the aorta," and "***if*** the prosthesis did not cover or seal the aortic valve, some blood would improperly flow through the damaged native aortic valve" are supported by Dr. Drasler's testimony only, not by "statements from Leonhardt or any other contemporaneous reference." *Id.* (alteration in original).

We disagree. As discussed above, Leonhardt discloses that the valve stent shown in Figure 3 is "fully deployed within the aorta above the aortic valve," and Patent Owner relies on this disclosure in arguing that Leonhardt does not disclose deploying a prosthetic valve in the aortic valve. Ex. 1004, 3:59–61; Prelim. Resp. 39. As such, we determine that Leonhardt supports at least the first of the two statements identified above and that Petitioner's rationale is not based on impermissible hindsight.

Third, Patent Owner argues that Leonhardt teaches away from the "opposing sides" limitation because "the only aortic valve embodiment

shown in Leonhardt places the prosthetic valve further up the aorta rather than proximate opposing sides of the native aortic valve." As we have previously mentioned, however, Leonhardt does not disclose placing its prosthetic valve only in the aorta above the aortic valve; Leonhardt also teaches placing its prosthetic valve in the aortic valve. Ex. 1004, 9:64–65. Accordingly, we are not persuaded that Leonhardt teaches away from the "opposing sides" limitation.

For these reasons, at this stage of the proceeding and on the current record, we are persuaded that Petitioner's reasons to combine Leonhardt and Gabbay are sufficient.

e) Conclusion

For the above reasons, we determine, based on the current record, that the Petition shows a reasonable likelihood that Petitioner would prevail in demonstrating that claim 1 is unpatentable over Leonhardt and Gabbay.

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

Because Petitioner has demonstrated a reasonable likelihood of success in proving that at least one claim of the '118 patent is unpatentable, we institute on all grounds and all claims raised in the Petition. *See SAS*, 138 S. Ct. at 1354, 1359–60; TPG 64. Therefore, it is not necessary for us to assess every claim challenged by Petitioner. Nevertheless, we note that Petitioner provides reasonable and detailed explanations, supported with the testimony of Dr. Drasler, indicating where Leonhardt and Gabbay disclose the limitations of claims 2, 5, 8–11, 13, 14, and 18–23. Pet. 51–66. Further, Patent Owner offers no particular arguments with respect to claims 2, 5, 8–11, 13, 14, and 18–23 for us to consider at this stage of the proceeding. *See generally* Prelim. Resp. For these reasons, we determine that the information presented in the Petition establishes that there is a reasonable

likelihood that Petitioner would prevail in its assertion that claims 2, 5, 8–11, 13, 14, and 18–23 are unpatentable over Leonhardt and Gabbay.

F. Asserted Obviousness Based on Leonhardt, Gabbay, and Bailey

Petitioner contends that claim 7 would have been obvious over either Leonhardt and Gabbay or Leonhardt, Gabbay, and Bailey. Pet. 67–76.

Claim 7 depends from claim 1 and recites "wherein the replacement valve prevents the flow of blood through the replacement valve in the second direction and allows the flow of blood through the replacement valve in the first direction at least partially during expansion of the carrier element to the second expanded." Ex. 1001, 80:22–27. Petitioner argues that Leonhardt's replacement valve prevents the flow of blood in a second direction and allows the flow of blood in the first direction. Pet. 71–73 (citing Ex. 1004, 1:11–14, 5:51–52, 11:24–36, Figs. 5, 9A–9D; Ex. 1002 ¶¶ 233–235). Petitioner also argues that Bailey discloses a prosthetic valve that allows the flow of blood through it in a second direction at least partially during the expansion of the prosthetic valve. *Id.* at 73–75 (citing Ex. 1005 ¶¶ 70, 72; Ex. 1002 ¶¶ 236–239). In addition, Petitioner provides reasons, supported with the testimony of Dr. Drasler, for why it would have been obvious to one of ordinary skill in the art to combine Leonhardt and Bailey. *Id.* at 67–71 (citing Ex. 1002 ¶¶ 221–229).

We find Petitioner's contentions sufficiently persuasive at this stage of the proceeding. Patent Owner argues only that this asserted ground does not address the alleged failure of Leonhardt and Gabbay to disclose each limitation of claim 1. Prelim. Resp. 48. We do not agree that the combination of Leonhardt and Gabbay fails to disclose each limitation of claim 1 for the reasons discussed above. *See supra* § III.E.3.

For the above reasons, we determine that the information presented in the Petition establishes that there is a reasonable likelihood that Petitioner would prevail in its assertion that claim 7 is are unpatentable over either the combination of Leonhardt and Gabbay of the combination of Leonhardt, Gabbay, and Bailey.

G. Asserted Obviousness Based on Leonhardt, Gabbay, and Moulopoulos

Petitioner argues that

> [t]o the extent [Patent Owner] argues further disclosure of exchanging **Leonhardt's** valve/stent 20 with a different replacement is required for claim 18 . . . **Leonhardt** in view **Gabbay** and in further view of **Moulopoulos's** teaching of exchanging of one artificial valve with another for reinsertion into the patient renders claim 18 obvious.

Pet. 76–77 (citing Ex. 1019, 1:58–65; Ex. 1002 ¶ 242).

Patent Owner has not argued that Leonhardt fails to disclose the subject matter of claim 18 at this stage of the proceeding. Instead, Patent Owner argues only that this asserted ground does not address the alleged failure of Leonhardt and Gabbay to disclose each limitation of claim 1. Prelim. Resp. 48. We do not agree that the combination of Leonhardt and Gabbay fails to disclose each limitation of claim 1 for the reasons discussed above. *See supra* § III.E.3.

In any event, because Petitioner has demonstrated a reasonable likelihood of success in proving that at least one claim of the '118 patent is unpatentable (*see infra* §§ III.E, III.F), we include this ground in the instituted *inter partes* review. *See SAS*, 138 S. Ct. at 1354, 1359–60; TPG 64.

IV. CONCLUSION

After considering the evidence and arguments of record, we determine that Petitioner has demonstrated a reasonable likelihood of success with respect to at least one of the challenged claims. Accordingly, an *inter partes* review of all of the claims and all of the grounds presented in the Petition is hereby instituted. *See SAS*, 138 S. Ct. at 1354, 1359–60; TPG 64.

At this stage of the proceeding, the Board has not made a final determination as to the patentability of any challenged claims or any underlying factual or legal issues. The final determination will be based on the record as developed during the *inter partes* review.

V. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that, pursuant to 35 U.S.C. § 314(a), an *inter partes* review of claims 1, 2, 5, 7–11, 13, 14, and 18–23 of the '118 patent is instituted with respect to all grounds set forth in the Petition; and

FURTHER ORDERED that, pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4(b), *inter partes* review of the '118 patent shall commence on the entry date of this Order, and notice is hereby given of the institution of a trial.

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