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Paper 35
Date: August 12, 2022

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.

IPR2021-00243
Patent 9,445,897 B2

Before, PATRICK R. SCANLON, KEVIN W. CHERRY, and JAMES J. MAYBERRY, *Administrative Patent Judges.*

SCANLON, *Administrative Patent Judge*.

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

I. BACKGROUND

Medtronic CoreValve LLC and Medtronic, Inc. (collectively, "Petitioner") challenges claims 1–4, 6–10, 16–22, and 24 of U.S. Patent No. 9,445,897 B2 (Ex. 1001, "the '897 patent"). We have jurisdiction under 35 U.S.C. § 6, and this Final Written Decision is issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73. For the reasons that follow, we determine that Petitioner has shown by a preponderance of the evidence that claims 1–4, 6–10, 16, and 17 of the '897 patent are unpatentable but has not shown by a preponderance of the evidence that claims 18–22 and 24 are unpatentable.

A. Procedural History

Petitioner filed a Corrected Petition (Paper 3, "Pet.") requesting an *inter partes* review of the challenged claims. Speyside Medical, LLC ("Patent Owner") filed a Preliminary Response (Paper 7). With our authorization, Petitioner filed a Preliminary Reply (Paper 9) and Patent Owner filed a Preliminary Sur-reply (Paper 10).

We instituted a trial as to all challenged claims. Paper 11 ("Decision on Institution" or "Dec. Inst.").

After institution, Patent Owner filed a Patent Owner Response (Paper 18, "PO Resp."), Petitioner filed a Reply (Paper 23, "Pet. Reply"), and Patent Owner filed a Sur-reply (Paper 28, "PO Sur-reply").

Petitioner relies on the Declaration of Dr. William J. Drasler (Ex. 1002, the Reply Declaration of Dr. William J. Drasler (Ex. 1070), the Affidavit of Duncan Hall (Ex. 1055), and the Affidavit of Elizabeth Rosenberg (Ex. 1048) in support of its contentions. Patent Owner relies on the Declaration of Jonathan Rourke (Ex. 2047) in support of its contentions.

An oral hearing was held on May 16, 2022. A transcript of the hearing is included in the record. Paper 34 ("Tr.").

B. Real Parties in Interest

Petitioner identifies Medtronic CoreValve LLC and Medtronic, Inc. as the real parties in interest. Pet. 5. 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 5, 2.

C. Related Matters

The '897 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. 5; Paper 5, 2. Both parties identify the following *inter partes* review proceedings as related to the '897 patent: IPR2021-00239 (challenging U.S. Patent No. 8,377,118); 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); and IPR2021-00244 (challenging U.S. Patent No. 9,603,708).[1] Pet. 5; Paper 5, 2.

D. The '897 Patent

The '897 patent, titled "Prosthetic Implant Delivery Device with Introducer Catheter," issued September 20, 2016, with claims 1–24. Ex. 1001, code (54), code (45), 33:19–34:59. The '897 patent is directed "to medical methods and devices . . . for percutaneously implanting a valve." *Id.* at 1:18–20. We reproduce Figure 5B of the '897 patent below.

[1] The Board denied institution in IPR2021-00240, IPR2021-00241, IPR2021-00242, and IPR2021-00310.

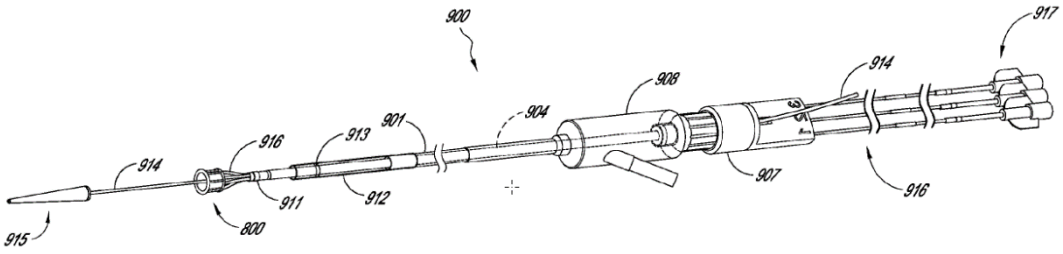

FIG. 5B

Figure 5B is a side perspective view of deployment catheter 900 with implant 800. *Id.* at 4:30–32, 18:64–66. Catheter 900 includes outer tubular member 901 having proximal end 902 and distal end 903, and inner tubular member 904 extending through outer tubular member 901. *Id.* at 19:53–58. Distal end 903 of outer tubular member 901 includes sheath jacket 912 that houses implant 800. *Id.* at 19:61–66. Inner tubular member 904 can comprise multiple lumens, one of which can accommodate guidewire tubing 914. *Id.* at 20:46–49. Guidewire tubing 914 is coupled to guidewire tip 915. *Id.* at 20:64–67. Guidewire tip 915 can have a tapered shape for direct insertion into an access vessel to dilate the access vessel for accommodating an introducer catheter. *Id.* at 21:45–51.

We reproduce Figure 8A of the '897 patent below.

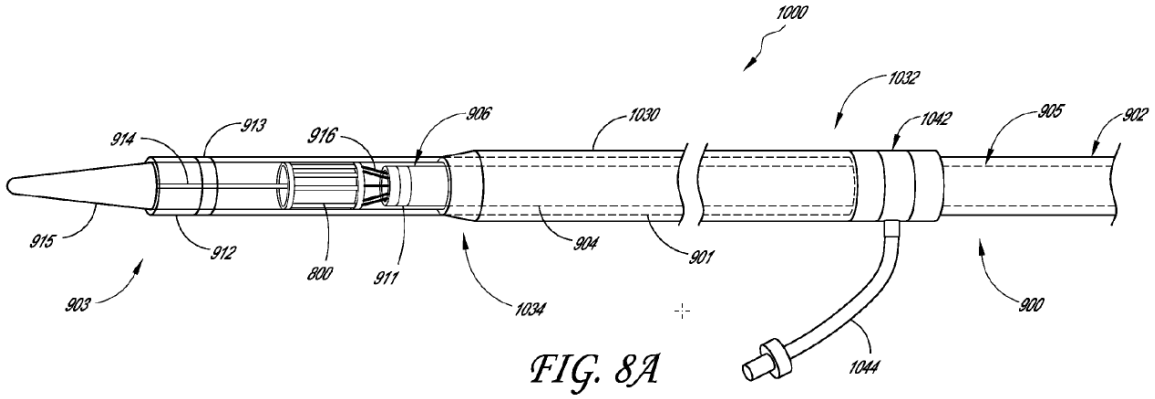

FIG. 8A

Figure 8A illustrates combined delivery system 1000 for delivering implant 800. Ex. 1001, 23:66–24:1. Combined delivery system 1000 includes

introducer catheter 1030 positioned at least partially over delivery catheter 900. *Id.* at 24:2–4. The '897 patent explains that "it is advantageous to use the combined delivery system 1000 because the introducer catheter 1030 can have a smaller diameter than would [be] possible if the introducer catheter 1030 and the delivery catheter 900 are separately introduced into the patient." *Id.* at 24:6–10. For example, the outer diameter of sheath jacket 912 can be larger than the inner diameter of introducer catheter 1030. *Id.* at 24:10–15.

E. Challenged Claims

Petitioner challenges claims 1–4, 6–10, 16–22, and 24 of the '897 patent, of which claim 1 is the sole independent claim. Claim 1 is reproduced below:

> 1. A method of positioning a prosthetic implant within a heart, the method comprising:
>
> advancing together a delivery catheter and an introducer catheter that is preassembled over the delivery catheter into a patient's vascular system, the delivery catheter comprising a prosthetic valve and a distal tip that can be inserted directly into the access vessel such that the distal tip dilates the access vessel for the introducer catheter,
>
> wherein during advancement, an outer diameter of a distal end of the delivery catheter being greater than an inner diameter of a distal end of the introducer catheter, the introducer catheter comprising a hemostasis valve assembly at a proximal end of the introducer catheter;
>
> translumenally advancing the prosthetic valve to a position proximate a native valve of the heart, the prosthetic valve being at least partially disposed within the distal end of the delivery catheter during advancement of the introducer catheter; and
>
> deploying the prosthetic valve.

Ex. 1001, 33:19–38.

F. Instituted Grounds of Unpatentability

We instituted *inter partes* review of the challenged claims based on the following grounds of unpatentability asserted by Petitioner:

Claims Challenged	35 U.S.C. §	Reference(s)/Basis
1–4, 6–10, 16, 17	103(a)	Lane[2]
1–4, 6–10, 16, 17	103(a)	Lane, Hartley[3]
3, 4	103(a)	Lane, Nguyen[4]
3, 4	103(a)	Lane, Hartley, Nguyen
16, 18–22, 24	103(a)	Lane, Thomas[5]
16, 18–22, 24	103(a)	Lane, Hartley, Thomas

Dec. Inst. 30; Pet. 9.

II. ANALYSIS

A. Legal Standards

To prevail in its challenge, Petitioner must demonstrate by a preponderance of the evidence that the claims are unpatentable. 35 U.S.C. § 316(e); 37 C.F.R. § 42.1(d). "In an IPR, the petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable." *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016) (citing 35 U.S.C. § 312(a)(3) (2012) (requiring *inter partes* review petitions to identify "with particularity . . . the evidence that supports the grounds for the challenge to each claim")). This burden of persuasion never shifts to the patent owner. *See Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015) (discussing the burden of proof in *inter partes* review).

[2] US 2011/0319989 A1, published Dec. 29, 2011 (Ex. 1023).
[3] US 2007/0185558 A1, published Aug. 9, 2007 (Ex. 1015).
[4] US 2008/0140189 A1, published June 12, 2008 (Ex. 1026).
[5] WO 2012/023980 A1, published Feb. 23, 2012 (Ex. 1006).

A patent claim is unpatentable under 35 U.S.C. § 103(a) if the differences between the claimed subject matter and the prior art are such that the subject matter, as a whole, would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of ordinary skill in the art; and (4) when in evidence, objective indicia of non-obviousness (also called secondary considerations), such as commercial success, long-felt but unsolved needs, and failure of others. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966). We analyze grounds based on obviousness in accordance with the above-stated principles.

B. 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 invention. *Graham*, 383 U.S. at 17. The person of ordinary skill in the art is a hypothetical person who is presumed to have known the relevant art at the time of the invention. *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. 18 (citing Ex. 1002 ¶¶ 31–34).

In response, Patent Owner adopts Petitioner's definition "for the purposes of this Petition" but adds that the professional experience "would include experience with *transcatheter* prosthetic cardiovascular implants and experience with delivery systems and methods used to implant such prostheses." PO Resp. 5. Patent Owner also contends that "[t]he parties' experts each agree with these added caveats." *Id.* (citing Ex. 2047, ¶¶ 17–20; Ex. 2048, 10:18–12:1).

In the Decision on Institution, we adopted Petitioner's proposed level of ordinary skill in the art, stating it was "consistent with the evidence of record, including the asserted prior art." Dec. Inst. 7. Petitioner does not challenge Patent Owner's modification to its proposed definition, and Petitioner's expert, Dr. Drasler, agrees that experience in the field of prosthetic cardiovascular implants would have included experience with transcatheter prosthetic cardiovascular implants as well as delivery systems and methods used to implant such prostheses. *See generally* Pet. Reply; Ex. 2048, 11:6–12:1. Thus, based on our review of the complete record, we adopt Petitioner's definition of the level of ordinary skill in the art, modified as proposed by Patent Owner. We note, however, that our analysis in this proceeding would not differ if we did not adopt the modification proposed by Patent Owner.

C. Claim Construction

"In an *inter partes* review proceeding, a claim of a patent . . . shall be construed using 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) (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 v. AWH Corp.*, 415 F.3d 1303, 1313–14 (Fed. Cir. 2005) (en banc). 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. *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 POSITA[6] in view of the specification." Pet. 19 (citing Ex. 1002 ¶ 56).

Patent Owner agrees that the plain and ordinary meaning of the claim terms should be applied, but submits that "there is a fundamental misunderstanding as to the meaning of 'introducer catheter' and 'delivery catheter' which necessitates construction." PO Resp. 35–36 (citing Ex. 2047 ¶¶ 68–71). Patent Owner offers construction for each of these terms and further proposes construing the term "outer tubular member." *Id.* at 36–41. We address the contested terms below.

1. "delivery catheter"

Patent Owner submits that "delivery catheter" should be defined as "an instrument comprising an elongate, flexible tubular body having a

[6] Person of ordinary skill in the art.

proximal end and a distal end, wherein the distal end houses the prosthetic implant and the proximal end includes a handle that controls the deployment of the implant." PO Resp. 36 (citing Ex. 2047 ¶ 72). Patent Owner argues that this proposed construction is well supported by the '897 patent's specification. *Id.* at 36–38 (citing Ex. 1001, 18:66–19:2, 20:19–29, 22:67–23:2, 25:38–42, 27:11–18; Ex. 2047 ¶¶ 75–79).

Petitioner maintains that no construction is necessary for "delivery catheter" and argues that Patent Owner "wrongly limits the term to require that 'the distal end houses the prosthetic implant'" because claim 1 only requires that "the prosthetic valve ***be[] at least partially disposed within*** the distal end of the delivery catheter during advancement of the introducer catheter." Pet. Reply 2 (alteration in original) (footnote omitted). Patent Owner's proposed construction, Petitioner argues, eliminates the "at least partially" language and renders the recited limitation "functionally meaningless." *Id.* (citing *Cat Tech. LLC v. Tubemaster, Inc.*, 528 F.3d 871, 885 (Fed. Cir. 2008)).

We agree with Petitioner. Patent Owner's proposal that the distal end of the delivery catheter "houses the prosthetic" is in tension with the express language of the claim because the proposed construction suggests that "houses" necessarily means more than "at least" part of the prosthesis is disposed in the distal end. Indeed, if "houses" was not more limiting than "at least partially disposed" there would be no need to further define the spatial relationship between the distal end of the catheter and the prosthetic valve.

Petitioner further argues that the Patent Owner's construction is improper because it "wrongly limits the term to require that 'the proximal end includes a handle that controls the deployment of the implant.'" Pet.

Reply at 3 (citing PO Resp. 37–38). Petitioner asserts that the claims do not recite a handle and the '897 patent's "specification makes clear that a handle is a separate, optional component that is not integral to a delivery catheter: inner tubular member 'can' be connected to handle 907 and outer tubular member 'can be connected'/'attach[ed]' to outer sheath handle 908." *Id.* (citing Ex. 1001, 20:19–29, 26:30–33, claim 10).

We again agree with Petitioner. Although the specification describes an embodiment in which proximal end 905 of inner tubular member 904 can be connected to handle 907 and proximal end 902 of outer tubular member 901 can be connected to handle 908 (Ex. 1001, 20:19–26), it is generally improper to read limitations from specific embodiments into the claims. *See Cadence Pharms. Inc. v. Exela PharmSci Inc.*, 780 F.3d 1364, 1369 (Fed. Cir. 2015) ("[E]ven if all of the embodiments discussed in the patent included a specific limitation, it would not be proper to import from the patent's written description limitations that are not found in the claims themselves." (internal quotations omitted)); *SuperGuide Corp. v. DirecTV Enters., Inc.*, 358 F.3d 870, 875 (Fed. Cir. 2004) ("Though understanding the claim language may be aided by the explanations contained in the written description, it is important not to import into a claim limitations that are not a part of the claim."). Furthermore, at the oral hearing, Patent Owner indicated that "the proximal end includes a handle that controls the deployment of the implant" part of its proposed construction is not necessary. Tr. 61:8–14.

In view of the above, we decline to adopt Patent Owner's proposed construction of "delivery catheter." Rather, we apply the plain and ordinary meaning of the term.

2. "introducer catheter"

Patent Owner argues that an "introducer catheter" should be construed as a "tubular instrument that is capable of being inserted into a patient's vasculature and held in place at the access site while the delivery catheter is passed through it and advanced to and from a patient's heart." PO Resp. 36 (citing Ex. 2047 ¶ 73).[7] Patent Owner asserts that the intrinsic and extrinsic record supports its proposed construction. *Id.* at 38–39 (citing Ex. 2047 ¶¶ 81–85).

For example, Patent Owner argues that the '897 patent's disclosure that "[i]n other embodiments, ***the introducer catheter 1030 is held in place while the delivery catheter 900 is further advanced as shown in FIG. 8B***" teaches that the preassembled introducer is designed to accommodate relative movement of the delivery catheter and is thus capable of being held in place at the access site while the delivery catheter is further advanced. *Id.* at 39 (quoting Ex. 1001, 26:63–27:5). Patent Owner also argues that the '897 patent's disclosure of "[a]fter the delivery catheter 900 is advanced over the aortic arch and past the aortic valve, the position of the outer tubular member 901 relative to the introducer catheter 1030 can be maintained by adjusting the seal assembly 1042 to form a seal around the outer tubular member 901" teaches that the introducer catheter is designed to allow the delivery catheter and prosthesis to freely advance relative to the introducer until the prosthesis is advanced to the patient's heart valve. *Id.* (quoting Ex. 1001, 27:6–18 (alteration in original)). Patent Owner also points to the '897 patent disclosing and claiming that "after deploying the prosthetic

[7] At the oral hearing, Patent Owner clarified that "capable of" modifies both the "being inserted into a patient's vasculature" and the "held in place at the access site" portions of the proposed construction. Tr. 20:19–21:10.

valve, . . . the delivery catheter [is retracted] until a proximal end of the sheath jacket abuts the distal end of the introducer catheter." *Id.* at 39–40 (citing Ex. 1001, 29:45–48; quoting *id.* at Claim 19); *see also* PO Sur-reply 10 ("[T]he retraction step of dependent Claim 19 . . . is possible only if the introducer catheter is capable of being held in place while the delivery catheter is advanced to and from a patient's heart.").

In addition, Patent Owner argues that its proposed construction "is consistent with the conventional understanding of an introducer catheter." PO Resp. 40. In particular, Patent Owner refers to the Cook introducer catheter that is identified in the '897 patent and Dwork,[8] a published patent application of Petitioner that Patent Owner asserts is part of the intrinsic record of the '897 patent. *Id.* (citing Ex. 1001, 24:46–51; Ex. 1021 ¶¶ 5, 7). Regarding extrinsic evidence, Patent Owner references three patent documents as supporting the proposed construction: Hibbs,[9] Heuser,[10] and Wiemeyer.[11] *Id.* at 40–41 (citing Ex. 2026, 1:17–49; Ex. 2027 ¶¶ 2–5; Ex. 2032 ¶ 7; Ex. 2047 ¶¶ 81–85).

Petitioner maintains that no construction is necessary but does not dispute Patent Owner's assertion "that an introducer catheter is 'a tubular instrument that is capable of being inserted into a patient's vasculature.'" Pet. Reply 4 (citing PO Resp. 36). Petitioner, however, does dispute the remaining portion of Patent Owner's proposed construction, arguing that "intrinsic and extrinsic evidence conflict with [Patent Owner's] attempt to further require that the introducer be 'held in place at the access site while

[8] US 2011/0257733 A1, published Oct. 20, 2011 (Ex. 1021).
[9] US 5,300,032, issued Apr. 5, 1994 (Ex. 2026).
[10] US 2010/0160863 A1, published June 24, 2010 (Ex. 2027).
[11] US 2011/0251679 A1, published Oct. 13, 2011 (Ex. 2032).

the delivery catheter is passed through it and advanced to and from a patient's heart.'" *Id.* at 4–5 (citing PO Response 36). Petitioner contends that, to the extent construction is required, "'introducer catheter' should be construed as 'a tubular instrument that is capable of being inserted and for introducing one or more catheters and/or devices into a patient's vasculature.'" *Id.* at 4 n.4 (citing Ex. 1070 ¶ 15).

Regarding Patent Owner's reliance on the '897 patent's disclosure of the introducer catheter being held in place while the delivery catheter is further advanced, Petitioner argues that the '897 patent also discloses the option of advancing "the entire combined delivery system 1000, including both the introducer catheter 1030 and the delivery catheter 900 . . . to a position proximate a native valve." *Id.* at 5 (quoting Ex. 1001, 27:2–5 (emphases omitted)). Petitioner also contends that the '897 patent discloses sending its integral introducer through tortuous arteries. *Id.* (citing Ex. 1001, 29:54–64; *see also* Tr. 70:7–71:4 (counsel for Petitioner arguing that the intrinsic evidence explains that certain embodiments relate to an introducer catheter that is held in place, while others do not). Petitioner further contends that "[t]he Federal Circuit has repeatedly 'cautioned against limiting the claimed invention to preferred embodiments or specific examples in the specification.'" *Id.* (citing *Texas Instruments, Inc. v. ITC*, 805 F.2d 1558, 1563 (Fed. Cir. 1986); *Phillips*, 415 F.3d at 1323; *SuperGuide Corp.*, 358 F.3d at 875).

Petitioner also disputes Patent Owner's reliance on Dwork, arguing that "the file history demonstrates that the claims are ***not*** limited to Dwork's conventional introducer. And even if the claims were so limited, Dwork itself makes clear that the 'introducer device' may 'conventionally' be 'held

stationary'—*i.e.*, they are not always held stationary." *Id.* at 6–7 (citing Ex. 1021 ¶ 7).

Regarding the extrinsic evidence cited by Patent Owner (Hibbs, Heuser, and Wiemeyer), Petitioner argues that this evidence merely "describes what was 'general,' 'typical' or 'conventional[]'" and thus demonstrates "that the term 'introducer catheter' was not limited to those applications." *Id.* at 9 (citing PO Resp. 40–41). In addition, Petitioner asserts that other prior art references "reflect[] that introducers designed to advance well-into the vasculature were well-known." *Id.* (citing Ex. 1023 ¶ 122, Figs. 23B–23C; Ex. 1005 ¶ 88; Ex. 1006 ¶¶ 60–61, Fig. 3B; Ex. 1021 ¶¶ 38–43, Fig. 11A; Ex. 1073, 3, 67; Ex. 1070 ¶ 19).

Based on the complete record, we are not persuaded that the "capable of" portion Patent Owner's construction should be adopted. First, we disagree that the '897 patent's specification limits the scope of the claimed introducer catheter as Patent Owner contends. The full passage from the specification cited by Patent Owner states:

> In some embodiments, the combined delivery system 1000 is advanced until the seal assembly 1042 reaches the patient. In other embodiments, the introducer catheter 1030 is held in place while the delivery catheter 900 is further advanced as shown in FIG. 8B. The delivery catheter 900 can be advanced to a position proximate a native valve. In other embodiments, the entire combined delivery system 1000, including both the introducer catheter 1030 and the delivery catheter 900 can be advanced to a position proximate a native valve.
>
> After the delivery catheter 900 is advanced over the aortic arch and past the aortic valve, the position of the outer tubular member 901 relative to the introducer catheter 1030 can be maintained by adjusting the seal assembly 1042 to form a seal around the outer tubular member 901.

Ex. 1001, 26:63–27:10. The '897 patent thus contemplates at least two alternatives: (1) embodiments in which the introducer catheter is held in place while the delivery catheter is further advanced to a position proximate a native valve, and (2) other embodiments in which both the introducer catheter and the delivery catheter are advanced to a position proximate a native valve. In the latter case, the introducer catheter would not necessarily need to be "capable of being . . . held in place at the access site while the delivery catheter is passed through it and advanced to and from a patient's heart." As such, the disclosure of the introducer catheter being held in place while the delivery catheter is further advanced is just an optional technique and not a requirement and, thus, does not warrant adding this technique to the construction.

As discussed above, it is generally improper to read limitations from specific embodiments into the claims. *See Cadence Pharms.*, 780 F.3d at 1369; *SuperGuide Corp.*, 358 F.3d at 875. Moreover,

> [a] construing court's reliance on the specification must not go so far as to "import limitations into claims from examples or embodiments appearing only in a patent's written description . . . unless the specification makes clear that 'the patentee . . . intends for the claims and the embodiments in the specification to be strictly coextensive.'"

Silicon Graphics, Inc. v. ATI Techs., Inc., 607 F.3d 784, 792 (Fed. Cir. 2010) (quoting *JVW Enters., Inc. v. Interact Accessories, Inc.*, 424 F.3d 1324, 1335 (Fed. Cir. 2005)). We see nothing in the specification of the '897 patent that clearly indicates the patentee intended the claims to be strictly coextensive with the embodiments in which the introducer catheter is held in place while the delivery catheter is further advanced to a position proximate a native valve. Indeed, by relying on these disclosed embodiments, Patent Owner's

proposed construction conflicts with the specification's statement that "the invention is not intended to be limited by the specific disclosures of preferred embodiments herein." Ex. 1001, 33:15–17.

Furthermore, inventors can act as their own lexicographers if they clearly set forth a definition of a claim term other than its ordinary and customary meaning. *Vasudevan Software, Inc. v. MicroStrategy, Inc.*, 782 F.3d 671, 677 (Fed. Cir. 2015). But any such definition must appear in the specification "with reasonable clarity, deliberateness, and precision." *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1249 (Fed. Cir. 1998); *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994). Absent any such definition, "limitations are not to be read into the claims from the specification." *In re Van Geuns*, 988 F.2d 1181, 1184 (Fed. Cir. 1993). Here, a definition of "introducer catheter" does not appear in the specification "with reasonable clarity, deliberateness, and precision." *See generally* Ex. 1001.

We also disagree that the recitation in Claim 19 that "after deploying the prosthetic valve, . . . the delivery catheter [is retracted] until a proximal end of the sheath jacket abuts the distal end of the introducer catheter" limits the scope of the claimed introducer catheter in the manner asserted by Patent Owner. Although the language of Claim 19 implies that distal end of the delivery catheter is advanced beyond the distal end of the introducer catheter, it does not require expressly that the introducer catheter is held in place at the access site while the delivery catheter is further advanced. Furthermore, this language does not change the fact that the '897 patent discloses advancing both the introducer catheter and the delivery catheter to a position proximate a native valve as an alternative to the option of holding the introducer catheter in place while the delivery catheter is further

advanced to a position proximate a native valve. And to the extent that Claim 19 does require that the introducer catheter is held in place at the access site while the delivery catheter is further advanced, "the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim." *Phillips*, 415 F.3d at 1314–15; *see also InterDigital Commc'ns, LLC v. ITC*, 690 F.3d 1318, 1324 (Fed. Cir. 2012) ("The doctrine of claim differentiation is at its strongest in this type of case, 'where the limitation that is sought to be "read into" an independent claim already appears in a dependent claim.'" (quoting *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 910 (Fed. Cir. 2004)).

In the Sur-reply, Patent Owner asserts that its proposed construction "accounts for" both of the alternative approaches disclosed in the '897 patent (i.e., (1) embodiments in which the introducer catheter is held in place while the delivery catheter is further advanced to a position proximate a native valve, and (2) other embodiments in which both the introducer catheter and the delivery catheter are advanced to a position proximate a native valve). PO Sur-reply 8. Specifically, Patent Owner argues that

> [i]n each use of the introducer catheter described by the '897 Patent, the introducer catheter remains capable of being held in place at the access site while the delivery catheter is passed through it and advanced to and from a patient's heart. Indeed, there are no described structural differences in the introducer catheter across these various uses; the '897 Patent is merely detailing the physician's options of how far to advance the introducer catheter into a patient's vasculature before proceeding to the next step of the procedure.

Id. at 8–9. This argument is not persuasive because the proposed construction precludes the embodiments in which both the introducer

catheter and the delivery catheter are advanced to a position proximate a native valve. For these embodiments, the introducer catheter may be capable of being held in place but not *while the delivery catheter is passed through it and advanced to and from a patient's heart* because both catheters are advanced to the heart valve together.

Similarly, we disagree with Patent Owner's argument that nothing in the proposed construction limits the distance the introducer catheter extends into a patient's vasculature. *See* Sur-reply 6. On the contrary, by requiring the introducer catheter be capable of being held in place while the delivery catheter is passed through it and advanced to and from a patient's heart, the proposed construction precludes the introducer catheter from being advanced to and held in place at the heart valve because, when the introducer catheter is held in place at the heart valve, the delivery catheter cannot be advanced further. That is, further advancement of the delivery catheter by passing it through the introducer catheter would not be possible when both catheters are already advanced to the patient's heart.

Second, we are not persuaded by Patent Owner's argument that its proposed construction "is consistent with the conventional understanding of an introducer catheter." *See* PO Resp. 40. Patent Owner cites passages from Paragraphs 5 and 7 of Dwork to support this assertion. *Id.* (citing Ex. 1021 ¶¶ 5, 7). The first passage is

> typical transcatheter heart valve implantation techniques entail the use of a separate introducer device to establish a portal to the patient's vasculature (e.g., femoral artery) and through which the prosthetic heart valve-loaded delivery device is inserted. The introducer device generally includes a relatively short sheath and a valve structure.

Ex. 1021 ¶ 5. This passage, however, pertains to "a separate introducer device" "through which the prosthetic heart valve-loaded delivery device is inserted" and, as such, would not reliably inform one of ordinary skill in the art with respect to the preassembled introducer catheter of claim 1. Also, the description of the introducer device generally including "a relatively short sheath" does not seem compatible with the '897 patent's embodiments in which both the introducer catheter and the delivery catheter are advanced to a position proximate a native valve. Indeed, Patent Owner argued that the claimed preassembled introducer catheter was patentably distinct from the introducer catheter of Dwork. Tr. 52:20–54:18. Thus, we disagree that Dwork's disclosure that its introducer device is held stationary (Ex. 1021 ¶ 7) supports Patent Owner's assertion that the claimed introducer catheter should be construed as capable of being held in place at the access site while the delivery catheter is passed through it and advanced to and from a patient's heart.

Last, the extrinsic evidence presented by Patent Owner and Mr. Rourke—such as Hibbs, Heuser, and Wiemeyer—is unavailing. *See* PO Resp. 40–41; PO Sur-reply 12–14; Ex. 2047 ¶¶ 81–85. Generally, extrinsic evidence is "less significant than the intrinsic record in determining the legally operative meaning of claim language." *Phillips*, 415 F.3d at 1317 (internal quotation marks omitted). Furthermore, to the extent this extrinsic evidence demonstrates the conventional understanding of an introducer catheter, we determine that conventional introducer catheters do not reliably inform one of ordinary skill in the art with respect to the preassembled introducer catheter of claim 1 for the reasons discussed above. Therefore, we find Patent Owner's extrinsic evidence, and Mr. Rourke's supporting testimony, do not overcome the intrinsic record of this case. *See id.* at 1318

("[A] court should discount any expert testimony that is clearly at odds with the claim construction mandated by the claims themselves, the written description, and the prosecution history, in other words, with the written record of the patent.") (citations and internal quotation marks omitted).

For these reasons, we decline to adopt the "capable of" portion of Patent Owner's construction. The parties do not dispute, however, that a construction of "introducer catheter" should include "a tubular instrument that is capable of being inserted into a patient's vasculature. *See* PO Resp. 36; Pet. Reply 4 n.4. Furthermore, we agree with Petitioner's assertion that the intrinsic record confirms that an introducer catheter is used to introduce one or more catheters and/or devices into a patient's vasculature. *See* Pet. Reply 4 (citing Ex. 1001, 3:49–51, 12:16–18, 21:45–51, 24:2–4, 29:59–64, 30:44–51, Claims 1, 2, 3, 7, 17). This assertion is supported by Dr. Drasler's testimony, which we credit. Ex. 1070 ¶ 15. Accordingly, we determine on the complete record that an "introducer catheter" is "a tubular instrument that is capable of being inserted into a patient's vasculature for introducing one or more catheters and/or devices into a patient's vasculature."

3. "outer tubular member"

Patent Owner argues that an "outer tubular member" should be construed as a "the outermost tubular portion of the delivery catheter, which provides the housing for the prosthetic implant at its distal end." PO Resp. 41 (citing Ex. 2047 ¶¶ 86–87). Petitioner argues that no construction is necessary but does not dispute "that 'outer tubular member' means 'an outermost tubular portion of the delivery catheter.'" Pet. Reply 9–10 (citing PO Resp. 41; Ex. 1001, 19:53–61). Petitioner argues, however, that Patent Owner's construction wrongly requires an "outer tubular member" to

provide the housing for the prosthetic implant at its distal end. *Id.* at 10 (citing PO Resp. 41).

We determine that we need not expressly construe this claim term to resolve the parties' disputes because doing so would have no effect on the analysis below. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017); *see also Realtime Data, LLC v. Iancu*, 912 F.3d 1368, 1375 (Fed. Cir. 2019) ("The Board is required to construe 'only those 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)).

D. Ground 1: Asserted Obviousness over Lane

Petitioner asserts that claims 1–4, 6–10, 16, and 17 are unpatentable under 35 U.S.C. § 103(a) based on Lane. Pet. 20–58. Patent Owner provides arguments addressing this asserted ground of unpatentability. PO Resp. 42–56. We first summarize Lane and then address the parties' contentions.

1. Lane

Lane, titled "Transcatheter Mitral Valve Prosthesis," was published on December 29, 2011. Ex. 1023, codes (54), (43). Lane "relates to the treatment of valve insufficiency, such as mitral insufficiency, also referred to as mitral regurgitation." *Id.* ¶ 3. Lane explains that, although transcatheter devices and methods for the delivery of replacement valve assemblies have been developed, it would be desirable to provide improved transcatheter devices and methods for the treatment of mitral insufficiency. *Id.* ¶¶ 6–7.

We reproduce Figures 16 and 18 of Lane below.

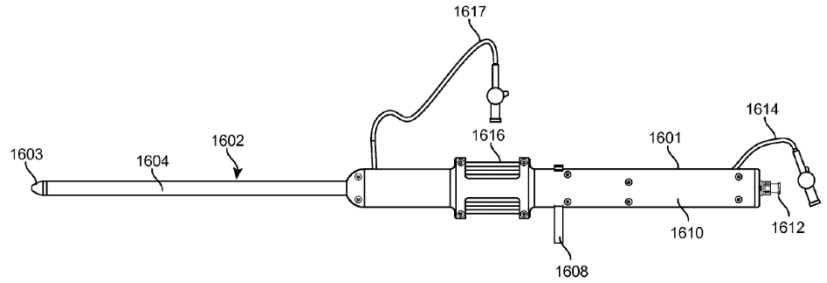

FIG. 16

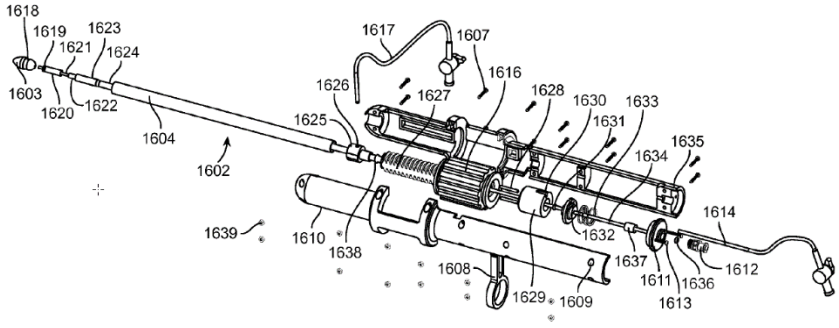

FIG. 18

Figure 16 is a side view of an exemplary embodiment of a delivery device for implanting a prosthetic heart valve transapically, and Figure 18 is an exploded view of the delivery device. Ex. 1023 ¶¶ 71, 73, 115.

The delivery device includes handle 1601, flexible sheath 1602 comprised of a plurality of concentric catheters, and tip 1603 for smoothly penetrating the apex of the heart. *Id.* ¶ 115. Flexible sheath 1602 comprises four concentrically nested catheters. *Id.* ¶ 122. The innermost catheter is guide-wire catheter 1621 that is connected to tip 1603. *Id.* Next is hub catheter 1622, which is stationary and supports hub 1620. *Id.* The next catheter is bell catheter 1624, which houses hub 1620 and can be advanced and retracted axially with respect to hub 1620. *Id.* The outermost catheter is sheath catheter 1604, which houses a prosthetic mitral valve (not shown). *Id.* Sheath catheter 1604 "is able to penetrate the apex of the heart (not shown), by supporting and directing a tip 1603 and assisting in the dilation of an incision in the heart wall muscle." *Id.* Alternatively, "the delivery

system may be modified and relative motion of the various components adjusted to allow the device to be used to deliver a prosthetic transseptally." *Id.* ¶ 115.

Handle 1601 includes thumbwheel 1616 for actuating sheath catheter 1604 and bell catheter 1624. *Id.* ¶¶ 117, 124. The delivery device further includes first hemostasis tune 1617 and second hemostasis tune 1614. *Id.* ¶¶ 118–119.

2. Independent Claim 1

Petitioner contends that Lane, when modified as proposed, discloses each limitation of independent claim 1. Pet. 31–47. To support its arguments, Petitioner identifies certain passages in Lane and explains the significance of each passage with respect to the corresponding claim limitation. *Id.* Petitioner also articulates reasons that one of ordinary skill in the art would have allegedly modified Lane to dilate the access point of the access vessel. *Id.* at 38–39. Patent Owner argues that Petitioner has failed to show that Lane discloses a preassembled introducer catheter. PO Resp. 42–50.

a) The "Advancing Together" Limitation

Claim 1 recites "advancing together a delivery catheter and an introducer catheter that is preassembled over the delivery catheter into a patient's vascular system" ("the 'advancing together' limitation"). Ex. 1001, 33:21–23. In addressing this limitation, Petitioner argues that Lane's guide-wire catheter 1621, hub catheter 1622, and bell catheter 1624 collectively correspond to the claimed delivery catheter. Pet. 32–33 (citing Ex. 1023 ¶¶ 115, 122, 138, Fig. 18). Petitioner also argues that Lane's sheath catheter 1604 corresponds to the claimed introducer catheter that is preassembled over the delivery catheter. *Id.* (citing Ex. 1023 ¶¶ 115, 122, 138, Fig. 18).

According to Petitioner, "because [Lane's] distal tip 1603 cannot pass through and instead 'abut[s] against' the sheath catheter 1604's distal edge, sheath catheter 1604 is preassembled over the other three catheters outside the patient." *Id.* at 32 (citing Ex. 1023 ¶ 123; Ex. 1002 ¶¶ 87–88) (second alteration in original). Petitioner asserts that the catheters are advanced together in this preassembled state into a patient's vascular system. *Id.* at 32–33 (asserting Lane discloses the catheters are "inserted into the access vessel during 'transseptal' delivery"), 35–36 (citing Ex. 1023 ¶ 138) (asserting Fig. 23B shows a transseptal pathway in which the delivery device passes up the vena cava into the right atrium).

Patent Owner argues that Lane's sheath catheter 1604 is not an introducer catheter because it is part of Lane's delivery apparatus. *Id.* at 43; PO Sur-reply 17–19. According to Patent Owner, Lane's "four concentrically nested catheters of the flexible sheath 1602, including the sheath catheter 1604, are all part of a single catheter controlled by a handle at the proximal end of the device," such that "[t]aken collectively, it is clear that 'the delivery apparatus' with 'handle' and 'flexible sheath 1602' is a 'delivery catheter' as claimed by the '897 Patent." *Id.* at 45–46 (citing Ex. 2047 ¶¶ 98–105). Patent Owner also argues that Dr. Drasler's testimony that Lane's sheath catheter 1604 satisfies the claimed introducer catheter is based solely on sheath catheter 1604 being the outermost of the four concentrically nested catheters, but being the outermost catheter does not make it an introducer catheter as claimed. *Id.* at 46–47 (Ex. 1002 ¶ 87; Ex. 2047 ¶ 108); *see also* PO Sur-reply 15 (arguing Petitioner provides no valid reasoning for asserting that sheath catheter 1604 is an introducer catheter because it is the outermost catheter).

Furthermore, Patent Owner argues that Lane's sheath catheter is not an introducer catheter because and it is "not capable of being inserted into a patient's vasculature and held in place at the access site while the delivery catheter is passed through it and advanced to and from a patient's heart." *Id.* at. 47–48; PO Sur-reply 15–18.

In the Reply, Petitioner argues that Patent Owner's arguments stem from its proposed claim constructions, which Petitioner asserts are erroneous. Pet. Reply 12. Patent Owner indicated during the oral hearing that "the parties are in agreement that the primary dispute in this proceeding is the claim construction of [the 'advancing together' limitation]." Tr. 35:17–20. Patent Owner also indicated that it made only one other argument with respect to claim 1 (which we discuss below) separate and apart from the argument based on claim construction. Tr. 36:18–37:21.

We agree that Patent Owner's arguments discussed above are predicated on its proposed construction of the term "introducer catheter," which we decline to adopt for the reasons set forth above. *See supra* § II.C.2. Instead, we construe an "introducer catheter" as "a tubular instrument that is capable of being inserted into a patient's vasculature for introducing one or more catheters and/or devices into a patient's vasculature." *Id.* There is no dispute that sheath catheter 1604 is a tubular instrument capable of being inserted into a patient's vasculature. Also, because Lane discloses inserting its delivery device, which includes the four nested catheters, into a patient's vasculature (Ex. 1023 ¶ 138), we are persuaded that sheath catheter 1604 acts to introduce the other three catheters into the vasculature. Accordingly, we agree with Petitioner and are persuaded on the complete record that sheath catheter 1604 is an "introducer catheter" as recited in claim 1.

In addition, although Lane's sheath catheter is part of the delivery apparatus, we are not persuaded that this precludes the sheath catheter from being an "introducer catheter" because the introducer catheter disclosed in the '897 patent is similarly part of a combined delivery system. *See* Pet. Reply 12–13 (citing Ex. 1023, ¶ 122, Fig. 18; Ex. 1001, 24:2–4, 24:63–65, Fig. 8A). We also agree with Petitioner that sheath catheter 1604 "is a distinct element of its [(i.e., Lane's)] system, and not unitary with the other catheters." *See id.* at 13 (citing Ex. 1001, ¶¶ 115, 117, 122–123, 127–128, Figs. 16–21; Ex. 1070 ¶ 25).

Next, Patent Owner argues that sheath catheter 1604 is not preassembled "over" a delivery catheter because "[i]t does not have the relative movement capabilities of an introducer catheter as claimed, and cannot operate independently of the control handle." PO. Resp. 49–50 (citing Ex. 2047 ¶ 112; Ex. 2048, 57:16–60:17). This argument is not persuasive because, in view of our rejection of Patent Owner's proposed claim construction, claim 1 does not recite relative movement capabilities for the introducer catheter. Also, we agree with Petitioner that sheath catheter 1604 is preassembled "over" the other three catheters because in Lane all of the catheters are concentrically nested. *See* Pet. Reply 10–11 (citing Pet. 32–33; Ex. 1002 ¶¶ 85–88; Ex. 1001 ¶ 122, Fig. 18).

Last, Patent Owner argues that Lane fails to disclose advancing a delivery catheter or introducer catheter "into a patient's vascular system" because Lane uses a transapical approach. PO. Resp. 50. But Petitioner relies on Lane's transseptal approach not the transapical approach to satisfy this claim element. Pet. 32, 35–36 (citing Ex. 1023 ¶ 0138, Fig. 23B); Pet. Reply 14. Patent Owner does not rebut Petitioner's argument that the transseptal approach reads on the claimed "into a patient's vascular system."

See generally PO Sur-reply. We are persuaded, based on the complete record, that the transseptal approach disclosed in Lane is a surgical technique in which the delivery and introducer catheters are advanced together into the vascular system.

Based on the full record before us, we determine that Petitioner has met its burden of establishing that Lane discloses the "advancing together" limitation.

b) The Remaining Aspects of Petitioner's Contentions

Patent Owner does not offer any arguments specifically addressing the remaining limitations of claim 1. *See generally* PO Resp. We need not set forth formal findings as to the undisputed assertions by Petitioner that Lane discloses or suggests these limitations. *See LG Elecs., Inc. v. Conversant Wireless Licensing S.A.R.L.*, 759 F. App'x 917, 925 (Fed. Cir. 2019) ("The Board is 'not required to address undisputed matters' or arguments about limitations with which it was never presented." (quoting *In re Nuvasive, Inc.*, 841 F.3d 966, 974 (Fed. Cir. 2016))). Also, we cautioned Patent Owner "that any arguments not raised in the response may be deemed waived." Paper 12, 8; *cf.* 37 C.F.R. § 42.23(a) ("Any material fact not specifically denied may be considered admitted."). Nevertheless, we have reviewed Petitioner's contentions with respect to the remaining limitations of claim 1 and find that Lane teaches these limitations as set forth by Petitioner. *See* Pet. 31–47.

c) Objective Indicia of Nonobviousness

(1) Legal Standard

We must consider any evidence of objective indicia of nonobviousness in the record before reaching our conclusion on obviousness. *WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1328 (Fed. Cir.

2016). Factual inquiries for an obviousness determination include secondary considerations based on evaluation and crediting of objective evidence of nonobviousness. *Graham*, 383 U.S. at 17 (1966).

For objective indicia of nonobviousness to be accorded substantial weight, its proponent must establish a nexus between the evidence and the merits of the claimed invention. *ClassCo, Inc., v. Apple, Inc.*, 838 F.3d 1214, 1220 (Fed. Cir. 2016). "[T]here is no nexus unless the evidence presented is 'reasonably commensurate with the scope of the claims.'" *Id.* (quoting *Rambus Inc. v. Rea*, 731 F.3d 1248, 1257 (Fed. Cir. 2013)). A patentee is entitled to a presumption of nexus "when the patentee shows that the asserted objective evidence is tied to a specific product and that product 'embodies the claimed features, and is coextensive with them.'" *Fox Factory, Inc. v. SRAM, LLC*, 944 F.3d 1366, 1373 (Fed. Cir. 2019) (quoting *Polaris Indus., Inc. v. Arctic Cat, Inc.*, 882 F.3d 1056, 1072 (Fed. Cir. 2018)). "A finding that a presumption of nexus is inappropriate does not end the inquiry into secondary considerations"; rather, "the patent owner is still afforded an opportunity to prove nexus by showing that the evidence of secondary considerations is the 'direct result of the unique characteristics of the claimed invention.'" *Id.* at 1373–74 (quoting *In re Huang*, 100 F.3d 125, 140 (Fed. Cir. 1996)); *see also Lectrosonics, Inc. v. Zaxcom, Inc.*, IPR2018-01129, Paper 33 at 33 (PTAB Jan. 24, 2020) (precedential) (explaining that the Board uses a two-step analysis in evaluating nexus between the claimed invention and objective evidence). Ultimately, "[t]he patentee bears the burden of showing that a nexus exists." *WMS Gaming, Inc. v. Int'l Game Tech.*, 184 F.3d 1339, 1359 (Fed. Cir. 1999).

(2) Analysis

Patent Owner submits that Petitioner's patent application (U.S. Patent Application No. 13/914,802 titled "Delivery System with Inline Sheath," to Deshmukh (Ex. 2039)) and commercial product (THV delivery system with an "inline sheath") "confirms that there was a long-felt but unmet need for the technology claimed in the '897 Patent." PO Resp. 67 (citing Ex. 2047 ¶ 161). Patent Owner also cites a journal article by Neches[12] as recognizing the need in the early 1970's. *Id.* at 68 (citing Ex. 2025, 6). Patent Owner further argues that "[a] clear nexus exists between the teachings of Deshmukh and the '897 Patent," and the '897 patent first "addressed the long-felt but unmet need for a delivery system that avoids the drawbacks associated with traditional introducer catheters that increase the diameter of vascular access, thus reducing the risk of access-related complications." *Id.* at 69 (citing Ex. 2047 ¶¶ 162–164); *see also id.* at 69–70 (explaining that "Petitioners' Instructions for Use [of the EnVeo delivery system] further confirm the nexus between the '897 Patent's claimed preassembled introducer catheter and the Enveo delivery system's inline sheath").

Petitioner argues that Patent Owner fails to establish nexus or show evidence of non-obviousness. Pet. Reply 26. Specifically, Petitioner submits that neither Deshmukh nor Petitioner's "EnVeo R Delivery System" show that there was a long-felt but unmet need. *Id.* at 27. Petitioner also argues that Patent Owner's evidence is not entitled to substantial weight because Patent Owner fails to demonstrate any nexus between the evidence and the *claims* of the '897 patent. *Id.* at 29. For instance, Petitioner asserts

[12] Neches et al., "Percutaneous Sheath Cardiac Catheterization," Am. J. of Cardiology, Vol. 30, 378–84 (Sept. 1972) (Ex. 2025).

that the novel element of Deshmukh—a rigid distal end of the introducer—is not claimed in the '897 patent. *Id.* Petitioner also asserts that Patent Owner does not even attempt to show the EnVeo delivery system meets the claims of the '897 patent. *Id.* In the Sur-reply, Patent Owner discusses Petitioner's arguments regarding the novelty of Deshmukh's introducer, but does not dispute Petitioner's assertion that Patent Owner fails to demonstrate any nexus between the evidence and the claims of the '897 patent. PO Sur-reply 26–27.

We agree with Petitioner that Patent Owner's evidence is not entitled to substantial weight. Patent Owner does not assert that the proffered evidence of secondary considerations is entitled to a presumption of nexus. Nor has Patent Owner satisfied its burden of showing that the evidence of secondary considerations is the "direct result of the unique characteristics of the claimed invention." *See Fox Factory*, 944 F.3d at 1373–74. As explained above (*see supra* § II.D.2.a), we are not persuaded that the claimed introducer is a "unique characteristic of the claimed invention." Mr. Rourke testifies that "[a] clear nexus exists between the teachings of Deshmukh and the '897 Patent." Ex. 2047 ¶¶ 162. This testimony is a conclusory statement that merely repeats Patent Owner's assertion in the Response. We do not credit this testimony because Mr. Rourke does not provide the underlying basis for the statement. *See* 37 C.F.R. § 42.65(a) ("Expert testimony that does not disclose the underlying facts or data on which the opinion is based is entitled to little or no weight."); *see also Nobel Biocare Servs. AG v. Instradent USA, Inc.*, 903 F.3d 1365, 1382 (Fed. Cir. 2018) (explaining that the Board can reject arguments based on expert testimony that lacks specificity or detail). Accordingly, we find that Patent

Owner has not established sufficiently a nexus between the merits of the claimed invention and the asserted evidence.

Furthermore, establishing long-felt need requires objective evidence that a recognized problem existed in the art for a long period *without* solution (*see Orthopedic Equip. Co., Inc. v. All Orthopedic Appliances, Inc.*, 707 F.2d 1376, 1382 (Fed. Cir. 1983); *In re Gershon*, 372 F.2d 535, 538 (CCPA 1967)), and another must not have satisfied the long-felt need before the invention of the challenged patent (*Newell Cos. v. Kenney Mfg. Co.*, 864 F.2d 757, 768 (Fed. Cir. 1988)). Here, Patent Owner does not submit sufficient evidence that others had not already solved the alleged long-felt need. For instance, Patent Owner asserts that Deshmukh describes a delivery system that includes an integrated introducer to meet the alleged long-felt need, but does not assert that this solution failed. PO Resp. 68. When asked during the oral hearing about evidence in the record regarding others trying but failing to solve the alleged long-felt need, Patent Owner pointed to Neches but does not explain, either during the hearing or in its briefing, how Neches shows a failure to solve the alleged long-felt need. Tr. 68:17–69:15. Accordingly, we find that Patent Owner has not provided credible evidence of a long-felt but unmet need.

For the above reasons, we find that Patent Owner's evidence of secondary considerations is not entitled to substantial weight.

d) Conclusion

For the foregoing reasons, we determine that Petitioner has shown by a preponderance of the evidence that Lane renders obvious claim 1.

3. Dependent Claims 2, 6, 7, 16, and 17

For each of claims 2, 6, 7, 16, and 17, Petitioner provides a detailed analysis of Lane's disclosures that teach every element of each claim.

Pet. 47–49, 51–52, 55–58. Petitioner also supports its contentions for these claims with the testimony of Dr. Drasler. *Id.* (citing Ex. 1002 ¶¶ 112–116, 127–133, 145–157). Patent Owner rests on its arguments for claim 1 and offers no specific argument disputing Petitioner's contentions with respect to these claims. PO Resp. 51; *see also* Tr. 37:23–38:6 (counsel for Patent Owner stating that claims 2, 6, 7, 16, and 17 stand or fall with the claim construction argument).

We have considered the evidence and arguments of record and determine that Petitioner has demonstrated by a preponderance of the evidence that Lane renders obvious claims 2, 6, 7, 16, and 17 for the reasons discussed in the Petition and as supported by the testimony of Dr. Drasler.

4. Dependent Claims 3 and 4

Claim 3 depends from claim 1 and additionally requires "inserting the introducer catheter into a femoral artery." Ex. 1001, 33:44–48. Petitioner contends that claim 3 is obvious over Lane because

> a POSITA would have understood, and at minimum found it obvious, to advance the prosthesis through the well-known retrograde arterial approach in which case the catheter would be inserted via the femoral artery, given Lane's disclosure of transluminal delivery and Zarbatany's (incorporated by reference in Lane) disclosure of direct venous access to advantageously avoid puncturing the atrial septum for transseptal delivery.

Pet. 50 (citing Ex. 1023 ¶¶ 87, 91, 138; Ex. 1005 ¶ 88; Ex. 1002 ¶¶ 117–121).

Patent Owner submits that claim 3 is not obvious for the same reasons as claim 1 and further argues that it would not have been routine to use a transfemoral approach because it "may require both modification of the delivery system and prosthesis to reduce the overall profile." PO Resp. 51–

52 (citing Ex. 2044, 4–22; Ex. 2048, 47:20–50:9, 52:20–53:5; Ex. 2047 ¶ 117). Patent Owner does not dispute that it was known as of 2012 to use a transfemoral approach to implant transcatheter heart valves, nor does Patent Owner dispute that it would have been desirable to use a transfemoral approach instead of a transseptal approach to avoid puncturing the septum. PO Resp. 51–52; PO Sur-reply 20–21.

In response, Petitioner further submits that the prior art is "replete" with teachings "demonstrating that POSITAs were fully capable of adapting catheters for retrograde and antegrade delivery and adapting as necessary to account for a variety of access cites." Reply 16 (citing Ex. 1023 ¶¶ 14, 24, 87, 101; Ex. 1005 ¶ 89; Ex. 1026 ¶¶ 232–233; Ex. 1009 280; Ex. 1018, 4:10–45, 7:10–14; Ex. 2034, 633–35; Pet. 31, 50, 61–64; Ex. 1070 ¶¶ 31–32); *see also* Pet. 31 (citing Ex. 1018, 7:28–38; Ex. 1004, 9:64–10:11; Ex. 1021 ¶ 3; Ex. 1026 ¶¶ 38, 232; Ex. 1002 ¶ 80). One of these cited prior art references, Nguyen, for example, teaches that an aortic valve may be introduced using a venous transseptal (antegrade) approach or "in a retrograde manner through a peripheral artery (femoral artery)." Ex. 1026 ¶ 38. Patent Owner maintains that the modification would not have been routine because it is "not clear" what adaptations would have been required and whether they would have been sufficient. PO Sur-reply 21.

We agree with Petitioner. That the device or prosthesis may have required modification to be implemented in a transfemoral approach does not mean that it would not have been obvious to do so. On this record, and especially in light of the teachings of the prior art, we are persuaded that Petitioner sufficiently establishes why one of ordinary skill in the art would have been motivated to use a transfemoral approach and that it would have been obvious to do so. Accordingly, we determine that Petitioner has

demonstrated by a preponderance of the evidence that Lane renders obvious claim 3.

Claim 4 depends from claim 1 and additionally requires "translumenally advancing the prosthetic valve to a position proximate the native valve of the heart comprises advancing the prosthetic valve through an aorta." Ex. 1001, 33:49–52. Petitioner contends that claim 4 is obvious because "Lane discloses replacing the aortic valve by delivering the prosthesis transluminally" and "one of ordinary skill in the art would have understood, and at minimum found it obvious, to transluminally advance the prosthesis through the well-known retrograde arterial approach via the aorta." Pet. 50 (citing Ex. 1023 ¶¶ 87, 91, 138; Ex. 1002 ¶¶ 125–126).

Patent Owner's arguments regarding claim 4 rest on its arguments for claim 3 (PO Resp. 53), so we need not separately address them. We have also considered the evidence and arguments of record and determine that Petitioner has demonstrated by a preponderance of the evidence that Lane renders obvious claim 4 for the reasons discussed in the Petition and as supported by the testimony of Dr. Drasler.

5. Dependent Claims 8 and 9

Claim 8 depends from claim 1 and additionally requires deploying the prosthetic valve by "retracting the delivery catheter to expose the prosthetic valve." Ex. 1001, 34:1–3. Petitioner contends that claim 8 is obvious over Lane because Lane discloses fully retracting the larger diameter section 1623 of bell catheter 1624 to completely free the heart valve. Pet. 52–53 (citing 1023 ¶¶ 31, 47, 49, 122, 124, 128–129; Ex. 1002 ¶¶ 134–137).

Patent Owner submits that claim 8 is not obvious for the same reasons as claim 1 and further argues that "retracting the delivery catheter to expose the prosthetic valve" is not met by Lane's disclosure of retracting bell

catheter 1624 because "[i]t is the sheath catheter 1604 that is retracted to expose the prosthetic valve." PO Resp. 53. According to Patent Owner, Petitioner cannot rely on the sheath catheter to satisfy claim 8 because Petitioner asserts that the sheath catheter corresponds to the introducer catheter not the delivery catheter. *Id.* at 53–54. Patent Owner also argues that when larger diameter section 1623 of bell catheter 1624 is retracted to completely free the heart valve, "the prosthesis [in Lane] has already been exposed and the quoted discussion is only describing the release of the prosthesis from the delivery system." *Id.* at 54; *see also* PO Sur-reply 22 (asserting that the valve disclosed in the '897 patent is exposed "as soon as any portion of it becomes unsheathed" whereas the valve in Lane is exposed as soon as the sheath catheter, not bell catheter, is unsheathed).

We disagree. The plain language of claim 8 only requires that "deploying the prosthetic valve comprises retracting the delivery catheter to expose the prosthetic valve." Ex. 1001, 34:1–3. Lane discloses that retracting bell catheter 1624 "completely frees the heart valve form the delivery system." Ex. 1023 ¶ 128. Therefore, Lane discloses retracting the deliver catheter (i.e., bell catheter 1624) to expose a portion of the prosthetic valve. That retraction of the sheath catheter also exposes some portion of the valve does not negate this fact.

Accordingly, we agree with Petitioner that this limitation is satisfied by Lane and determine that Petitioner has demonstrated by a preponderance of the evidence that Lane renders obvious claim 8.

Claim 9 depends from claim 8 and additionally requires "holding the prosthetic valve stationary as the delivery catheter is retracted." Ex. 1001, 34:4–6. Petitioner contends that claim 9 is obvious because Lane discloses fully retracting bell catheter 1624 after the valve prosthesis is anchored in

place. Pet. 54 (citing Ex. 1023 ¶¶ 26, 31, 122, 124, 128–129; Ex. 1002 ¶¶ 138–141).

Patent Owner's arguments regarding claim 9 rest on its arguments for claim 8 (PO Resp. 55), so we need not separately address them. We have also considered the evidence and arguments of record and determine that Petitioner has demonstrated by a preponderance of the evidence that Lane renders obvious claim 9 for the reasons discussed in the Petition and as supported by the testimony of Dr. Drasler.

6. Dependent Claim 10

Claim 10 depends from claim 1 and additionally requires that the delivery catheter "comprises an outer tubular member and an inner tubular member to push the prosthetic valve out of the outer tubular member." Ex. 1001, 34:7–9. Petitioner contends that the outer tubular member is met by Lane's bell catheter 1624 and the inner tubular member is met by guide-wire catheter 1621 and hub catheter 1622. Pet. 54–55 (citing Ex. 1023 ¶ 122, Fig. 18; Ex. 1002 ¶¶ 142–144).

Patent Owner argues that claim 10 is not obvious for the same reasons as claim 1 and further disputes that Lane's bell catheter 1624 is an "outer tubular member" as claimed. PO Resp. 55–56 (citing Ex. 2047 ¶ 131). Instead, Patent Owner contends that sheath catheter 1604, not bell catheter 1624, is the outermost catheter of Lane's delivery system. *Id.* at 56 (citing Ex. 1023 ¶ 122; Ex. 2047 ¶ 131). This argument, however, appears to depend on Patent Owner's assertion that sheath catheter 1604 is part of Lane's delivery catheter, which assertion we find unpersuasive for the reasons discussed above. *See supra* § II.D.2.a. Instead, we are persuaded by Petitioner's contention that guide-wire catheter 1621, hub catheter 1622, and bell catheter 1624 collectively correspond to the claimed delivery catheter,

while sheath catheter 1604 corresponds to the claimed introducer catheter. *See id.* Thus, we determine that bell catheter 1624 is the outermost tubular portion of Lane's delivery catheter.

Accordingly, we agree with Petitioner that this limitation is satisfied by Lane and determine that Petitioner has demonstrated by a preponderance of the evidence that Lane renders obvious claim 10.

E. Petitioner's Alternate Challenges: Grounds 2–4

Petitioner contends that claims 1–4, 6–10, 16, and 17 would have been rendered obvious by Lane in view of Hartley, and that claims 3 and 4 would have been rendered obvious by either Lane in view of Nguyen or Lane in view of Hartley and Nguyen. Pet. 58–64. Because of our determination that Petitioner establishes by a preponderance of the evidence that claims 1–4, 6–10, 16, and 17 would have been unpatentable based on Ground 1, we do not reach Petitioner's alternate challenges to claims 1–4, 6–10, 16, and 17 set forth in Grounds 2–4. *See SAS Inst. Inc. v. Iancu*, 138 S. Ct. 1348, 1359 (2018) (holding that a petitioner "is entitled to a final written decision addressing all of the claims it has challenged"); *see also Boston Sci. Scimed, Inc. v. Cook Grp. Inc.*, 809 F. App'x 984, 990 (Fed. Cir. 2020) (nonprecedential) (stating that the "Board need not address issues that are not necessary to the resolution of the proceeding," such as "alternative arguments with respect to claims [the Board] found unpatentable on other grounds").

F. Grounds 5 and 6: Asserted Obviousness Based on Lane and Thomas and Lane, Hartley, and Thomas

Petitioner asserts that claims 16, 18–22, and 24 would have been rendered obvious by either the combination of Lane and Thomas or the combination of Lane, Hartley and Thomas. Pet. 64–82. Patent Owner

provides arguments addressing this asserted ground of unpatentability. PO Resp. 58–67. We first summarize Thomas and then address the parties' contentions.

1. Thomas

Thomas, titled "Sleeve for Facilitating Movement of a Transfemoral Catheter," was published on February 23, 2012. Ex. 1006, codes (54), (43). Thomas relates to "prosthetic heart valve replacement, and more particularly to devices, systems, and methods for reducing friction when using catheters and similar devices for transfemoral delivery of collapsible prosthetic heart valves." *Id.* ¶ 2.

We reproduce Figure 3A of Thomas below.

FIG. 3A

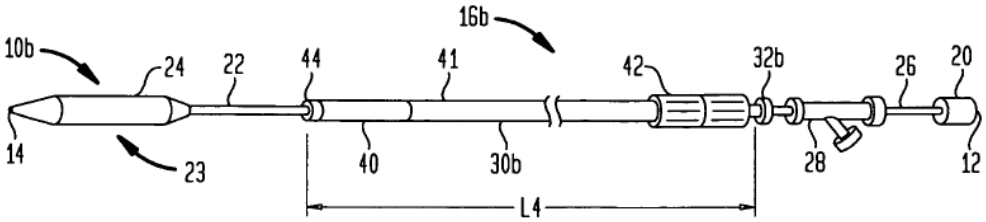

Figure 3A is a side view of an exemplary embodiment of a transfemoral delivery device for implanting a prosthetic heart valve. Ex. 1006 ¶¶ 28, 56, 57.

The delivery device includes catheter assembly 16b and steerable sleeve 30b. *Id.* ¶ 57. The catheter assembly includes inner shaft 26, outer shaft 22 assembled over the inner shaft for sliding movement therebetween, and valve compartment 23 for holding a prosthetic heart valve in a collapsed condition around inner shaft 26. *Id.* "A distal sheath 24 encloses the compartment 23 and is connected to the distal end of the outer shaft 22 so

that sliding movement of the outer shaft 22 along the inner shaft 26 results in a corresponding movement of the distal sheath 24 relative to the compartment 23 for deployment of the heart valve." *Id*.

Steerable sleeve 30b can be retracted proximally so that the distal sheath 24 will have sufficient room to retract and fully expose the compartment 23 to deploy the heart valve. *Id.* ¶ 66. The steerable sleeve includes a steerable portion, steering actuator 42, a pull-ring (not shown), and one or more pull-wires (not shown) coupled to the pull-ring and a pull mechanism of steering actuator 42. *Id.* ¶ 59. A user may operate steering actuator 42 to maneuver steerable portion 40 of sleeve 30b. *Id.* ¶ 65. "As the steering actuator 42 is rotated, a pull mechanism (not shown) of the steering actuator 42 may pull a pull-wire extending along one side of the sleeve 30b that pulls one side of the pull-ring and bends the steerable portion 40 of the sleeve 30b." *Id.*

2. Dependent Claim 16

Claim 16 depends from claim 1 and additionally requires the steps "partially deploying the prosthetic valve," "adjusting an angular position of the prosthetic valve," and "fully deploying the prosthetic valve." Ex. 1001, 34:24–28. Petitioner relies on Thomas "[t]o the extent it is argued that additional disclosure of adjusting an angular position of the prosthesis is necessary." Pet. 64. Specifically, Petitioner contends that Thomas discloses using its pull-wires to adjust the angular position of the prosthesis within distal sheath 24, and a "POSITA would have been motivated to apply Thomas's teachings of pull-wires to Lane's alignment mechanism to achieve the beneficial and predictable result of incorporating an additional control modality over alignment of the prosthesis." Pet. 67–69 (citing Ex. 1006 ¶¶ 59, 65–66, 68, Fig. 3B; Ex. 1002 ¶¶ 175–176). Patent Owner does not

specifically address Petitioner's determination that Thomas renders obvious adjusting an angular position of the prosthesis, resting instead on its arguments against Lane for Ground 1. PO Resp. 62–63.

We have considered the evidence and arguments of record and determine that Petitioner has demonstrated by a preponderance of the evidence that Lane and Thomas, or Lane, Hartley, and Thomas, render obvious claim 16 for the reasons discussed in the Petition and as supported by the testimony of Dr. Drasler.

3. Dependent Claims 18 and 19

Claim 18 depends from claim 1 and additionally requires that the distal end of the delivery catheter comprises a sheath jacket having an outer diameter greater than the inner diameter of the introducer catheter. Ex. 1001, 34:32–37. Claim 19 depends from claim 18 and recites "after deploying the prosthetic valve, retracting the delivery catheter until a proximal end of the sheath jacket abuts the distal end of the introducer catheter." *Id.* at 34:38–41.

Petitioner submits that claim 18 is obvious over Lane and Thomas because

> [a] POSITA would have been motivated to apply Thomas's teachings of distal sheath 24 to Lane's "concentrically nested" catheters to achieve the beneficial and predictable result of extending the "bumped up" portion bell catheter 1624 (with a larger diameter 1623) to cover the prosthesis's entire length—forming a "sheath jacket," while allowing sheath catheter 1604's diameter to advantageously be smaller.

Pet. 70 (citing Ex. 1002 ¶¶ 181–182). Petitioner further argues that reducing the sheath catheter's "diameter and profile would beneficially reduce friction against vasculature during delivery device advancement and removal." *Id.* (citing Ex. 1021 ¶¶ 7, 39; Ex. 1007, 2:37–44; Ex. 1011, 28–29; Ex. 1002

¶ 183). In addition, Petitioner argues that "a POSITA have been motivated to have modified section 1623 (forming the "sheath jacket" around the valve prosthesis) to abut shoulder 1618 of tip 1603 and the proximal portion of the modified section 1623 abut the smaller diameter sheath catheter 1604" to maintain the "piercing stiffness" taught by Lane. *Id.* at 70–71 (citing Ex. 1023, Fig. 20; Ex. 1002 ¶ 184).

In response, Patent Owner submits that claims 18–22 and 24 are not obvious for the same reasons cited with respect to Ground 1, and further argues that Petitioner's proposed modification is "convoluted and driven by hindsight." PO Resp. 65. Specifically, Patent Owner contends that Petitioner's proposed combination requires the following series of modifications to Lane:

> First, the sheath catheter 1604 would be truncated so that it no longer houses the prosthesis. Second, the diameter of the truncated sheath catheter would be decreased. Third, the distal end of the bell catheter would be widened and lengthened to abut the distal tip and cover the prosthesis. Fourth, the proximal portion of the modified end of the bell catheter would be positioned so as to abut the "smaller diameter sheath catheter 1604" and the material construction of the modified bell catheter would be modified so that it is sufficiently rigid to aid in piercing the access vessel.

Id. at 63 (citing Ex. 2047 ¶ 154). Patent Owner then contends that, because sheath catheter 1604 already functions as a "sheath jacket" housing the prosthetic valve and is able to penetrate the apex of the heart, "a POSITA would not have been motivated to alter the structure of sheath catheter 1604 in favor of bell catheter 1624 being modified to perform the same functions that sheath catheter 1604 is already designed to perform." *Id.* at 66 (citing Ex. 1023 ¶ 122; Ex. 2047 ¶ 157). Patent Owner also argues that the proposed modifications would destroy the functionality of both sheath

catheter 1604 and bell catheter 1624 and alter the principle of operation. *Id.* at 66–67 (citing Ex. 2047 ¶¶ 157–158; *Plas-Pak Indus., Inc. v. Sulzer Mixpac AG*, 600 Fed. Appx. 755, 758–59 (Fed. Cir. 2015)); *see also* PO Sur-reply 24 ("[A] POSITA would not have been motivated to make Petitioners' proposed modifications as they would alter the principle of operation of both Lane's sheath catheter 1604 and bell catheter 1624.").

In its Reply, Petitioner counters that the proposed modifications are "well within a POSITA's skill" (Pet. Reply 23–24) and that its motivation for combining the references is proper because Lane does not teach away from the modifications and applying Thomas's teachings would not result in an inoperable system (*id.* at 25). Petitioner further argues that modifying bell catheter 1624 to perform some of the sheath catheter's functions do not change the basic principles under which the prior art was designed to operate. *Id.* at 25-26 (citing *In re Urbanski*, 809 F.3d 1237, 1244 (Fed. Cir. 2016)).

> Patent Owner submits that the opposite is true because
>
> > [b]y truncating (or retracting the position of) the sheath catheter and decreasing its diameter as proposed by Petitioners, sheath catheter 1604 would no longer house the prosthetic valve, it would no longer penetrate the apex of the heart given its proximate positioning along the delivery system, and it could no longer assist in the dilation of an incision because of both its positioning along the delivery system and because of its reduced diameter.

PO Sur-reply 24–25. When asked at the oral hearing whether the proposed modification would render the sheath catheter superfluous, Petitioner responded that it would not because the sheath catheter is still introducing the other catheters and could assist with delivery. Tr. 85:13–86:9.

We are not persuaded by Petitioner's arguments. As Patent Owner explains, the sheath catheter is intended to perform multiple functions, including housing the prosthetic valve and penetrating the apex of the heart "by supporting and directing a tip 1603 and assisting in the dilation of an incision in the heart wall muscle." Ex 1023 ¶ 0122. Even if Petitioner's proposed modification would not render Lane's system inoperable, we agree with Patent Owner that Petitioner's proposed modifications deprive the sheath catheter of its primary functions. Petitioner does not explain how the sheath catheter would still be suitable for performing dilation, and the modification intentionally deprives the sheath catheter of its housing function which plays a fundamental role in delivering the prosthesis. *See e.g.*, Ex. 1023 ¶¶ 127–128.

We also agree with Patent Owner's contention that the proposed modifications would alter Lane's principle of operation. Lane discloses that rotation of thumbwheel 1616 causes translation of screw insert 1627, and sheath catheter 1604 moves together with screw insert 1627 because of the direct attachment of these two elements. Ex. 1023 ¶ 123. Bell catheter 1624, however, is only retracted when thumbwheel 1616 is rotated to the extent that screw insert 1627 contacts pins 1628 connected to bell catheter 1624. *Id.* ¶ 124.

With this arrangement, a user deploys a prosthetic valve by first manipulating thumbwheel 1616 to retract sheath catheter 1604 past larger diameter section 1623 of bell catheter 1624 and a portion of the prosthetic heart valve residing concentrically above guide-wire catheter 1621. *Id.* ¶ 127. Most of the prosthetic valve expands into its expanded configuration at this point, although the valve commissures remain collapsed and captured in hub slots 1619. *Id.* ¶ 130; *see also id.* ¶ 129 ("The valve may be

releasably held by slots by disposing the commissure tabs . . . of the prosthetic valve into slots 1619 and then retracting slots 1619 under tip 1623 of bell catheter 1624."). Next, after pin lock 1608 is removed, sheath catheter 1604 is further retracted, which now also causes bell catheter 1624 to be retracted. *Id.* ¶ 128. "Once the larger diameter section 1623 of the bell catheter 1624 has been withdrawn, the hub slots 1619 become uncovered which allows the heart valve anchor (not shown) to fully expand." *Id.* Lane thus discloses a *two-step process* for releasing the prosthetic valve from the delivery device depicted in Figures 16–19B; *see also id* ¶¶ 26–31 (describing expanding and anchoring regions of the prosthetic valve and then subsequently releasing the valve commissures).

We agree with Patent Owner that, when Lane is modified in the manner proposed, retraction of the modified bell catheter would prematurely release the proximal end of the prosthesis. PO Resp. 66–67 (citing Ex. 2047 ¶ 158); *see also* Tr. 66:20–67:3 (counsel for Patent Owner arguing that one of ordinary skill in the art would not make the proposed modification because it prevents the prosthesis from being held at its proximal end to aid in the deployment of the valve). This result would defeat Lane's desire to hold the commissures in a collapsed state until after the other portion of the prosthesis is expanded and anchored.

Last, we agree with Patent Owner that a person of ordinary skill in the art would have no reason to use sheath catheter 1604 after the proposed modifications are made. *See* Tr. 65:23–25. We see no reason to retain sheath catheter 1604 in the modified device because it would no longer serve its primary purpose of housing the prosthetic valve. Indeed, removing sheath catheter 1604 as superfluous would reduce the outer diameter even more, in accord with Petitioner's asserted rationale for modifying Lane's

device in the first place. Petitioner's argument that the modified sheath is functional because it is "still the thing introducing the [bell catheter] and the hub catheter and the guidewire" (Tr. 85:13–86:9) is unavailing because we see no reason why the bell catheter would not able to introduce the hub catheter and guide-wire catheter in the absence of sheath catheter 1604.

For these reasons, we agree with Patent Owner that one of ordinary skill in the art would not have been motivated to modify Lane as proposed and determine that Petitioner has not demonstrated by a preponderance of the evidence that claim 18 is unpatentable over the combination of Lane and Thomas. Ground 6 does not rely on Hartley to address the above issues (*see* Pet. 64–82) and is therefore unpersuasive for the reasons set forth above. Thus, we also determine that Petitioner has not demonstrated by a preponderance of the evidence that claim 18 is unpatentable over the combination of Lane, Hartley, and Thomas.

Claim 19 depends on claim 18. Petitioner's challenge to claim 19 does not overcome the deficiencies discussed above with respect to claim 18. *See* Pet. 74–76. Accordingly, we also determine that Petitioner has not demonstrated by a preponderance of the evidence that claim 19 is unpatentable over either asserted combination for at least the same reasons discussed above with respect to claim 18.

4. Dependent Claims 20–22, and 24

Claim 20 depends from claim 1 and further recites that "the delivery catheter comprises an outer tubular member and a guidewire tubing extending through the outer tubular member." Ex. 1001, 34:42–47. Claims 21 and 24 depend from claim 20, and claim 22 depends from claim 21. *Id.* Petitioner's argument that Lane and Thomas render obvious claim 20 relies on the assertion that "a POSITA would have been motivated to apply

Thomas's teachings to distally extend Lane's section 1623 of bell catheter 1624 to provide a 'sheath jacket' such that bell catheter 1624 becomes the outer tubular member." Pet. 77 (citing 1002 ¶ 205).

Because we determine that it would not have been obvious to provide a sheath jacket based on the teachings of Lane and Thomas (*see supra* § II.F.3), we also determine that the alleged byproduct of this modification, i.e., a bell catheter becoming the outer tubular member, also would not have been obvious over Lane and Thomas. Accordingly, Petitioner has not demonstrated by a preponderance of the evidence that claim 20 is unpatentable over the combination of Lane and Thomas. Because claims 21, 22, and 24 depend directly or indirectly from claim 20, and Petitioner's challenge to these dependent claims does not overcome the deficiencies with respect to claim 20, we also find that Petitioner has not demonstrated by a preponderance of the evidence that claims 21, 22, and 24 are unpatentable over the combination of Lane and Thomas for the same reasons.

Ground 6 does not rely on Hartley to address the issues above (*see* Pet. 73–82) and is therefore unpersuasive for the reasons set forth in our analysis of Ground 5.

III. CONCLUSION[13]

In summary:

Claims	35 U.S.C. §	Reference(s)/Basis	Claims Shown Unpatentable	Claims Not shown Unpatentable
1–4, 6–10, 16, 17	103	Lane	1–4, 6–10, 16, 17	
1–4, 6–10, 16, 17	103[14]	Lane, Hartley		
3, 4	103[15]	Lane, Nguyen		
3, 4	103[16]	Lane, Hartley, Nguyen		
16, 18–22, 24	103	Lane, Thomas	16	18–22, 24
16, 18–22, 24	103	Lane, Thomas, Hartley	16	18–22, 24
Overall Outcome			1–4, 6–10, 16, 17	18–22, 24

IV. ORDER

In consideration of the foregoing, it is hereby:

[13] Should Patent Owner wish to pursue amendment of the challenged claims 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).
[14] As explained above, we do not reach this alternative ground.
[15] As explained above, we do not reach this alternative ground.
[16] As explained above, we do not reach this alternative ground.

ORDERED that claims 1–4, 6–10, 16, and 17 of U.S. Patent No. 9,445,897 B2 are determined to be unpatentable;

FURTHER ORDERED that claims 18–22 and 24 of U.S. Patent No. 9,445,897 B2 are not determined to be unpatentable; and

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

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